OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
June 10, 2026
4:00pm

Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105

Viewing Access Only:
Please register for the webinar at:
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The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – June 10, 2026

DATE: June 3, 2026

NOTE: The DUR Board will meet at 4:00pm at the Oklahoma Health Care Authority (OHCA) at 4345 N. Lincoln Blvd. in Oklahoma City, Oklahoma.

There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.

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Enclosed are the following items related to the June meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit – Appendix B

Evaluation of Pediatric Opioid Prescribing in Medicaid Beneficiaries – Appendix C

Action Item – Vote to Prior Authorize Voyxact® (Sibeprenlimab-szsi) and Update the Approval Criteria for the Primary Immunoglobulin A Nephropathy (IgAN) – Appendix D

Action Item – Vote to Prior Authorize Arynta™ (Lisdexamfetamine Oral Solution) and Atoncy™ (Atomoxetine Oral Solution) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications – Appendix E

Action Item – Vote to Prior Authorize Itvisma® (Onasemnogene Abeparvovec-brve) and Update the Approval Criteria for the Spinal Muscular Atrophy (SMA) Medications – Appendix F

Action Item – Vote to Prior Authorize Jascayd® (Nerandomilast) and Update the Approval Criteria for the Interstitial Lung Disease (ILD) Medications – Appendix G

Action Item – Vote to Prior Authorize Rethymic® (Allogeneic Processed Thymus Tissue-agdc) – Appendix H

Action Item – Vote to Prior Authorize Eydenzelt® (Aflibercept-boav) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications – Appendix I

Action Item – Vote to Prior Authorize Avgemsi™ (Gemcitabine), Emrelis™ (Telisotuzumab Vedotin-tllv), Ensacove™ (Ensartinib), Hernexeos® (Zongertinib), Hyrnuo® (Sevabertinib), Ibtrozi™ (Taletrectinib), and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) and Update the Approval Criteria for the Lung Cancer Medications – Appendix J

Action Item – Annual Review of Zokinvy® (Lonafarnib) – Appendix K

Annual Review Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Inlexzo™ (Gemcitabine Intravesical System), Kyxata™ (Carboplatin), Lifyorli™ (Relacorilant), and Zusduri™ (Mitomycin Intravesical Solution) – Appendix L

Annual Review of the SoonerCare Pharmacy Benefit – Appendix M

Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection) – Appendix N

Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Bysanti™ (Milsaperidone) – Appendix O

Annual Review of Antiviral Medications and 30-Day Notice to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder) and Xofluza® (Baloxavir) – Appendix P

Annual Review of Urea Cycle Disorder (UCD) Medications and 30-Day Notice to Prior Authorize Loargys® (Pegzilarginase-nbln) – Appendix Q

Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Cafergot® (Ergotamine/Caffeine Tablet), Desmoda™ (Desmopressin Oral Solution), Dicyclomine 40mg Tablet, Griseofulvin Ultramicrosize 165mg Tablet, Hydroxyzine Oral Solution Unit Dose Cups (UDCs), Khindivi™ (Hydrocortisone Oral Solution), Migergot® (Ergotamine/Caffeine Suppository), Ontralfy™ (Tizanidine Oral Solution), PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet, Quiofic™ (Folic Acid Oral Solution), Relgaabi™ (Gabapentin 200mg Capsule), and Vykoura™ (Leucovorin Injection) – Appendix R

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – Appendix S

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – June 10, 2026 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

NOTE: ***The DUR Board will meet at 4:00pm at OHCA (see address above). There will be Zoom access to this meeting; however, Zoom access will be set up in view-only mode with no voting, speaking, video, or chat box privileges. Zoom access will allow for viewing of the presentation slides as well as audio of the presentations and discussion during the meeting; however, the DUR Board meeting will not be delayed or rescheduled due to any technical issues that may arise.***

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Cassidy Blaiss –	participating in person
Ms. Jennifer Boyett –	participating in person
Dr. Christen Ground –	participating in person
Dr. Bret Haymore –	participating in person
Dr. Bethany Holderread –	participating in person
Dr. Matt John –	participating in person
Dr. Craig Kupiec –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Jennifer Weakley –	participating in person

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Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 928 6649 0447
Passcode: 80744869

Public Comment for Meeting:

- Speakers who wish to sign up for public comment at the OHCA DUR Board meeting may do so in writing by visiting the DUR Board page on the OHCA website at www.oklahoma.gov/ohca/about/boards-and-committees/drug-utilization-review/dur-board and completing the Speaker Registration Form. Completed Speaker Registration forms should be submitted to DURPublicComment@okhca.org. Forms must be received after the DUR Board agenda has been posted and no later than 24 hours before the meeting.
- The DUR Board meeting will allow public comment and time will be limited to 40 minutes total for all speakers during the meeting. Each speaker will be given 5 minutes to speak at the public hearing. If more than 8 speakers properly request to speak, time will be divided evenly.
- Only 1 speaker per manufacturer will be allowed.
- Any speakers who sign up for public comment must attend the DUR Board meeting in person at OHCA (see above address). Public comment through Zoom will not be allowed for the DUR Board meeting.
- In lieu of speaking at the DUR Board meeting, written correspondence by members or providers may be submitted to DURPublicComment@okhca.org. Other written correspondence is not permitted.

Items to be presented by Dr. Haymore, Chairman:

2. **Public Comment Forum**
   A. Acknowledgement of Speakers for Public Comment

Items to be presented by Dr. Haymore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. April 8, 2026 DUR Board Meeting Minutes
   B. April 8, 2026 DUR Board Recommendations Memorandum
   C. Correspondence

Non-presentation items reviewed by Dr. DeRemer, Dr. Haymore, Chairman:

4. **Update on Medication Coverage Authorization Unit – See Appendix B**
   A. Pharmacy Help Desk Activity for April 2026
   B. Medication Coverage Activity for April 2026
   C. Pharmacy Help Desk Activity for May 2026
   D. Medication Coverage Activity for May 2026

Items to be presented by Dr. Dorsey, Dr. Haymore, Chairman:

5. **Evaluation of Pediatric Opioid Prescribing in Medicaid Beneficiaries – See Appendix C**
   A. Introduction
   B. Clinical Practice Guidance for Pediatric Opioid Prescribing

C. Provider Mailing
D. Data Analysis
E. Conclusions

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

6. **Action Item – Vote to Prior Authorize Voyxact® (Sibeprenlimab-szsi) and Update the Approval Criteria for the Primary Immunoglobulin A Nephropathy (IgAN) – See Appendix D**

A. Market News and Updates
B. Voyxact® (Sibeprenlimab-szsi) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. Wilson, Dr. Haymore, Chairman:

7. **Action Item – Vote to Prior Authorize Arynta™ (Lisdexamfetamine Oral Solution) and Atoncy™ (Atomoxetine Oral Solution) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications – See Appendix E**

A. Market News and Updates
B. Product Summaries
C. College of Pharmacy Recommendations

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

8. **Action Item – Vote to Prior Authorize Itvisma® (Onasemnogene Abeparvovec-brve) and Update the Approval Criteria for the Spinal Muscular Atrophy (SMA) Medications – See Appendix F**

A. Market News and Updates
B. Itvisma® (Onasemnogene Abeparvovec-brve) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. Grimes, Dr. Haymore, Chairman:

9. **Action Item – Vote to Prior Authorize Jascayd® (Nerandomilast) and Update the Approval Criteria for the Interstitial Lung Disease (ILD) Medications – See Appendix G**

A. Market News and Updates
B. Jascayd® (Nerandomilast) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. Dorsey, Dr. Haymore, Chairman:

10. **Action Item – Vote to Prior Authorize Rethymic® (Allogeneic Processed Thymus Tissue-agdc) – See Appendix H**

A. Market News and Updates
B. Rethymic® (Allogeneic Processed Thymus Tissue-agdc) Product Summary
C. College of Pharmacy Recommendations

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

11. **Action Item – Vote to Prior Authorize Eydenzelt® (Aflibercept-boav) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications – See Appendix I**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

Items to be presented by Dr. Sinko, Dr. Haymore, Chairman:

12. **Action Item – Vote to Prior Authorize Avgemsi™ (Gemcitabine), Emrelis™ (Telisotuzumab Vedotin-tllv), Ensacove™ (Ensartinib), Hernexeos® (Zongertinib), Hyrnuo® (Sevabertinib), Ibtrozi™ (Taletrectinib), and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) and Update the Approval Criteria for the Lung Cancer Medications – See Appendix J**
    A. Market News and Updates
    B. Product Summaries
    C. Cost Comparison: Gemcitabine Products
    D. College of Pharmacy Recommendations

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

13. **Action Item – Annual Review of Zokinvy® (Lonafarnib) – See Appendix K**
    A. Current Prior Authorization Criteria
    B. Utilization of Zokinvy® (Lonafarnib)
    C. Prior Authorization of Zokinvy® (Lonafarnib)
    D. Market News and Updates
    E. College of Pharmacy Recommendations

Items to be presented by Dr. Sinko, Dr. Haymore, Chairman:

14. **Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Inlexzo™ (Gemcitabine Intravesical System), Kyxata™ (Carboplatin), Lifyorli™ (Relacorilant), and Zusduri™ (Mitomycin Intravesical Solution) – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of Genitourinary and Gynecologic Cancer Medications
    C. Prior Authorization of Genitourinary and Gynecologic Cancer Medications
    D. Market News and Updates
    E. Product Summaries
    F. Cost Comparison: Carboplatin Products
    G. College of Pharmacy Recommendations
    H. Utilization Details of Genitourinary and Gynecologic Cancer Medications

Items to be presented by Dr. Dorsey, Dr. Haymore, Chairman:

15. **Annual Review of the SoonerCare Pharmacy Benefit – See Appendix M**
    A. Summary
    B. Medicaid Drug Rebate Program
    C. Alternative Payment Models

D. Drug Approval Trends
E. Traditional Versus Specialty Pharmacy Products
F. Top 10 Traditional Therapeutic Categories by Reimbursement
G. Top 10 Specialty Therapeutic Categories by Reimbursement
H. Top 10 Medications by Reimbursement
I. Cost Per Claim
J. Market Projections
K. Conclusion
L. Top 50 Reimbursed Drugs
M. Top 50 Medications by Number of Claims
N. Fiscal Year Comparisons

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

16. **Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection) – See Appendix N**

A. Current Prior Authorization Criteria
B. Utilization of Anti-Emetic Medications
C. Prior Authorization of Anti-Emetic Medications
D. Market News and Updates
E. Nereus™ (Tradipitant) Product Summary
F. Cost Comparison: Palonosetron Products
G. College of Pharmacy Recommendations
H. Utilization Details of Anti-Emetic Medications

Items to be presented by Dr. O'Halloran, Dr. Haymore, Chairman:

17. **Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Bysanti™ (Milsaperidone) – See Appendix O**

A. Current Prior Authorization Criteria
B. Utilization of Atypical Antipsychotics
C. Prior Authorization of Atypical Antipsychotics
D. Oklahoma Resources
E. Market News and Updates
F. Bysanti™ (Milsaperidone) Product Summary
G. Cost Comparison: Atypical Antipsychotics for Adjunct Treatment of MDD
H. College of Pharmacy Recommendations
I. Utilization Details of Atypical Antipsychotics

Items to be presented by Dr. DeRemer, Dr. Haymore, Chairman:

18. **Annual Review of Antiviral Medications and 30-Day Notice to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder) and Xofluza® (Baloxavir) – See Appendix P**

A. Current Prior Authorization Criteria
B. Utilization of Antiviral Medications
C. Prior Authorization of Antiviral Medications

D. Market News and Updates
E. Hepcludex® (Bulevirtide-gmod) Product Summary
F. Cost Comparison: Oral Influenza Antiviral Medications
G. College of Pharmacy Recommendations
H. Utilization Details of Antiviral Medications

Items to be presented by Dr. Grimes, Dr. Haymore, Chairman:

19. Annual Review of Urea Cycle Disorder (UCD) Medications and 30-Day Notice to Prior Authorize Loargys® (Pegzilarginase-nbln) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of UCD Medications
C. Prior Authorization of UCD Medications
D. Market News and Updates
E. Loargys® (Pegzilarginase-nbln) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of UCD Medications

Items to be presented by Dr. Moss, Dr. Haymore, Chairman:

20. Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Cafergot® (Ergotamine/Caffeine Tablet), Desmoda™ (Desmopressin Oral Solution), Dicyclomine 40mg Tablet, Griseofulvin Ultramicrosize 165mg Tablet, Hydroxyzine Oral Solution Unit Dose Cups (UDCs), Khindivi™ (Hydrocortisone Oral Solution), Migergot® (Ergotamine/Caffeine Suppository), Ontralfy™ (Tizanidine Oral Solution), PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet, Quiofic™ (Folic Acid Oral Solution), Relgaabi™ (Gabapentin 200mg Capsule), and Vykoura™ (Leucovorin Injection) – Appendix R

A. Introduction
B. Current Prior Authorization Criteria
C. Utilization of Various Special Formulations
D. Prior Authorization of Various Special Formulations
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Various Special Formulations

Non-presentation items reviewed by Dr. DeRemer, Dr. Haymore, Chairman:

21. U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates – See Appendix S

Items to be presented by Dr. Adams, Dr. Haymore, Chairman:

22. Future Business* (Upcoming Product and Class Reviews)

A. Alzheimer's Medications
B. Anti-Diabetic Medications and Kerendia® (Finerenone)

C. Anti-Ulcer Medications
D. Colorectal Cancer (CRC) Medications
E. Epidermolysis Bullosa (EB) Medications
F. Heart Failure Medications
G. Testosterone Products

*Future product and class reviews subject to change.

23. Adjournment

NOTE: An analysis of the atypical [Aged, Blind, and Disabled (ABD)] patient subgroup of the Oklahoma Medicaid population has been performed pertaining to all recommendations included in this DUR Board meeting packet to ensure fair and knowledgeable deliberation of the potential impact of the recommendations on this patient population.

NOTE: Oklahoma Medicaid transitioned from a fee-for-service (FFS) pharmacy benefit to a managed care pharmacy benefit for most members on April 1, 2024. At that time, the majority of SoonerCare members were transitioned to one of the three managed care SoonerSelect plans: Aetna, Humana, or Oklahoma Complete Health. SoonerSelect data has been provided to the College of Pharmacy and has been used in analyses throughout this DUR Board meeting packet. The data included in this DUR Board meeting packet combines FFS and managed care utilization data. The managed care utilization and prior authorization (PA) data reported in this packet is based solely on the data provided by the SoonerSelect plans.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING APRIL 8, 2026

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP		X
Jennifer Boyett, MHS, PA-C	X	
Christen Ground, D.O.	X	
Bret Haymore, M.D.; Chairman	X	
Bethany Holderread, Pharm.D.	X	
Matt John, Pharm. D., MBA	X	
T. Craig Kupiec II, M.D., MSPH	X	
Lee Muñoz, D.Ph.	X	
Edna Patatanian, Pharm.D., FASHP; Vice Chairwoman	X	
Jennifer Weakley, M.D., DipABLM	X	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Alanah Canfield Miller, Pharm.D.; Clinical Pharmacist	X	
Michaela DeRemer, Pharm.D., MBA, BCIDP, BCPS; Clinical Pharmacist	X	
Darius Dorsey, Pharm.D.; Pharmacy Resident	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Lezlie Grimes, Pharm.D.; Clinical Pharmacist	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Whitney Bueno, Pharm.D., BCOP		X
Christine Hughes, Pharm.D., MBA, BCOP		X
Lauren Sinko, Pharm.D., BCOP	X	
Graduate Students: Matthew Dickson, Pharm.D.	X	
Mark Wendelboe	X	
Visiting Pharmacy Student(s): Andee Allen	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Josh Anderson, Chief of Staff		X
Mark Brandenburg, M.D., MSC; Medical Director	X	
Clay Bullard; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	

Melissa Miller, State Medicaid Director		X
Christine Picart, QA/QI	X	
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
***Legal representative**		
Travis Dennis, J.D.; Deputy General Counsel		X
Gentry Kincade, J.D.; Deputy General Counsel	X	
Gwendolyn Maxey, J.D.; Deputy General Counsel		X
Conner Mulvaney, J.D.; Deputy General Counsel		X

OTHERS PRESENT:	
Lee Stout, Chiesi	Mike Thiem, Incyte
Scott Burns, Johnson & Johnson	Kellie Vazzana, Alkermes
Taylor Charles, Artia Solutions	Ginger Papesh, Novo Nordisk
Gary Parenteau, Dexcom	John Omick, Travere Therapeutics
Lisa Henzel, Kura Oncology	Judi Ross, PantherRx Rare
Mae Kwong, Soleno Therapeutics	Lindsey Baker, Genentech
Phillip Lohec, Viartris Inc	Trinh Nguyen, Rhythm Pharmaceuticals
Michelle Steele, Rhythm Pharmaceuticals	Jennifer Golwyn, Ascendis
Sergio Mayorga, Concis Labs	Benjamin Skoog, Acadia
Michael Leake, OK Attorney General's Office	Jill Frandeen, Abbott
David Mendoza, Otsuka	Michael Faithe, Jazz
Todd Dickerson, Jazz	Hasib Bhojwani, Collegium
Paul Miner, Ascendis	Bob Atkins, Biogen
Payal Tejani, Biogen	Deidra Williams, Humana
Kristen Winters, Centene	Irene Chung, Aetna
Brent Parker Merck	David Prather, Novo Nordisk
Michele Banks	Cody Banks

PRESENT FOR PUBLIC COMMENT:	
Paul Miner, Ascendis	Michele Banks
Hadib Bhojwani, Collegium	Michael Faithe, Jazz

AGENDA ITEM NO. 1: **CALL TO ORDER**
1A: ROLL CALL
Dr. Haymore called the meeting to order at 4:00pm. Roll call by Dr. Wilcox established the presence of a quorum.
ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**
2A: AGENDA ITEM NO. 8 PAUL MINER
2B: AGENDA ITEM NO. 8 MICHELE BANKS
2C: AGENDA ITEM NO. 16 HADIB BHOJWANI
2D: AGENDA ITEM NO. 16 MICHAEL FAITHE
ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MEETING MINUTES**
3A: MARCH 11, 2026 DUR MINUTES
Materials included in agenda packet; presented by Dr. Haymore

Dr. Patatanian moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT
4A: PHARMACY HELPDESK ACTIVITY FOR MARCH 2026
4B: MEDICATION COVERAGE ACTIVITY FOR MARCH 2026
Non-presentation item; materials included in agenda packet by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: SOONERPSYCH AND PEDIATRIC SOONERPSYCH ANTIPSYCHOTIC MONITORING PROGRAM UPDATE
5A: SOONERPSYCH PRESCRIBER MAILING SUMMARY
5B: SOONERPSYCH EXAMPLE GAUGE
5C: SOONERPSYCH TRENDS
5D: PEDIATRIC SOONERPSYCH PRESCRIBER MAILING SUMMARY
5E: PEDIATRIC SOONERPSYCH TRENDS
5F: CONCLUSIONS
5G: SUMMARY
Materials included in agenda packet; presented by Dr. Travers
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE NYPOZI™ (FILGRASTIM-TXID) AND UPDATE THE APPROVAL CRITERIA FOR THE GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND STEM CELL MOBILIZERS
6A: MARKET NEWS AND UPDATES
6B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE FESILTY™ (FIBRINOGEN, HUMAN-CHMT)
7A: MARKET NEWS AND UPDATES
7B: FESILTY™ (FIBRINOGEN, HUMAN-CHMT) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE DAYBUE® STIX (TROFINETIDE PACKET), PALSONIFY™ (PALTUSOTINE), VYKAT™ XR [DIAZOXIDE CHOLINE EXTENDED-RELEASE (ER)], AND YUVIWEL® (NAVEPEGRITIDE) AND UPDATE THE APPROVAL CRITERIA FOR THE GROWTH-RELATED DISORDER MEDICATIONS
8A: MARKET NEWS AND UPDATES
8B: PRODUCT SUMMARIES
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Kupiec moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE WASKYRA™ (ETUVETIDIGENE AUTOTEMCEL)

9A: MARKET NEWS AND UPDATES
9B: WASKYRA™ (ETUVETIDIGENE AUTOTEMCEL) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Ground moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> VOTE TO PRIOR AUTHORIZE TRYPTYR® (ACOLTREMON 0.003% OPHTHALMIC SOLUTION) AND UPDATE THE APPROVAL CRITERIA FOR THE DRY EYE DISEASE (DED) MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: TRYPTYR® (ACOLTREMON 0.003% OPHTHALMIC SOLUTION) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Grimes
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> VOTE TO PRIOR AUTHORIZE ZOLYMBUS™ (BIMATOPROST 0.1% GEL) AND UPDATE THE APPROVAL CRITERIA FOR THE GLAUCOMA MEDICATIONS
11A: MARKET NEWS AND UPDATES
11B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Muñoz moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> VOTE TO PRIOR AUTHORIZE CLINDESSE® (CLINDAMYCIN PHOSPHATE 2% VAGINAL CREAM) AND UPDATE THE APPROVAL CRITERIA FOR THE TOPICAL ANTIBIOTIC PRODUCTS
12A: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> VOTE TO PRIOR AUTHORIZE KOMZIFTI™ (ZIFTOMENIB), LYMPHIR™ (DENILEUKIN DIFTITOX-CXDL), LUNSUMIO VELO™ (MOSUNETUZUMAB-AXGB), NILOTINIB D-TARTRATE, AND PHYRAGO™ (DASATINIB) AND UPDATE THE APPROVAL CRITERIA FOR THE LEUKEMIA AND LYMPHOMA MEDICATIONS
13A: MARKET NEWS AND UPDATES
13B: PRODUCT SUMMARIES
13C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Holderread moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF MULTIPLE SCLEROSIS (MS) MEDICATIONS
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF MS MEDICATIONS
14C: PRIOR AUTHORIZATION OF MS MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS

14F: UTILIZATION DETAILS OF MS MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF LUNG CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AVGEMSI™ (GEMCITABINE), EMRELIS™ (TELISOTUZUMAB VEDOTIN-TLLV), ENSACOVE™ (ENSARTINIB), HERNEXEOS® (ZONGERTINIB), HYRNUO® (SEVABERTINIB), IBTROZI™ (TALETRECTINIB), AND RYBREVANT FASPRO™ (AMIVANTAMAB/HYALURONIDASE-LPUJ)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF LUNG CANCER MEDICATIONS
15C: PRIOR AUTHORIZATION OF LUNG CANCER MEDICATIONS
15D: MARKET NEWS AND UPDATES
15E: PRODUCT SUMMARIES
15F: COST COMPARISON: GEMCITABINE PRODUCTS
15G: COLLEGE OF PHARMACY RECOMMENDATIONS
15H: UTILIZATION DETAILS OF LUNG CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 16:</u> ANNUAL REVIEW OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ARYNTA™ (LISDEXAMFETAMINE ORAL SOLUTION) AND ATONCY™ (ATOMOXETINE ORAL SOLUTION)
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
16C: PRIOR AUTHORIZATION OF ADHD AND NARCOLEPSY MEDICATIONS
16D: OKLAHOMA RESOURCES
16E: MARKET NEWS AND UPDATES
16F: PRODUCT SUMMARIES
16G: COLLEGE OF PHARMACY RECOMMENDATIONS
16H: UTILIZATION DETAILS OF ADHD AND NARCOLEPSY MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 17:</u> ANNUAL REVIEW OF PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE VOYXACT® (SIBEPRENLIMAB-SZSI)
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF IGAN MEDICATIONS
17C: PRIOR AUTHORIZATION OF IGAN MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: VOYXACT® (SIBEPRENLIMAB-SZSI) PRODUCT SUMMARY
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF IGAN MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 18:</u> ANNUAL REVIEW OF SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ITVISMA® (ONASEMNOGENE ABEPARVOVEC-BRVE)
18A: CURRENT PRIOR AUTHORIZATION CRITERIA

18B: UTILIZATION OF SMA MEDICATIONS
18C: PRIOR AUTHORIZATION OF SMA MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: ITVISMA® (ONASEMNOGENE ABEPARVOVEC-BRVE) PRODUCT SUMMARY
18F: COLLEGE OF PHARMACY RECOMMENDATIONS
18G: UTILIZATION DETAILS OF SMA MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 19: ANNUAL REVIEW OF INTERSTITIAL LUNG DISEASE (ILD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE JASCAYD® (NERANDOMILAST)
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF ILD MEDICATIONS
19C: PRIOR AUTHORIZATION OF ILD MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: JASCAYD® (NERANDOMILAST) PRODUCT SUMMARY
19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF ILD MEDICATIONS
Materials included in agenda packet; presented by Dr. Grimes
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 20: 30-DAY NOTICE TO PRIOR AUTHORIZE RETHYMIC® (ALLOGENEIC PROCESSED THYMUS TISSUE-AGDC)
20A: INTRODUCTION
20B: RETHYMIC® (ALLOGENEIC PROCESSED THYMUS TISSUE-AGDC) PRODUCT SUMMARY
20C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Dorsey
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 21: ANNUAL REVIEW OF AGE-RELATED MACULAR DEGENERATION (AMD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EYDENZELT® (AFLIBERCEPT-BOAV)
21A: CURRENT PRIOR AUTHORIZATION CRITERIA
21B: UTILIZATION OF AMD MEDICATIONS
21C: PRIOR AUTHORIZATION OF AMD MEDICATIONS
21D: MARKET NEWS AND UPDATES
21E: COLLEGE OF PHARMACY RECOMMENDATIONS
21F: UTILIZATION DETAILS OF AMD MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

AGENDA ITEM NO. 22: ANNUAL REVIEW OF SOFDRA™ (SOFPIRONIUM 12.45% TOPICAL GEL)
22A: CURRENT PRIOR AUTHORIZATION CRITERIA
22B: UTILIZATION OF SOFDRA™ (SOFPIRONIUM 12.45% TOPICAL GEL)
22C: PRIOR AUTHORIZATION OF SOFDRA™ (SOFPIRONIUM 12.45% TOPICAL GEL)
22D: MARKET NEWS AND UPDATES
22E: COLLEGE OF PHARMACY RECOMMENDATIONS
Non-presentation item; materials included in agenda packet by Dr. DeRemer
ACTION: NONE REQUIRED

AGENDA ITEM NO. 23: **U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES**

Non-presentation item; materials included in agenda packet by Dr. O'Halloran

ACTION: NONE REQUIRED

AGENDA ITEM NO. 24: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**

24A: ANTI-EMETIC MEDICATIONS
24B: ANTIVIRAL MEDICATIONS
24C: ATYPICAL ANTIPSYCHOTIC MEDICATIONS
24D: GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
24E: UREA CYCLE DISORDER (UCD) MEDICATIONS
24F: VARIOUS SPECIAL FORMULATIONS

*Future product and class reviews subject to change.

Non-presentation item; materials included in agenda packet by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 25: **ADJOURNMENT**

The meeting was adjourned at 5:44pm.

The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: April 10, 2026

To: Terry Cothran, D.Ph.
Pharmacy Director
Oklahoma Health Care Authority

From: Michyla Adams, Pharm.D.
Drug Utilization Review (DUR) Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting on April 8, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: SoonerPsych and Pediatric SoonerPsych Antipsychotic Monitoring Program Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Nypozi™ (Filgrastim-txid) and Update the Approval Criteria for the Granulocyte Colony-Stimulating Factors (G-CSFs) and Stem Cell Mobilizers

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Nypozi™ (filgrastim-txid) with the following criteria (changes shown in red):

Nivestym® (Filgrastim-aafi), Nypozi™ (Filgrastim-txid), and Releuko® (Filgrastim-ayow) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Granix® (tbo-filgrastim), Neupogen® (filgrastim), or Zarxio® (filgrastim-sndz) must be provided. Biosimilars and/or reference

products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

The College of Pharmacy also recommends removing the prior authorization for Udenyca® (pegfilgrastim-cbqv) as a medical benefit and recommends updating the approval criteria for the pegfilgrastim products based on net costs (changes shown in red):

~~Neulasta® (Pegfilgrastim),~~ Nyvepria® (Pegfilgrastim-apgf), Stimufend® (Pegfilgrastim-fpgk), and Udenyca® (Pegfilgrastim-cbqv) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® (pegfilgrastim), Neulasta® Onpro® (pegfilgrastim) as a medical only benefit, ~~Nyvepria® (pegfilgrastim-apgf),~~ Udenyca® (pegfilgrastim-cbqv) as a medical only benefit, or Ziextenzo® (pegfilgrastim-bmez) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
3. Neulasta® Onpro® (pegfilgrastim) and Udenyca® (pegfilgrastim-cbqv) ~~and Nyvepria® (pegfilgrastim-apgf)~~ will be covered as a medical only benefit without prior authorization.

Lastly, the College of Pharmacy recommends updating the approval criteria for Rolvedon® (eflapegrastim-xnst) and Ryzneuta® (efbemalenograstim alfa-vuxw) based on net costs (changes shown in red):

Rolvedon® (Eflapegrastim-xnst) and Ryzneuta® (Efbemalenograstim Alfa-vuxw) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Fulphila® (pegfilgrastim-jmdb), Fylnetra® (pegfilgrastim-pbbk), Neulasta® (pegfilgrastim), Neulasta® Onpro® (pegfilgrastim) as a medical only benefit, ~~Nyvepria® (pegfilgrastim-apgf),~~ Udenyca® (pegfilgrastim-cbqv) as a medical only benefit, or Ziextenzo® (pegfilgrastim-bmez) must be provided; and
3. Neulasta® Onpro® (pegfilgrastim) and Udenyca® (pegfilgrastim-cbqv) ~~and Nyvepria® (pegfilgrastim-apgf)~~ will be covered as a medical only benefit without prior authorization.

<u>Recommendation 4: Vote to Prior Authorize Fesilty™ (Fibrinogen, Human-chmt)</u>

MOTION CARRIED by unanimous approval.
The College of Pharmacy recommends the prior authorization of Fesilty™ (fibrinogen, human-chmt) with the following criteria (shown in red):

Fesilty™ (Fibrinogen, Human-chmt) Approval Criteria:

1. An FDA approved diagnosis of congenital fibrinogen deficiency, including afibrinogenemia or hypofibrinogenemia; and
2. Member must not have dysfibrinogenemia; and
3. Documented plasma fibrinogen activity ≤0.5g/L and antigen ≤0.5g/L; and
4. Fesilty™ must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of congenital fibrinogen deficiency; and
5. A patient-specific, clinically significant reason why the member cannot use RiaSTAP® [fibrinogen concentrate (human)] or Fibryga® [fibrinogen (human)], which are available without prior authorization, must be provided; and
6. Fesilty™ will not be used concomitantly with RiaSTAP® or Fibryga®; and
7. Fesilty™ will be used for the treatment of acute bleeding or for the perioperative management of bleeding; and
8. Approval lengths will be based on duration of need.

Recommendation 5: Vote to Prior Authorize Daybue® Stix (Trofinetide Packet), Palsonify™ (Paltusotine), Vykat™ XR [Diazoxide Choline Extended-Release (ER)], and Yuviwel® (Navepegritide) and Update the Approval Criteria for the Growth-Related Disorder Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Palsonify™ (paltusotine), Vykat™ XR (diazoxide choline ER), and Yuviwel® (navepegritide) with the following criteria (shown in red):

Palsonify™ (Paltusotine) Approval Criteria:

1. An FDA approved diagnosis of acromegaly confirmed by 1 of the following:
   a. Serum growth hormone (GH) level >1ng/mL after a 2-hour oral glucose tolerance test (OGTT); or
   b. Elevated insulin-like growth factor 1 (IGF-1) (above the age and gender adjusted normal range); and
2. Member has had an inadequate response to surgery or is not a candidate for surgery; and
3. Member must be 18 years of age or older; and
4. Member must have a documented trial with long-acting injectable octreotide or lanreotide depot, which do not require prior authorization, with an inadequate response or a patient-specific, clinically significant

reason why both of these are not appropriate for the member must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Mycapssa® (octreotide) and Signifor® LAR (pasireotide) must be provided; and
6. Must be prescribed by, or in consultation with, an endocrinologist; and
7. Initial approvals will be for the duration of 6 months. Reauthorization (for the duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment.

Vykat™ XR [Diazoxide Choline Extended-Release (ER)] Approval Criteria:

1. An FDA approved diagnosis of Prader-Willi syndrome (PWS) confirmed by chromosome analysis (results of genetic testing must be submitted); and
2. Member must be 4 years of age or older; and
3. Prescriber must confirm member has moderate to severe hyperphagia related to PWS; and
4. Must be prescribed by, or in consultation with, a geneticist, endocrinologist, psychiatrist, or other specialist with expertise in the treatment of PWS; and
5. The member's caregiver has implemented and intends to continue strategies to establish a food-secure environment (e.g., locked food storage); and
6. Prescriber must confirm the member is able to successfully swallow the number of tablets necessary to achieve the target maintenance dose; and
7. Prescriber must confirm the member does not have hepatic impairment or renal impairment; and
8. Fasting plasma glucose and hemoglobin A1c (HbA1c) must be evaluated prior to initiating treatment with Vykat™ XR; and
    a. For members with hyperglycemia, the prescriber must confirm the member's blood glucose has been optimized prior to initiating treatment; and
    b. Prescriber must agree to monitor blood glucose and HbA1c periodically during treatment; and
9. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Vykat™ XR, and agrees to modify the dose, if necessary; and
10. Member's recent weight (taken within the past month) must be provided to authorize the appropriate amount of drug required according to package labeling; and
11. Initial approvals will be for the duration of 6 months; and
12. Subsequent approvals (for the duration of 6 months) require all the following to be met:

a. Prescriber must verify the member is tolerating and responding well to the medication as demonstrated by an improvement in hyperphagic symptoms; and
b. Member has been adherent to therapy; and
c. Member's recent weight (taken within the past month) must be provided to ensure the requested dose is still appropriate for member's weight.

Yuviwel® (Navepegritide) Approval Criteria:

1. Member must have an FDA approved indication of achondroplasia; and
   a. Diagnosis must be confirmed by genetic testing identifying a pathogenic mutation in the *FGFR3* gene; and
2. Member must be 2 years of age or older; and
3. Prescriber must verify member has open epiphyses; and
4. The member's baseline height (cm) and growth velocity (GV) (cm/year) must be provided; and
5. Yuviwel® must be prescribed by a geneticist, endocrinologist, or other specialist with expertise in the treatment of achondroplasia; and
6. Member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing per package labeling; and
7. Prescriber must verify the member or member's caregiver has been counseled on proper administration and storage of Yuviwel®; and
8. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Voxzogo® (vosoritide) must be provided; and
9. A quantity limit of 4 kits per 28 days will apply; or
   a. For members weighing ≥56kg, a quantity limit override will be approved for 8 kits per 28 days; and
10. Initial and subsequent approvals will be for the duration of 6 months. For additional approval consideration:
    a. Member's current height must be provided and must demonstrate an improvement in GV from baseline; and
    b. Member's recent weight must be provided and dosing must be appropriate; and
    c. Member should be compliant; and
    d. Prescriber must verify member still has open epiphyses; and
11. Yuviwel® will not be approved following epiphyseal closure.

Additionally, the College of Pharmacy recommends the prior authorization of Daybue® Stix (trofinetide packet) with criteria similar to Daybue® (trofinetide oral solution) with the following changes (shown in red):

Daybue® (Trofinetide Oral Solution) and Daybue® Stix (Trofinetide Packet) Approval Criteria:

1. A diagnosis of typical Rett syndrome confirmed by all of the following:

a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:
    i. A period of regression followed by recovery or stabilization; and
    ii. Partial or complete loss of acquired purposeful hand skills; and
    iii. Partial or complete loss of acquired spoken language; and
    iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and
    v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
    vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and
    vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and
b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene; and

2. Member must be 2 years of age or older; and
3. Daybue® must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and
4. Prescriber must agree to counsel members and caregivers on the risks of diarrhea, weight loss, and vomiting (including aspiration and aspiration pneumonia) associated with Daybue®, and will monitor appropriately for these adverse effects; and
5. Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue®, including the use of a calibrated device for measuring each dose; and
6. Prescriber must verify the member does not have severe renal impairment; and
    a. If the member has moderate renal impairment, the prescriber must agree to reduce the dose as required in the package labeling; and
7. Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to ensure accurate weight-based dosing according to package labeling; and
8. Requests for Daybue® Stix packets will require a patient-specific, clinically significant reason why the member cannot use Daybue® oral solution; and
9. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and
10. The following quantity limits will apply:

a. Oral Solution: A quantity limit of 3,600mL per 30 days will apply; or
b. Packets: A quantity limit of 60 packets per 30 days will apply.

Next, the College of Pharmacy recommends updating the approval criteria for Skytrofa® (lonapegsomatropin-tcgd) and Sogroya® (somapacitan-beco) based on new FDA approved indications with the following changes (shown in red):

Skytrofa® (Lonapegsomatropin-tcgd) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
   a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting the initial growth hormone approval criteria (listed under "Initial Approval") for the member's specific diagnosis; ~~and~~ or
   b. Adult GHD confirmed by 1 of the following:
      i. Insulin tolerance test (ITT) with peak growth hormone (GH) response <5ng/mL; or
      ii. Glucagon stimulation test (GST) with peak growth hormone (GH) response as follows:
         1. Member's recent body mass index (BMI) must be provided; and
         2. If BMI is ≤30kg/m^2: Peak GH response is ≤3ng/mL; or
         3. If BMI is >30kg/m^2: Peak GH response is ≤1ng/mL; or
      iii. ≥3 other pituitary hormone deficiencies (e.g., adrenal, thyroid, gonadal, vasopressin) with insulin-like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; and
2. Member's weight must be ≥11.5kg; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
4. Prescriber must verify the member has been counseled on proper administration and storage of Skytrofa®; and
5. Initial approvals will be as follows:
   a. For pediatric members, initial approvals will be for the 0.24mg/kg weekly dose, using the specific dose recommended in the package labeling; ~~and~~ or
   b. For adult members, initial approvals will be for 0.7mg, 1.4mg, or 2.1mg per week depending on the member's age and oral estrogen use per package labeling; and
6. Initial approvals will be for the duration of 6 months. For additional approval consideration:
   a. Dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. Growth velocity should not be <2.5cm/year if not on adult dosing; and
   ~~e. Prescriber must verify member still has open epiphyses; and~~

f. For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be ≤ +2; and
g. For members initially approved as adults, the prescriber must verify the member is responding well to treatment as demonstrated by a reduction in truncal fat percentage or normalization of IGF-1 level (IGF-1 SDS of -0.5 to 1.75); and

~~7. Skytrofa® will not be approved following epiphyseal closure. Skytrofa® is contraindicated in children with closed epiphyses.~~

8. A maximum approved dose of 6.3mg per week will apply for members with adult GHD.

Sogroya® (Somapacitan-beco) Approval Criteria:

1. Member must have a confirmed diagnosis of 1 of the following:
   a. Pediatric growth hormone deficiency (GHD) or panhypopituitarism meeting all the "Initial Approval" criteria for the member's specific diagnosis; or
   b. Adult GHD confirmed by 1 of the following:
      i. Insulin tolerance test (ITT) or glucagon test with a peak growth hormone (GH) response <3ng/mL; or
      ii. ≥3 pituitary hormone deficiencies and insulin like growth factor-1 (IGF-1) standard deviation score (SDS) <-2.0; ~~and~~ or
   c. Idiopathic short stature (ISS) meeting all the "Initial Approval" criteria; or
   d. Noonan syndrome (NS) meeting all the "Initial Approval" criteria; or
   e. Small for gestational age (SGA) meeting all the "Initial Approval" criteria; and
2. Member must be 2.5 years of age or older; and
3. Sogroya® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
4. Member's baseline IGF-1 level and SDS must be provided; and
5. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use all Tier-1 product(s) must be provided; and
6. Prescriber must verify the member does not have active malignancy or active proliferative or severe non-proliferative diabetic retinopathy; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Sogroya®; and
8. Approval quantity will be based on the FDA approved dosing in accordance with the package labeling; and
9. Initial approvals will be for the duration of 6 months. For additional approval consideration:
   a. Dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and

d. Growth velocity (GV) should not be <2.5cm/year if not on adult dosing; and
e. For members on adult dosing, recent IGF-1 level and SDS should be submitted and SDS should be ≤ +2; and
f. For members initially approved as adults, the prescriber must verify the member is responding well to treatment as demonstrated by a reduction in truncal fat percentage or normalization of IGF-1 level (IGF-1 SDS of -0.5 to 1.75); and

10. If the member's diagnosis is ISS, NS, or SGA, treatment may continue until 1 of the following:
    a. Epiphyseal closure; or
    b. Covered height [Boys: 165.1cm (65 inches); Girls: 152.4cm (60 inches)]; or
    c. GV <2.5cm/year; and
11. A maximum approved dose of 8mg per week will apply for members with adult GHD.

Lastly, the College of Pharmacy recommends updating the initial approval criteria for growth hormone for a diagnosis of ISS to be consistent with the FDA approved age range for Sogroya® (changes shown in red):

Idiopathic Short Stature Approval Criteria:

1. Initial Approval:
    a. Member must be ~~8~~ 2.5 years of age or older; and
    b. Growth hormone therapy must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
    c. Member's growth velocity (GV) must be <10% on a GV curve for gender and age; and
    d. Member's height must be ≥2.25 standard deviations (SD) below the mean for age and gender; and
    e. Member must have evidence of delayed bone age (undefined delay) and open epiphyses; and
    f. Member's growth chart and parental heights must be provided; and
        i. If the form is completed, a growth chart is not required; and
        ii. Parental heights are not always available.
2. Approval Length: 6 months if criteria met and compliant. No adult dosing will be approved for this indication. Once epiphyses are closed, covered height has been met, or GV is <2.5cm/year, therapy should be discontinued.
3. Dosing:
    a. Pediatric Dosing: FDA approved dosing varies by product. See the "Growth Hormone Dosing" section above for current guideline-based dosing considerations. Treatment may continue until 1 of the following:

i. Epiphyseal closure; or
ii. Covered height [boys: 165.1cm (65 inches); girls: 152.4cm (60 inches)]; or
iii. GV <2.5cm/year; and

b. Adult Dosing: No proven benefit to continuing growth hormone treatment in adulthood.

4. Continuation Approval:
   a. Medications and dosing should be appropriate; and
   b. Member should have had a recent office visit with new information regarding heights provided; and
   c. Member should be compliant; and
   d. Epiphyses are open; and
   e. GV should not be <2.5cm/year.

Recommendation 6: Vote to Prior Authorize Waskyra™ (Etuvetidigene Autotemcel)

The College of Pharmacy recommends the prior authorization of Waskyra™ (etuvetidigene autotemcel) with the following criteria (shown in red):

Waskyra™ (Etuvetidigene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of Wiskott-Aldrich Syndrome (WAS); and
2. Diagnosis must be confirmed by molecular genetic testing confirming a mutation in the *WAS* gene (results of genetic testing must be submitted) and at least 1 of the following:
   a. Severe *WAS* mutation as indicated by molecular genetic testing; or
   b. Absence of WAS protein (WASP) expression in hematopoietic cells; or
   c. Severe Zhu clinical score of ≥3; and
3. Member must be male; and
4. Member must be 6 months of age or older; and
5. Must be prescribed by a geneticist, hematologist/oncologist, immunologist, or other specialist with expertise in the treatment of WAS and the administration of Waskyra™; and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched related stem cell donor; and
7. Member must not have any contraindications to the use of Waskyra™, including:
   a. Hypersensitivity to the active substance or to any of the excipients; and
   b. Previous treatment with hematopoietic stem cell transplantation (HSCT) within 6 months prior to screening or HSCT with evidence of residual donor cell; and
   c. Previous treatment with hematopoietic stem cell gene therapy; and

    d. Contraindications to the mobilization and the conditioning regimen; and
8. Prescriber must verify the member is eligible to undergo HSCT (i.e., HSCT must be appropriate for a member to be treated with Waskyra™); and
9. Prescriber must verify the member will be monitored for signs and symptoms of the following:
    a. Cytopenia for at least 8 weeks after treatment; and
    b. Engraftment failure after treatment; and
    c. Hepatic veno-occlusive diseases, including assessment of liver function tests for 1 month after infusion; and
    d. Infection before and after treatment with Waskyra™; and
10. Waskyra™ must be administered at a Waskyra™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific dose from receipt to storage to administration; and
11. Approvals will be for 1 dose per member per lifetime.

Recommendation 7: Vote to Prior Authorize Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) and Update the Approval Criteria for the Dry Eye Disease (DED) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Tryptyr® (acoltremon 0.003% ophthalmic solution) with the following criteria (shown in red):

Tryptyr® (Acoltremon 0.003% Ophthalmic Solution) Approval Criteria:
1. An FDA approved indication to treat the signs and symptoms of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
7. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Additionally, the College of Pharmacy recommends to designate Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials as brand preferred based on net costs with the following criteria (shown in red):

Cyclosporine 0.05% Ophthalmic Emulsion (Generic Restasis® Single-Use Vials) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials must be provided.

Lastly, the College of Pharmacy recommends updating the Cequa® (cyclosporine 0.09% ophthalmic solution), Eysuvis® (loteprednol etabonate 0.25% ophthalmic suspension), Miebo® (perfluorohexyloctane ophthalmic solution), Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion), Tyrvaya® (varenicline nasal spray), Vevye® (cyclosporine 0.1% ophthalmic solution), and Xiidra® (lifitegrast 5% ophthalmic solution) approval criteria for clarity and based on net costs (changes shown in red):

Cequa® (Cyclosporine 0.09% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to increase tear production in members with keratoconjunctivitis sicca (dry eye); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
7. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Eysuvis® (Loteprednol Etabonate 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. ~~A documented trial of intermittent or regular artificial tear use within the past 3 months; and~~
4. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
5. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and

6. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which ~~is~~ are available without a prior authorization, must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids ~~including Lotemax® (loteprednol 0.5% suspension)~~ must be provided; and
8. Member must not have any contraindications to Eysuvis®; and
9. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Miebo® (Perfluorohexyloctane Ophthalmic Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use ~~Tryptyr® (acoltremon ophthalmic solution) and~~ Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of ~~12~~ 3mL per 30 days will apply.

Restasis MultiDose® (Cyclosporine 0.05% Ophthalmic Emulsion) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® in the individual dosage formulation (single-use vials), which is available without a prior authorization, must be provided; and
2. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided.

Tyrvaya® (Varenicline Nasal Spray) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 18 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per product) in the last 30 days that failed to relieve signs and symptoms of DED; and

4. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. ~~A patient-specific, clinically significant reason why the member cannot use all available ophthalmic preparations for the treatment of DED must be provided; and~~
6. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of 8.4mL (2 bottles) per 30 days will apply.

Vevye® (Cyclosporine 0.1% Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without prior authorization, must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use ~~and~~ Xiidra® (lifitegrast ophthalmic solution) must be provided; and
7. A quantity limit of 2mL per 50 days will apply.

Xiidra® (Lifitegrast 5% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 17 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per trial) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use brand name Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A quantity limit of 2 vials per day will apply.

Recommendation 8: Vote to Prior Authorize Zolymbus™ (Bimatoprost 0.01% Gel) and Update the Approval Criteria for the Glaucoma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the current Glaucoma Medications Product Based Prior Authorization (PBPA) category based on the new FDA approval and net costs (changes shown in red):

1. The prior authorization of Zolymbus™ (bimatoprost 0.01% gel) and placement into the Special PA Tier; and
2. Moving Betimol® (timolol 0.5%) from Tier-2 to the Special PA Tier; and
3. Moving Istalol® (timolol maleate 0.5%) from the Special PA Tier to Tier-2.

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
Alpha-2 Adrenergic Agonists		
brimonidine (Alphagan® 0.2%)	apraclonidine (Iopidine® 0.5%, 1%)	brimonidine (Alphagan-P® 0.15%)
brimonidine (Alphagan® P 0.1%) – **Brand Preferred**		
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
Beta-Blockers		
betaxolol (Betoptic-S® 0.25%)	betaxolol (Betoptic® 0.5%)	**timolol (Betimol® 0.5%)**
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	~~**timolol maleate (Istalol® 0.5%)**~~
carteolol (Ocupress® 1%)	~~**timolol (Betimol® 0.5%)**~~	timolol maleate (Timoptic® in Ocudose® 0.25%, 0.5%)
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)	**timolol maleate (Istalol® 0.5%)**	
levobunolol (Betagan® 0.5%)	timolol maleate (Timoptic-XE® 0.25%, 0.5%)	
timolol maleate (Timoptic® 0.25%, 0.5%)		
Carbonic Anhydrase Inhibitors		
acetazolamide (Diamox® 500mg caps; 125mg, 250mg tabs)+	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	methazolamide (Neptazane® 25mg, 50mg tabs)+
brinzolamide (Azopt® 1%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
dorzolamide (Trusopt® 2%)		
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)		

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
Cholinergic Agonists/Cholinesterase Inhibitors		
pilocarpine (Isopto® Carpine 1%, 2%, 4%)		
Prostaglandin Analogs		
bimatoprost (Lumigan® 0.01%)	bimatoprost (Lumigan® 0.03%)	**bimatoprost gel (Zolymbus™ 0.01%)**
latanoprost (Xalatan® 0.005%)		latanoprost (Iyuzeh™ 0.005%)
netarsudil/latanoprost (Rocklatan®)		latanoprostene bunod (Vyzulta® 0.024%)
tafluprost (Zioptan® 0.0015%) – **Brand Preferred**		
travoprost (Travatan-Z® 0.004%) – **Brand Preferred**		
Rho Kinase Inhibitors		
netarsudil (Rhopressa® 0.02%)		
netarsudil/latanoprost (Rocklatan®)		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
†Indicates available oral medications.
Please note: Combination products are included in both applicable pharmaceutical classes; therefore, combination products are listed twice in the tier chart.
caps = capsules; PA = prior authorization; tabs = tablets

The College of Pharmacy also recommends updating the prior authorization criteria for iDose® TR (travoprost intracameral implant) based on the FDA label update (changes shown in red):

iDose® TR (Travoprost Intracameral Implant) Approval Criteria:

1. An FDA approved indication to reduce intraocular pressure (IOP) in members with open-angle glaucoma (OAG) or ocular hypertension (OHT); and
2. Member must be 18 years of age or older; and
3. iDose® TR must be prescribed by, or in consultation with, an ophthalmologist; and
4. A patient-specific, clinically significant reason why the member requires iDose® TR and cannot utilize ophthalmic preparations, such as solution or suspension, to treat OAG or OHT must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Durysta® (bimatoprost intracameral implant) must be provided; and
~~6. The affected eye has not received prior treatment with iDose® TR; and~~
7. Member has no contraindications to iDose® TR; and

8. A quantity limit of (1) iDose® TR 75mcg implant per eye per ~~lifetime~~ year will apply; and
9. For reauthorization, the prescriber must verify the member is an appropriate candidate for re-administration of iDose® TR based on corneal endothelial cell density parameters defined in the package labeling.

Recommendation 9: Vote to Prior Authorize Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) and Update the Approval Criteria for the Topical Antibiotic Products

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Clindesse® (clindamycin phosphate 2% vaginal cream) with the following criteria based on net costs (changes shown in red):

Clindesse® (Clindamycin Phosphate 2% Vaginal Cream) and Xaciato® (Clindamycin 2% Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and
2. A patient specific, clinically significant reason why the member cannot use Cleocin® (clindamycin 2% vaginal cream~~), Clindesse® (clindamycin phosphate 2% vaginal cream),~~ and Cleocin® vaginal ovules (clindamycin phosphate 2.5g vaginal suppositories), which are available without a prior authorization, must be provided~~.~~; and
3. Requests for Clindesse® will also require a patient specific, clinically significant reason why the member cannot use Xaciato®.

Recommendation 10: Vote to Prior Authorize Komzifti™ (Ziftomenib), Lymphir™ (Denileukin Diftitox-cxdl), Lunsumio VELO™ (Mosunetuzumab-axgb), Nilotinib D-Tartrate, and Phyrago™ (Dasatinib) and Update the Approval Criteria for the Leukemia and Lymphoma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Komzifti™ (ziftomenib) and Lymphir™ (denileukin diftitox-cxdl), with the following criteria (shown in red):

Komzifti™ (Ziftomenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of AML; and
2. Disease is relapsed or refractory; and
3. Disease is positive for a susceptible nucleophosmin 1 (*NPM1*) mutation; and
4. Member has no satisfactory alternative treatment options; and
5. Member is 18 years of age or older.

Lymphir™ (Denileukin Diftitox-cxdl) Approval Criteria [Cutaneous T-Cell Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory stage I-III cutaneous T-cell lymphoma; and
2. Member must be 18 years of age or older; and
3. Expression of CD25 on ≥20% of malignant cells by immunohistochemistry (IHC); and
4. Has received at least 1 prior systemic therapy.

Next, the College of Pharmacy recommends the prior authorization of Nilotinib D-Tartrate, Lunsumio VELO™ (mosunetuzumab-axgb), and Phyrago™ (dasatinib) with criteria similar to Danziten® (nilotinib tartrate), Lunsumio™ (mosunetuzumab-axgb), and Sprycel® (dasatinib), respectively (changes shown in red):

Danziten® (Nilotinib Tartrate) and Nilotinib D-Tartrate Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of CML; and
2. Member must have 1 of the following:
    a. Newly diagnosed chronic, accelerated, or blast phase CML; or
    b. Philadelphia chromosome positive (Ph+) CML chronic phase (CP) resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy; or
    c. Post-hematopoietic stem cell transplant; and
3. A patient-specific, clinically significant reason the member cannot use Tasigna® (nilotinib) must be provided.

Lunsumio™ (Mosunetuzumab-axgb) and Lunsumio VELO™ (Mosunetuzumab-axgb) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after ≥2 lines of systemic therapy.

Phyrago™ (Dasatinib) and Sprycel® (Dasatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Member must have 1 of the following:
    a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
    b. Maintenance therapy including:
        i. As a single agent if unfit for additional therapies; or
        ii. As a single agent if member previously received blinatumomab plus a tyrosine kinase inhibitor (TKI); or
        iii. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or

iv. Post-hematopoietic stem cell transplantation; or
c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy; and
3. Member does not have the following mutations of BCR-ABL1: T315I/A, F317L/V/I/C, or V299L; and
4. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

Phyrago™ (Dasatinib) and Sprycel® (Dasatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:
1. Diagnosis of CML; and
2. Member must have 1 of the following:
   a. Chronic, accelerated, or blast phase CML; or
   b. Post-hematopoietic stem cell transplantation; and
3. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

Phyrago™ (Dasatinib) and Sprycel® (Dasatinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:
1. Diagnosis of soft tissue sarcoma – GIST; and
2. Used for gross residual disease (R2 resection), unresectable primary disease, tumor rupture, or recurrent/metastatic disease; and
3. Used as second-line therapy as single agent; and
4. Member has progressive disease after treatment with avapritinib; and
5. PDGFRA exon 18 mutations that are insensitive to imatinib (including D842V); and
6. For Phyrago™, a patient-specific, clinically significant reason why the member cannot use generic dasatinib (Sprycel®) must be provided.

Next, the College of Pharmacy recommends updating the approval criteria for Epkinly® (epcoritamab-bysp), Gazyva® (obinutuzumab), Jaypirca® (pirtobrutinib), Monjuvi® (tafasitamab-cxix), and Revuforj® (revumenib) based on recent FDA approvals (changes shown in red):

Epkinly® (Epcoritamab-bysp) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:
1. Diagnosis of relapsed or refractory ~~follicular lymphoma (FL) or diffuse large B-cell lymphoma (~~DLBCL~~)~~ not otherwise specified, including DLBCL arising from indolent lymphomas and/or high-grade B-cell lymphomas; and
2. Has received ≥2 lines of systemic therapy.

Epkinly® (Epcoritamab-bysp) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:
1. Diagnosis of relapsed or refractory FL; and
2. Used in 1 of the following settings:
   a. Has received ≥2 lines of systemic therapy; and

i. Used as a single agent; or

b. Has received ≥1 line of systemic therapy; and
    i. Used in combination with lenalidomide and rituximab.

Gazyva® (Obinutuzumab) Approval Criteria [Lupus Nephritis (LN) Diagnosis]:

1. An FDA approved indication for the treatment of active LN in members who are receiving standard therapy; and
2. Member must be 18 years of age or older; and
3. Documented inadequate response to at least 2 of the following medications appropriate to member's specific disease state:
    a. High-dose oral corticosteroids; or
    b. Azathioprine; or
    c. Mycophenolate; or
    d. Cyclophosphamide; or
    e. Hydroxychloroquine/chloroquine; and
4. Will not be approved for combination use with other biologic therapies (e.g., anifrolumab, belimumab).

Jaypirca® (Pirtobrutinib) Approval Criteria [Chronic Lymphocytic/Small Lymphocytic Lymphoma (CLL/SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. ~~As second-line or subsequent therapy following resistance or intolerance to prior covalent Bruton's kinase (BTK) inhibitor and a BCL-2 inhibitor; or~~
3. Disease is relapsed or refractory; and
4. Previously treated with a covalent Bruton's kinase (BTK) inhibitor or a BCL-2 inhibitor; or
5. Demonstrates histologic (Richter) transformation to diffuse large B-cell lymphoma (DLBCL).

Monjuvi® (Tafasitamab-cxix) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Diagnosis of classic FL; and
2. Member must be 18 years of age or older; and
3. Used as second line or later line of therapy (no response, relapsed, or progressive disease); and
4. Used in combination with lenalidomide and rituximab; and
5. Member has received at least 1 prior systemic therapy including an anti-CD20 monoclonal antibody.

Revuforj® (Revumenib) Approval Criteria [Acute Leukemia Diagnosis]:

1. Diagnosis of acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL); and
2. Disease is relapsed or refractory; and
3. Must meet 1 of the following:

a. Leukemia is positive for a lysine methyltransferase 2A gene (KMT2A) translocation; ~~and~~ or
b. Susceptible nucleophosmin 1 (*NPM1*) mutation with no satisfactory alternative treatment options; and

4. Member is 1 year of age or older; and
5. Member's recent weight (kg) must be provided; and
   a. For members weighing <40kg, the member's recent body surface area (BSA) must be provided in order to authorize the appropriate amount of drug.

Next, the College of Pharmacy recommends updating the approval criteria for Breyanzi® (lisocabtagene maraleucel), Kymriah® (tisagenlecleucel), Tecartus® (brexucabtagene autoleucel), and Yescarta® (axicabtagene ciloleucel) based on the removal of the Risk Evaluation and Mitigation Strategy (REMS) requirements, other FDA approvals, and net costs (changes shown in red):

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy including a Burton tyrosine kinase (BTK) inhibitor and a B cell lymphoma-2 (BCL-2) inhibitor; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
5. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Follicular Lymphoma Diagnosis]:

1. Diagnosis of FL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~,~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and

~~5. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene ciloleucel) are not appropriate for the member must be provided; and~~
6. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Large B Cell Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma; and
    a. One of the following:
        i. Refractory disease to frontline chemoimmunotherapy; or
        ii. Relapse within 12 months of frontline chemoimmunotherapy; or
        iii. Relapse within 12 months of frontline chemoimmunotherapy and member is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidity or age; or
        iv. Relapse or refractory disease after 2 or more lines of systemic therapy; and
2. Member does not have primary central nervous system (CNS) lymphoma; and
3. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~;~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
~~4. A patient-specific, clinically significant reason why Kymriah® (tisagenlecleucel) or Yescarta® (axicabtagene) is not appropriate for the member must be provided.~~
5. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. Diagnosis of MCL; and
2. Relapsed or refractory disease after 2 or more lines of systemic therapy including a Bruton tyrosine kinase (BTK) inhibitor; and
3. Member does not have primary central nervous system (CNS) lymphoma; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~;~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
~~5. A patient-specific, clinically significant reason why Tecartus® (brexucabtagene autoleucel) is not appropriate for the member must be provided; and~~
6. Approvals will be for 1 dose per member per lifetime.

Breyanzi® (Lisocabtagene Maraleucel) Approval Criteria [Marginal Zone Lymphoma (MZL) Diagnosis]:

1. Diagnosis of MZL; and
2. Disease is relapsed or refractory; and
3. Member has received at least 2 prior lines of systemic therapy; and
4. Health care facilities must be a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and
5. Approvals will be for 1 dose per member per lifetime.

Kymriah® (Tisagenlecleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Members must meet all of the following:
   a. B-cell precursor ALL; and
   b. Member must be 25 years of age or younger; and
   c. Refractory or in second or later relapse:
      i. Philadelphia chromosome negative (Ph-) ALL: Must be refractory or with ≥2 relapses; or
      ii. Philadelphia chromosome positive (Ph+) ALL: Must have failed ≥2 tyrosine kinase inhibitors (TKIs); and
   d. Therapies to consider prior to tisagenlecleucel if appropriate: Clinical trial, multi-agent chemotherapy with or without hematopoietic cell transplantation (HCT), blinatumomab (category 1 recommendation), and inotuzumab (category 1 recommendation); and
2. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities~~, and must comply with the Kymriah Risk Evaluation and Mitigation Strategy (REMS) requirements~~; and
3. Approvals will be for 1 dose per member per lifetime.

Kymriah® (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Relapsed/refractory disease; and
3. Member must be 18 years of age or older; and
4. Member must not have primary central nervous system lymphoma; and
5. Member must have had ≥2 lines of therapy; and
6. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS) and

neurologic toxicities~~, and must comply with the Kymriah Risk Evaluation and Mitigation Strategy (REMS) requirements~~; and
7. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of acute lymphoblastic leukemia (ALL); and
2. Relapsed or refractory disease; and
3. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~;~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
4. Approvals will be for 1 dose per member per lifetime.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of mantle cell lymphoma; and
2. Relapsed or refractory disease; and
3. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~;~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
4. Approvals will be for 1 dose per member per lifetime.

Yescarta® (Axicabtagene Ciloleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Diagnosis of large B-cell lymphoma [including diffuse large B cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Member must be 18 years of age or older; and
3. Relapsed or refractory disease used in 1 of the following settings; and
    a. After 2 or more lines of therapy; or
    b. After 1 line of therapy, if member is refractory to first-line chemotherapy or relapses within 12 months of first-line chemotherapy; and
4. Health care facilities must be ~~on the certified list~~ a qualified treatment center to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS)~~;~~ and neurologic toxicities~~, and comply with the risk evaluation and mitigation strategy (REMS) requirements~~; and
~~5. For large B-cell lymphoma (including DLBCL, high grade B-cell lymphoma, and DLBCL arising from FL), member must not have primary central nervous system lymphoma.~~
6. Approvals will be for 1 dose per member per lifetime.

The College of Pharmacy also recommends updating the approval criteria for Adcetris® (brentuximab vedotin), Blincyto® (blinatumomab), Calquence® (acalabrutinib), Iclusig® (ponatinib), Imbruvica® (ibrutinib), Poteligeo® (mogamulizumab-kpkc), and Venclexta® (venetoclax) based on National Comprehensive Cancer Network (NCCN) recommendations (changes shown in red):

Adcetris® (Brentuximab Vedotin) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) or High Grade Lymphoma Diagnosis]:

1. Diagnosis of DLBCL or high grade lymphoma; and
2. As a single agent; and
    a. CD30+ disease; and
    b. For DLBCL relapsed/refractory disease in non-autologous stem cell transplant (SCT) candidates or non-candidates for chimeric antigen receptor (CAR) T-cell therapy; or
3. Used in combination with lenalidomide and a rituximab product; and
    a. CD30+ disease; and
    b. Relapsed or refractory disease after 2 or more lines of systemic therapy; and
    c. Ineligible for autologous hematopoietic stem cell transplantation (HSCT) or CAR T-cell therapy.~~; or~~

~~4. Used in combination with nivolumab; and~~

~~a. CD30+ disease; and~~

~~b. Relapsed or refractory primary mediastinal large B-cell lymphoma.~~

Blincyto® (Blinatumomab) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Philadelphia chromosome negative (Ph-) ALL; and
    a. Member must be 1 month of age or older; and
    b. Used in 1 of the following settings:
        i. As consolidation therapy as a component of multiphase chemotherapy; or
        ii. As consolidation in adolescents/young adults or adults younger than 65 years of age without substantial comorbidity with persistent or late clearance minimal residual disease positive (MRD+) following a complete response to induction; or
        iii. As maintenance therapy in combination with mercaptopurine, vincristine, methotrexate, and prednisone (POMP) as a component of maintenance; or
        iv. For management of relapsed/refractory Ph- ALL; or
2. Diagnosis of Philadelphia chromosome positive (Ph+) ALL; and
    a. Member must be 1 month of age or older; and
    b. Used in 1 of the following settings:

i. In combination with a tyrosine kinase inhibitor (TKI) as either frontline consolidation or induction if not a candidate for multiagent chemotherapy; or
ii. With or without a TKI as consolidation in adolescents/young adults or adults younger than 65 years of age without substantial comorbidity with persistent or late clearance MRD+ following a complete response to induction; or
iii. As maintenance therapy in combination with POMP as a component of maintenance if refractory to TKIs; or
iv. For management of relapsed/refractory Ph+ ALL after failure of 2 TKIs.

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. Used as a single agent; or
3. In combination with obinutuzumab and/or venetoclax.

Iclusig® (Ponatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of Ph+ ALL; and
2. Used in 1 of the following settings:
   a. Newly diagnosed Ph+ ALL; and
      i. Used in combination with chemotherapy; or
      ii. Used in combination with blinatumomab; or
      iii. Used in combination with corticosteroids or as single agent in those unfit for chemotherapy; or
   b. Maintenance therapy either as a single agent or in combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
   c. Relapsed/refractory disease either as a single agent, in combination with chemotherapy not previously given, or in patients with T315I mutations.

Imbruvica® (Ibrutinib) Approval Criteria [B-Cell Lymphomas Diagnosis]:

1. Diagnosis of B-cell lymphoma [including diffuse large B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, post-transplant lymphoproliferative disorders, and high-grade B-cell lymphoma]; and
2. As second-line or subsequent therapy; and
3. Member is not a candidate for CAR T-cell therapy or has no intention to proceed to transplant.

~~**Imbruvica® (Ibrutinib) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis or Acquired Immunodeficiency Syndrome (AIDS)-Related B-Cell Lymphoma Diagnosis]:**~~

~~1. Diagnosis of non-germinal center DLBCL; and~~

~~2. As second-line or subsequent therapy; and~~
~~3. Member is not a candidate for CAR T-cell therapy or has no intention to proceed to transplant.~~

~~Imbruvica® (Ibrutinib) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:~~

~~1. Diagnosis of gastric or nongastric MALT lymphoma, nodal or splenic MZL; and~~
~~2. As second-line or subsequent therapy for refractory or progressive disease.~~

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Adult T-Cell Leukemia/Lymphoma (ATLL) Diagnosis]:

1. Diagnosis of ATLL; and
2. Used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP); and
   a. No intention to proceed to transplant; or
3. As a single-agent in relapsed/refractory disease.

Venclexta® (Venetoclax) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Diagnosis of CLL/SLL; and
2. As first-line therapy in combination with acalabrutinib and/or obinutuzumab for a maximum duration of 12 months; or
3. As first-line therapy in combination with ibrutinib; or
4. Relapsed/refractory disease in combination with obinutuzumab, rituximab, or as a single agent.

Venclexta® (Venetoclax) Approval Criteria [Systemic Light Chain Amyloidosis Diagnosis]

1. Diagnosis of relapsed/refractory systemic light chain amyloidosis; and
2. Presence of t(11;14) translocation; and
3. Be used as a single agent; or
4. In combination with dexamethasone; or
5. In combination with daratumumab.

Venclexta® (Venetoclax) Approval Criteria [Multiple Myeloma Diagnosis]

1. Diagnosis of relapsed or progressive multiple myeloma and
2. Presence of t(11;14) translocation; and
3. In combination with dexamethasone; or
4. In combination with dexamethasone and daratumumab; or
5. In combination with dexamethasone and either bortezomib, carfilzomib, or ixazomib.

Lastly, the College of Pharmacy recommends removing the criteria and SoonerCare coverage for Tazverik® (tazemetostat) based on the withdrawal of the medication from the market by the manufacture (changes shown in red):

~~**Tazverik® (Tazemetostat) Approval Criteria [Epitheloid Sarcoma Diagnosis]:**~~

~~1. Diagnosis of metastatic or locally advanced epithelioid sarcoma; and~~
~~2. Member is not eligible for complete resection; and~~
~~3. Member must be 16 years of age or older.~~

~~**Tazverik® (Tazemetostat) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

~~1. Diagnosis of FL; and~~
~~2. Treatment of adult members with relapsed/refractory disease; and~~
~~3. Must meet 1 of the following:~~
~~a. Subsequent therapy and EZH2 mutation positive after 2 or more prior systemic therapies; or~~
~~b. Second line therapy irrespective of EZH2 mutation status for older or infirm members with indications for treatment where other options are not expected to be tolerable; or~~
~~c. Third line and/or subsequent therapy (and not previously given) irrespective of EZH2 mutation status in members with indications for treatment.~~

Recommendation 11: Fiscal Year 2025 Annual Review of Multiple Sclerosis (MS) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the MS medications approval criteria (changes shown in red):

1. Updating the MS interferon medications, Aubagio® (teriflunomide), Bafiertam® (monomethyl fumarate), Briumvi® (ublituximab-xiiy), Gilenya® (fingolimod), Kesimpta® (ofatumumab), Mayzent® (siponimod), Ocrevus® (ocrelizumab), Ocrevus Zunovo® (ocrelizumab/hyaluronidase-ocsq), Ponvory® (ponesimod), Tascenso ODT® (fingolimod ODT), Tecfidera® (dimethyl fumarate), Tyruko® (natalizumab-sztn), Tysabri® (natalizumab), Vumerity® (diroximel fumarate), and Zeposia® (ozanimod) approval criteria based on clinical practice and to require all recommended clinical monitoring appropriate to the package labeling; and
2. Updating the Mavenclad® (cladribine) approval criteria based on clinical practice and designating it as brand preferred; and
3. Updating the Copaxone® (glatiramer acetate) approval criteria based on clinical practice and net costs.

Multiple Sclerosis Interferon Medications	
Tier-1	**Tier-2**
interferon β - 1a (Avonex®)	interferon β - 1a (Rebif®)
interferon β - 1b (Betaseron®)	interferon β - 1b (Extavia®)
peginterferon β - 1a (Plegridy®)	

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Multiple Sclerosis (MS) Interferon Medications Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of MS, or secondary progressive forms of MS; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Authorization of Tier-2 medications requires previous failure of preferred Tier-1 medication(s) defined as:
    a. Occurrence of an exacerbation after 6 months; or
    b. Significant increase in magnetic resonance imaging (MRI) lesion after 6 months; or
    c. Adverse reactions or intolerable side effects; and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. ~~Compliance will be checked for continued approval every 6 months.~~
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Aubagio® (Teriflunomide) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. ~~All of the following will be required for initiation of treatment:~~
    ~~a. Verification that female members are not pregnant and are currently using reliable contraception; and~~
    ~~b. Verification that the member has no active infection(s); and~~
    ~~c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
    ~~d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
    ~~e. Blood pressure (BP) measurement and verification that BP is being monitored; and~~
    ~~f. Verification that the member does not have tuberculosis (TB), or completion of standard medical treatment for members with TB; and~~
5. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Aubagio®; and
6. Prescriber must confirm that the member does not have any contraindications for use of teriflunomide; and

7. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy; and
8. Female and male members of reproductive potential must be willing to use effective contraception during treatment with Aubagio® and until plasma concentrations are <0.02mcg/mL after discontinuing treatment; and
9. ~~Initial approvals of Aubagio® will be for 6 months, after which time all of the following will be required for further approval:~~
   a. ~~Medication compliance; and~~
   b. ~~Repeat CBC and verification that counts are acceptable to the prescriber; and~~
   c. ~~Repeat LFTs and verification that levels are acceptable to the prescriber; and~~
   d. ~~Verification that female members are not pregnant and will continue using reliable contraception; and~~
   e. ~~Verification that BP and signs of renal failure are being monitored; and~~
10. ~~Compliance will be checked for continued approval every 6 months; and~~
11. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 30 tablets per 30 days will apply.

Bafiertam® (Monomethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no serious active infection(s); and
5. Prescriber must confirm that the member does not have any contraindications for use of monomethyl fumarate; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Bafiertam®; and
7. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
8. ~~Complete blood counts (CBC), including lymphocyte count, and verification that levels are acceptable to the prescriber; and~~

~~9. Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and~~
10. Intolerable adverse effects associated with a trial of Tecfidera® (dimethyl fumarate) and Vumerity® (diroximel fumarate) that are not expected to occur with Bafiertam® or a patient-specific, clinically significant reason why trials of Tecfidera® and Vumerity® are not appropriate for the member must be provided; and
~~11. Verification that CBC, including lymphocyte count, levels are acceptable to the prescriber in addition to compliance will be required for continued approval every 6 months; and~~
12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 4 capsules per day will apply.

Briumvi® (Ublituximab-xiiy) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Briumvi® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Briumvi® will be administered; and
    a. Briumvi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Briumvi® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver ~~must~~ will be trained on the proper storage of Briumvi®; and
5. Prescriber must confirm that member will be monitored for 1 hour following the first 2 infusions and as indicated for subsequent infusions; and
6. Prescriber must confirm that the member does not have any contraindications for use of ublituximab-xiiy; and
7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Briumvi®; and
~~8. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating Briumvi® therapy and member does not have active HBV; and~~

9. Verification from the prescriber that member has no active infection(s); and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving Briumvi® therapy and for 6 months after the last infusion of Briumvi®; and
12. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

Copaxone® (Glatiramer Acetate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must verify that the member has no history of hypersensitivity reactions, including anaphylaxis, to glatiramer acetate and verify that the member ~~has been~~ will be counseled on the symptoms of anaphylaxis and instructed to seek immediate medical care should anaphylaxis symptoms occur; and
5. ~~Approvals for the 40mg strength of Copaxone® will require a patient-specific, clinically significant reason why the member cannot use the 20mg strength; and~~
6. ~~Approvals for the generic formulation of either strength of Copaxone®, including Glatopa®, will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and~~
7. Brand name Copaxone® 20mg/mL is preferred. Requests for the 20mg/mL generic formulation, including Glatopa®, and the 40mg strength will require a patient-specific, clinically significant reason why the member cannot use brand name Copaxone® 20mg/mL; and
8. ~~Compliance will be checked for continued approval every 6 months.~~
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Gilenya® (Fingolimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and

2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that member will be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
5. ~~Member must not have any contraindications for use of Gilenya® including:~~
   a. ~~Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or~~
   b. ~~Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and~~
   c. ~~Baseline QTc interval ≥500msec; and~~
   d. ~~Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs; and~~
6. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Gilenya® as per package labeling, including:~~
   a. ~~Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and~~
   b. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
   c. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
   d. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
   e. ~~Skin examination and verification that member will be monitored throughout therapy; and~~
   f. ~~Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Gilenya®; and~~
7. Prescriber must confirm that the member does not have any contraindications for use of fingolimod; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Gilenya®; and
9. Verification from the prescriber that member has no active infection(s); and

10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must be willing to use effective contraception during treatment with Gilenya® and for at least 2 months after discontinuing treatment; and
~~12. Compliance will be checked for continued approval every 6 months.~~
13. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Kesimpta® (Ofatumumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that the member does not have any contraindications for use of ofatumumab; and
5. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Kesimpta®; and
~~6. The prescriber must verify Hepatitis B virus (HBV) screening is performed before the first dose of Kesimpta® and the member does not have an active HBV infection; and~~
~~7. Prescriber must agree to monitor quantitative serum immunoglobulin level before, during, and after discontinuation of treatment with Kesimpta® until B-cell repletion; and~~
8. Prescriber must verify the member has no active infection(s); and
9. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
10. Prescriber must verify the first injection of Kesimpta® will be administered by a health care professional prepared to manage injection-related adverse reactions; and
11. Kesimpta® must be shipped via cold chain supply and the member or member's caregiver ~~must~~ will be trained on the proper storage and subcutaneous (sub-Q) administration of Kesimpta®; and
12. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of treatment with Kesimpta®; and

13. Female members of reproductive potential must use an effective method of contraception during treatment and for 6 months after stopping Kesimpta®; and
14. A quantity limit of 1 syringe or prefilled Sensoready® Pen per month will apply. Initial dosing titration will be approved for a quantity limit override upon meeting Kesimpta® approval criteria; and
~~15. Compliance will be checked for continued approval every 6 months.~~
16. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Mavenclad® (Cladribine) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include relapsing remitting disease and active secondary progressive disease, in adults; and
2. Requests for use in patients with clinically isolated syndrome (CIS) will not generally be approved; and
3. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
6. Prescriber must confirm that the member does not have any contraindications for use of cladribine; and
7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Mavenclad®; and
8. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
9. Prescriber must confirm member does not have an active malignancy; and
10. Prescriber must confirm that female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
11. Prescriber must attest that female and male members of reproductive potential plan to use effective contraception during cladribine dosing and for 6 months after the last dose in each treatment course; and
~~12. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
13. Verification from the prescriber that member has no active infection(s); and
~~14. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~

15. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
16. Mavenclad® is brand preferred. Requests for generic cladribine will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
17. Quantity limits according to package labeling will apply; and
18. Approvals will be for 1 year of therapy (1 treatment course/2 cycles) at a time. Lifetime approval duration will be limited to a maximum of 2 treatment courses according to package labeling.

Mayzent® (Siponimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Member must have been assessed for CYP2C9 genotype:
    a. Members with a CYP2C9*3/*3 genotype will not generally be approved; or
    b. Members with a CYP2C9*1/*3 or *2/*3 genotype will not be approved for doses exceeding 1mg per day; or
    c. All other genotypes CYP2C9 *1/*1, *1/*2, or *2/*2 will be approved for 2mg per day; and
5. ~~Member must not have any contraindication for use of siponimod including:~~
    ~~a. CYP2C9*3/*3 genotype; or~~
    ~~b. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or Class III/IV HF in the last 6 months; or~~
    ~~c. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and~~
6. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Mayzent® as per package labeling, including:~~
    ~~a. Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and~~
    ~~b. Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring~~
    ~~c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~

~~d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
~~e. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
~~f. Skin examination and verification that member will be monitored throughout therapy; and~~
~~g. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Mayzent®; and~~

7. Prescriber must confirm that the member does not have any contraindications for use of siponimod; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Mayzent®; and
9. Member must not have received prior treatment with alemtuzumab; and
10. Verification from the prescriber that member has no active infection(s); and
11. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
12. Verification from the prescriber that members with sinus bradycardia (HR <55 beats per minute), first- or second-degree AV block (Mobitz type I), or a history of HF or MI will be monitored following the first dose for a minimum of 6 hours; and
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
14. Female members of reproductive potential must be willing to use effective contraception during treatment with Mayzent® and for at least 10 days after discontinuing treatment; and
15. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
~~16. Compliance will be checked for continued approval every 6 months; and~~
17. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
18. Quantity limits according to package labeling will apply.

Ocrevus® (Ocrelizumab) and Ocrevus Zunovo® (Ocrelizumab/ Hyaluronidase-ocsq) Approval Criteria:

1. An FDA approved diagnosis of primary progressive forms of multiple sclerosis (MS) or relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician that is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease modifying therapies; and
4. Ocrevus® and Ocrevus Zunovo® must be administered by a health care professional in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion/injection reactions. Approvals will not be granted for self-administration. Prior authorization requests must indicate how the requested product will be administered; and
    a. Ocrevus® and Ocrevus Zunovo® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Ocrevus® and Ocrevus Zunovo® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member or member's caregiver ~~must~~ will be trained on the proper storage of the requested product; and
5. Prescriber must confirm that member will be monitored appropriately per package labeling after each infusion or injection; and
6. ~~Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating ocrelizumab therapy and member does not have active HBV; and~~
7. Prescriber must confirm that the member does not have any contraindications for use of ocrelizumab; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for the requested product; and
9. Verification from the prescriber that member has no active infection(s); and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving ocrelizumab therapy and for 6 months after the last dose infusion of ocrelizumab; and
12. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

Ponvory® (Ponesimod) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that members with sinus bradycardia (HR <55 beats per minute), first- or second-degree atrioventricular (AV) block (Mobitz type I), or a history of heart failure (HF) or myocardial infarction (MI) will be monitored following the first dose for a minimum of 4 hours; and
5. ~~Member must not have any contraindications for use of Ponvory® including:~~
   a. ~~MI, unstable angina, stroke, transient ischemic attack (TIA), decompensated HF requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or~~
   b. ~~Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless member has a functioning pacemaker; and~~
6. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Ponvory® as per package labeling, including:~~
   a. ~~Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and~~
   b. ~~Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring~~
   c. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
   d. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
   e. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
   f. ~~Skin examination and verification that member will be monitored throughout therapy; and~~
   g. ~~Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Ponvory®; and~~
7. Prescriber must confirm that the member does not have any contraindications for use of ponesimod; and

8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Ponvory®; and
9. Member must not have received prior treatment with alemtuzumab; and
10. Verification from the prescriber that the member has no active infection(s); and
11. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
12. ~~Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and~~
13. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
14. Female members of reproductive potential must be willing to use effective contraception during treatment with Ponvory® and for at least 1 week after discontinuing treatment; and
15. Member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; and
16. ~~Compliance will be checked for continued approval every 6 months; and~~
17. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
18. A quantity limit of 30 tablets per 30 days will apply for the 20mg tablet. A quantity limit of 14 tablets per 14 days will apply for the Ponvory® starter pack.

Tascenso ODT® [Fingolimod Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Prescriber must confirm that member will be observed in the prescriber's office for signs and symptoms of bradycardia for 6 hours after the first dose; and
5. ~~Member must not have any contraindications for use of Tascenso ODT® including:~~

a. ~~Myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or~~
b. ~~Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; and~~
c. ~~Baseline QTc interval ≥500msec; and~~
d. ~~Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs; and~~

6. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Tascenso ODT® as per package labeling, including:~~
   a. ~~Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and~~
   b. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
   c. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
   d. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
   e. ~~Skin examination and verification that member will be monitored throughout therapy; and~~
   f. ~~Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Tascenso ODT®; and~~
7. Prescriber must confirm that the member does not have any contraindications for use of fingolimod; and
8. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Tascenso ODT®; and
9. Verification from the prescriber that member has no active infection(s); and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. Female members of reproductive potential must not be pregnant, must have a negative pregnancy test prior to initiation of therapy, and must be willing to use effective contraception during treatment with Tascenso ODT® and for at least 2 months after discontinuing treatment; and
12. A patient-specific, clinically significant reason why the member cannot use Gilenya® (fingolimod) capsules must be provided; and
13. ~~Compliance will be checked for continued approval every 6 months.~~

14. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Tecfidera® (Dimethyl Fumarate) Approval Criteria:

1. An FDA approved diagnosis of clinically isolated syndrome, relapsing forms of multiple sclerosis (MS), or secondary progressive forms of MS in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no active infection(s); and
5. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Tecfidera®; and
7. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
8. ~~Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and~~
9. ~~Compliance will be checked for continued approval every 6 months; and~~
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
11. A quantity limit of 60 tablets per 30 days will apply.

Tyruko® (Natalizumab-sztn) and Tysabri® (Natalizumab) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, or Crohn's disease in adults; and
2. For a diagnosis of MS, the following criteria will apply:
    a. Prescriber must be a neurologist or an advanced care practitioner with a supervising physician who is a neurologist; and
    b. Approvals will not be granted for concurrent use with other disease-modifying therapies; or
3. For a diagnosis of Crohn's disease, the following criteria will apply:
    a. Treatment with at least 2 different first-line therapeutic categories for Crohn's disease that have failed to yield an adequate clinical

response, or a patient-specific, clinically significant reason why the member cannot use all available first- and second-line alternatives must be provided; and

4. For Tyruko®, a patient-specific, clinically significant reason why the member cannot use Tysabri® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
5. For Tyruko®, prescriber, infusion center, and member must enroll in the Risk Evaluation and Mitigation Strategy (REMS) program; and
6. For Tysabri®, prescriber, infusion center, and member must enroll in the TOUCH Prescribing Program; and
7. ~~Compliance will be checked for continued approval every 6 months.~~
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Vumerity® (Diroximel Fumarate) Approval Criteria:

1. An FDA approved diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and
2. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
4. Verification from the prescriber that member has no serious active infection(s); and
5. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
6. ~~Liver function tests (LFTs) and total bilirubin levels and verification that levels are acceptable to the prescriber; and~~
7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Vumerity®; and
8. Verification from the prescriber that member does not have moderate or severe renal impairment; and
9. Verification from the prescriber that the member ~~has been~~ will be counseled on proper administration of Vumerity® including caloric and fat intake limits at the time of dosing; and
10. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
11. ~~Compliance will be checked for continued approval every 6 months; and~~

12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 120 capsules per 30 days will apply.

Zeposia® (Ozanimod) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following in adults:
    a. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease; or
    b. Moderately to severely active ulcerative colitis (UC); and
2. For the diagnosis of MS:
    a. Prescriber must be a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
    b. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
3. ~~Member must not have any contraindications for use of Zeposia® including:~~
    ~~a. Experienced myocardial infarction (MI), unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure (HF) requiring hospitalization, or NYHA Class III/IV HF in the last 6 months; or~~
    ~~b. Presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, unless member has a functioning pacemaker; or~~
    ~~c. Have severe untreated sleep apnea; or~~
    ~~d. Concurrent use of monoamine oxidase inhibitors (MAOIs); and~~
4. ~~Verification from the prescriber that all baseline assessments have been completed prior to initiating Zeposia® as per package labeling, including:~~
    ~~a. Member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present; and~~
    ~~b. Member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and the member will be followed with appropriate monitoring; and~~
    ~~c. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
    ~~d. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
    ~~e. Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
    ~~f. Skin examination and verification that member will be monitored throughout therapy; and~~
    ~~g. Member has a previous confirmed history of chickenpox or vaccination against varicella. Members without a history of~~

~~chickenpox or varicella vaccination should receive a full course of the varicella vaccine prior to commencing treatment with Zeposia®; and~~

5. Prescriber must confirm that the member does not have any contraindications for use of ozanimod; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Zeposia®; and
7. Member must not have received prior treatment with alemtuzumab; and
8. Verification from the prescriber that member has no active infection(s); and
9. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
10. Member must not be concurrently using strong CYP2C8 inhibitors/ inducers; and
11. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
12. Female members of reproductive potential must be willing to use effective contraception during treatment with Zeposia® and for at least 3 months after discontinuing treatment; and
13. For the diagnosis of MS, member must have had an inadequate response to Gilenya® (fingolimod) or a patient-specific, clinically significant reason why fingolimod is not appropriate for the member must be provided; or
14. For the diagnosis of UC, member must have had an inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunomodulators (e.g., 6-mercaptopurine, azathioprine), and a biologic [e.g., tumor necrosis factor (TNF) blocker]. Tier structure applies; and

~~15. Compliance will be checked for continued approval every 6 months; and~~

16. Initial approvals will be for the duration of 6 months. Reauthorization may be granted for the duration of 1 year, if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
17. A quantity limit of 30 capsules per 30 days will apply.

Recommendation 12: Fiscal Year 2025 Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Avgemsi™ (Gemcitabine), Emrelis™ (Telisotuzumab Vedotin-tllv), Ensacove™ (Ensartinib), Hernexeos® (Zongertinib), Hyrnuo® (Sevabertinib), Ibtrozi™ (Taletrectinib), and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2026.

Recommendation 13: Fiscal Year 2025 Annual Review of Attention-Deficit/ Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Arynta™ (Lisdexamfetamine Oral Solution) and Atoncy™ (Atomoxetine Oral Solution)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2026.

Recommendation 14: Fiscal Year 2025 Annual Review of Primary Immunoglobulin A Nephropathy (IgAN) Medications and 30-Day Notice to Prior Authorize Voyxact® (Sibeprenlimab-szsi)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2026.

Recommendation 15: Fiscal Year 2025 Annual Review of Spinal Muscular Atrophy (SMA) Medications and 30-Day Notice to Prior Authorize Itvisma® (Onasemnogene Abeparvovec-brve)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN APRIL 2026.

Recommendation 16: Fiscal Year 2025 Annual Review of Interstitial Lung Disease (ILD) Medications and 30-Day Notice to Prior Authorize Jascayd® (Nerandomilast)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2026.

Recommendation 17: 30-Day Notice to Prior Authorize Rethymic® (Allogeneic Processed Thymus Tissue–agdc)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2026.

Recommendation 18: Fiscal Year 2025 Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Eydenzelt® (Aflibercept-boav)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2026.

Recommendation 19: Fiscal Year 2025 Annual Review of Sofdra™ (Sofpironium 12.45% Topical Gel)

NO ACTION REQUIRED.

Recommendation 20: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

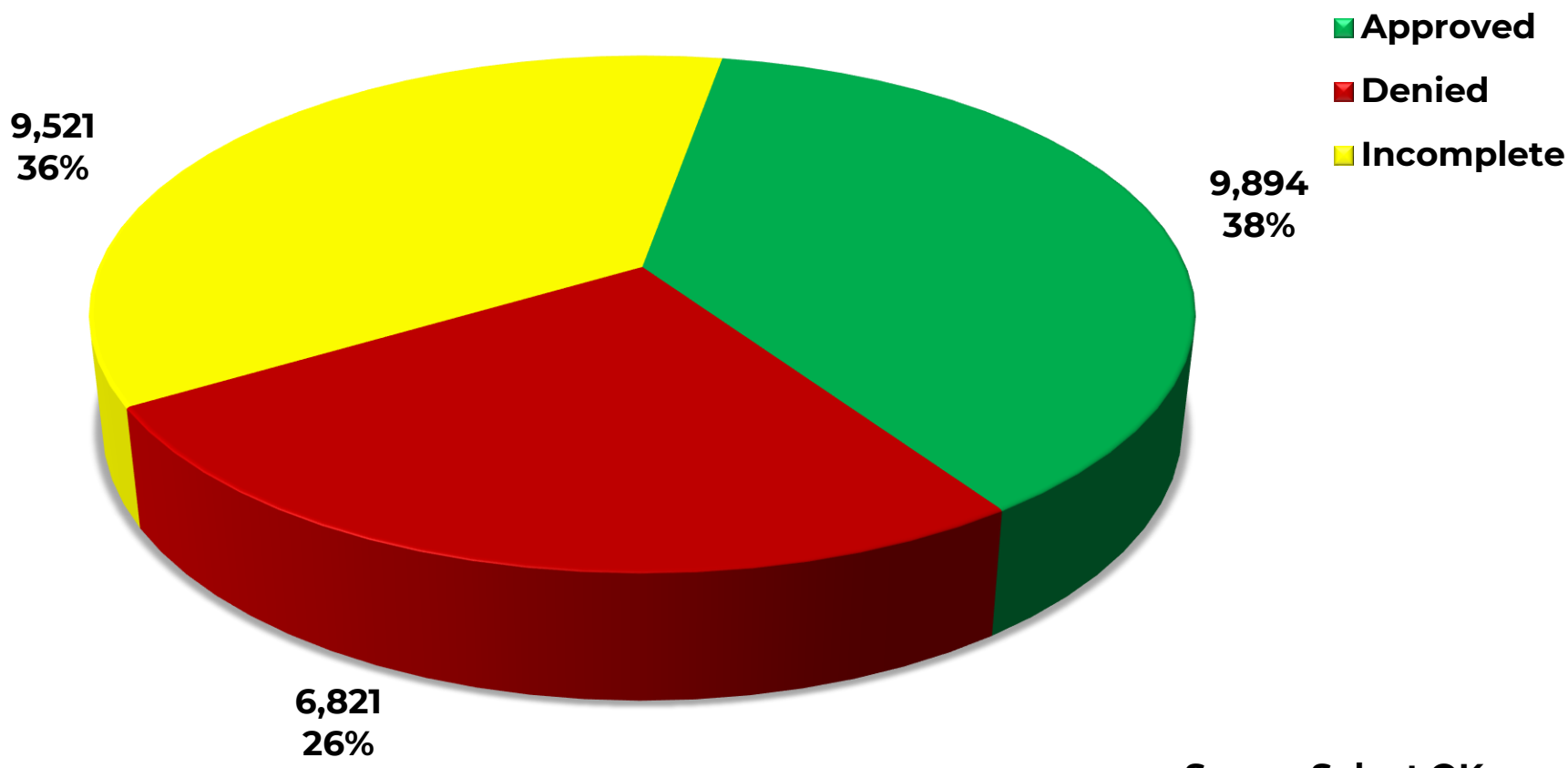
Recommendation 21: Future Business

NO ACTION REQUIRED.

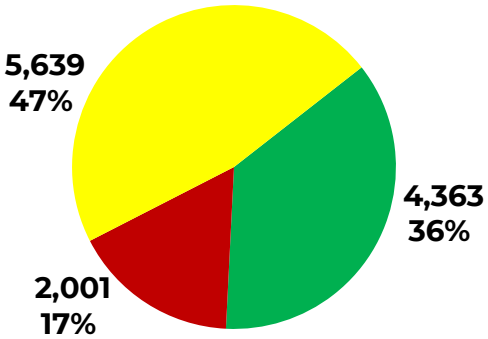
- There is no DUR Board meeting scheduled for May 2026.

Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: APRIL 2026



SoonerCare FFS



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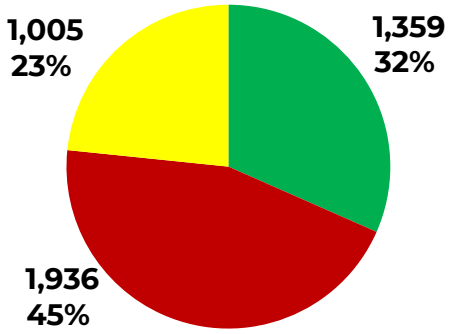

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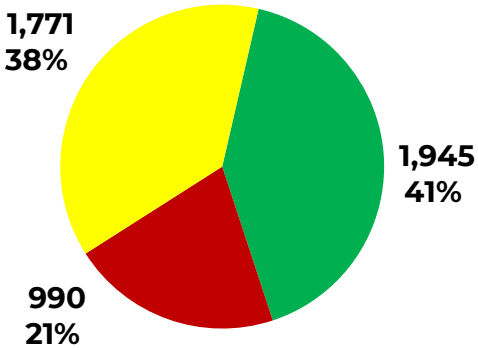
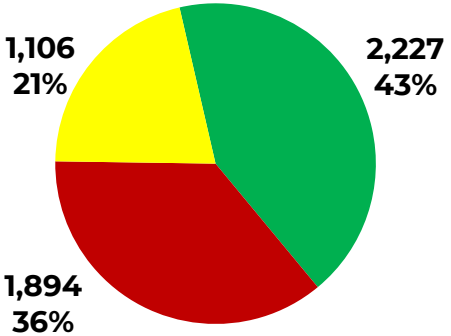
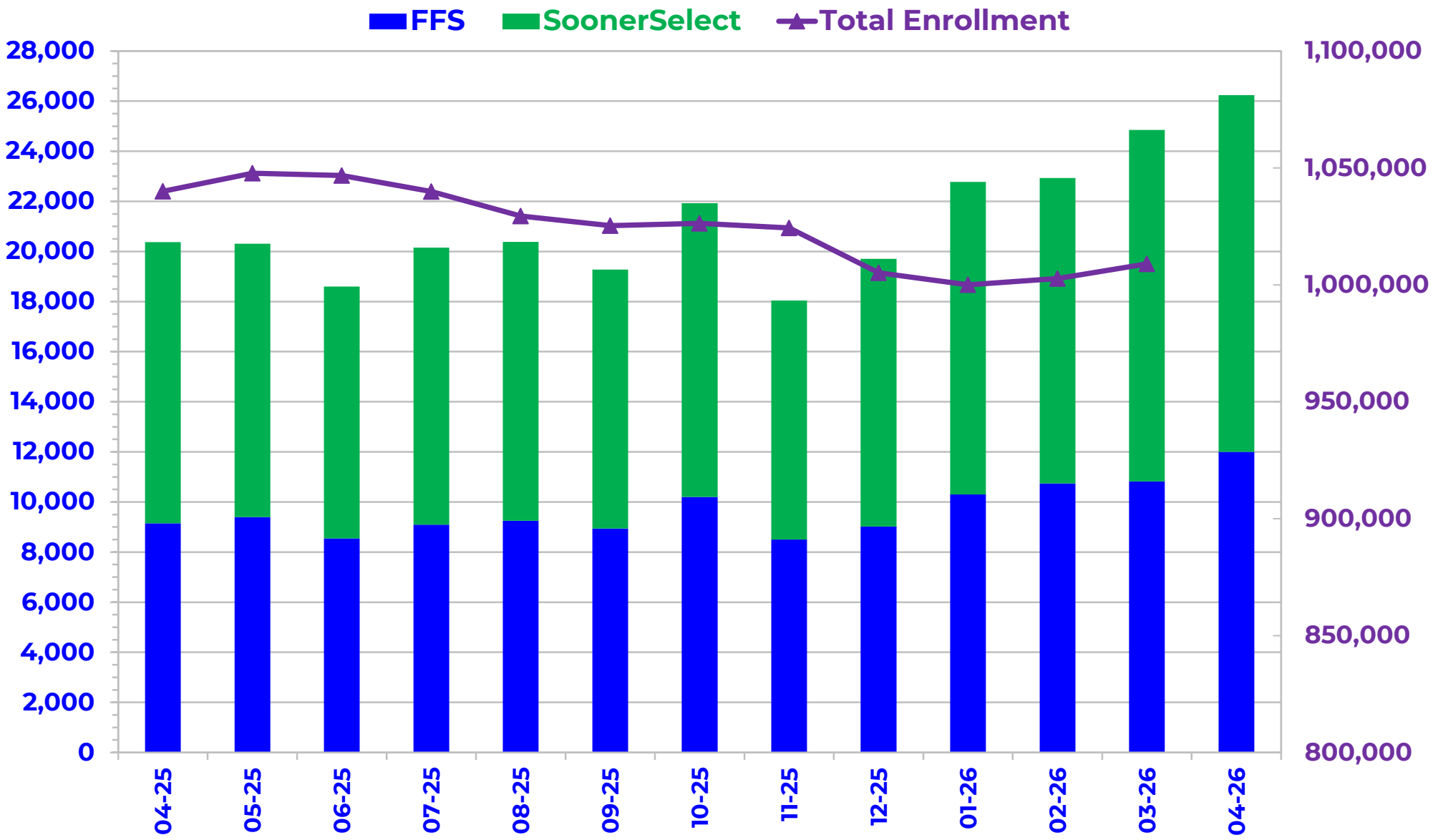


SoonerSelect OK Complete Health



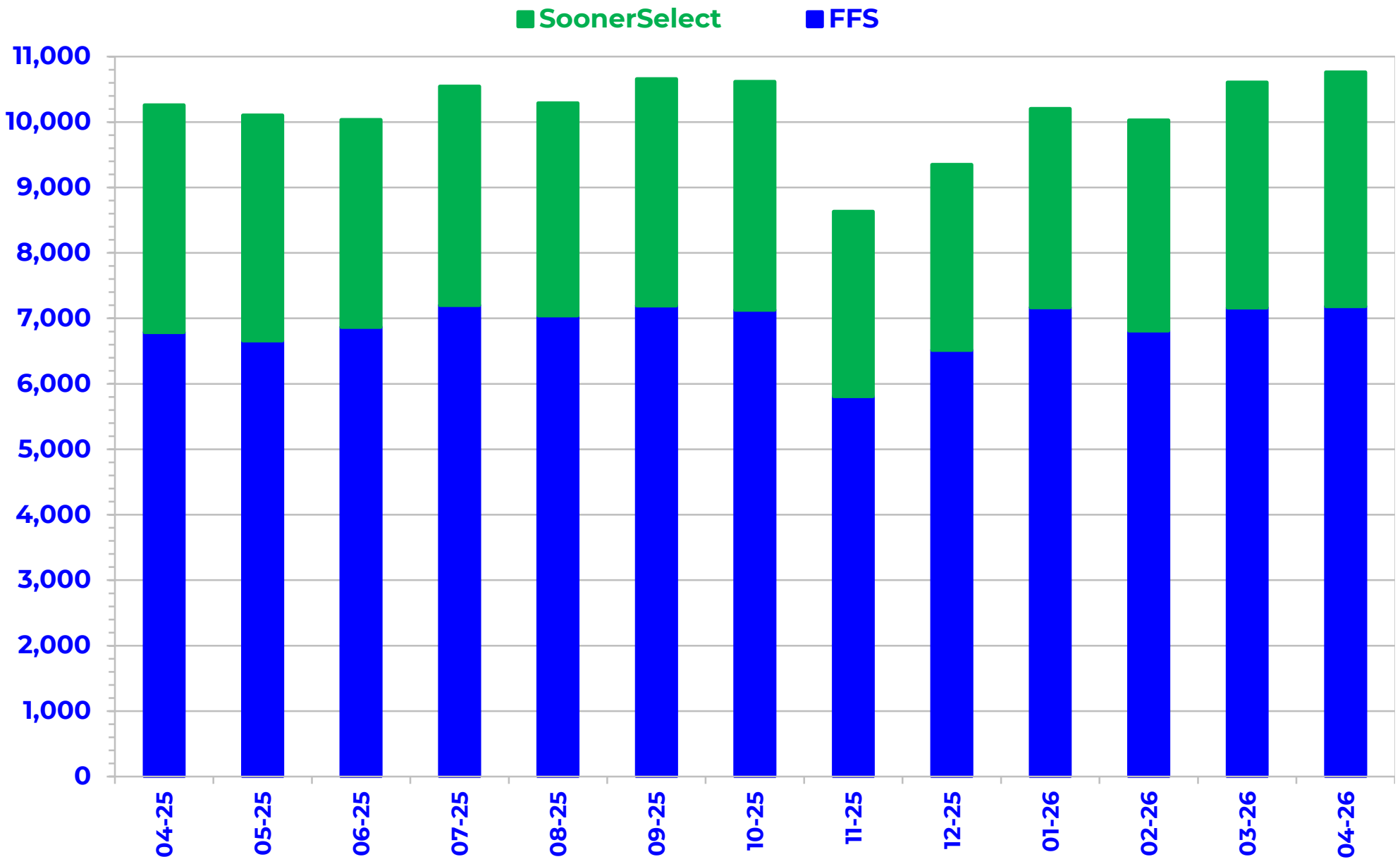
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: APRIL 2025 – APRIL 2026



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: APRIL 2025 – APRIL 2026



SoonerCare FFS Prior Authorization Activity

4/1/2026 Through 4/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	1,010	560	108	342	354
Analgesics - Anti-Inflammatory	319	110	60	149	330
Analgesics - Nonnarcotic	19	0	3	16	0
Analgesics - Opioid	401	151	38	212	134
Androgens - Anabolic	94	15	26	53	359
Anorectal and Related Products	3	0	1	2	0
Anorexiants Non-Amphetamine	1	0	1	0	0
Anthelmintics	8	1	1	6	7
Anti-Infective Agents - Misc.	42	11	8	23	19
Anti-Obesity Agents	452	77	207	168	72
Antianxiety Agents	32	5	3	24	255
Antiarrhythmics	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	618	96	100	422	493
Antibiotics	52	20	4	28	159
Anticoagulants	17	2	2	13	359
Anticonvulsants	365	170	19	176	371
Antidepressants	296	61	46	189	572
Antidiabetics	1,825	558	337	930	368
Antidiarrheal/Probiotic Agents	1	0	1	0	0
Antidotes and Specific Antagonists	2	1	0	1	360
Antiemetics	18	4	1	13	98
Antifungals	9	3	0	6	146
Antihistamines	30	4	14	12	250
Antihyperlipidemics	82	9	19	54	380
Antihypertensives	76	36	3	37	562
Antimalarials	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	235	158	9	68	190
Antiparkinson and Related Therapy Agents	11	2	3	6	359
Antipsychotics/Antimanic Agents	562	184	75	303	388
Antivirals	23	8	5	10	54
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	322	209	26	87	977
Beta Blockers	27	9	1	17	889
Calcium Channel Blockers	21	5	3	13	742
Cardiovascular Agents - Misc.	161	75	7	79	485
Chemicals	1	0	1	0	0
Contraceptives	40	15	5	20	515
Corticosteroids	8	1	2	5	81
Cough/Cold/Allergy	2	0	2	0	0
Dermatologicals	561	144	152	265	237
Diagnostic Products	59	29	3	27	191
Digestive Aids	11	6	0	5	357
Diuretics	13	9	1	3	645
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	1	1	0	360
Emergency PA	1	1	0	0	0
Endocrine and Metabolic Agents - Misc.	217	88	37	92	235

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Estrogens	28	5	2	21	360
Gastrointestinal Agents - Misc.	420	110	101	209	283
Genitourinary Agents - Misc.	7	3	1	3	1091
Gout Agents	6	1	3	2	110
Hematological Agents - Misc.	30	12	1	17	359
Hematopoietic Agents	50	22	8	20	129
Hemostatics	1	0	1	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	58	4	23	31	312
Laxatives	37	16	1	20	150
Medical Devices and Supplies	367	80	85	202	300
Migraine Products	513	136	115	262	256
Minerals and Electrolytes	15	6	1	8	131
Miscellaneous Therapeutic Classes	92	40	10	42	328
Mouth/Throat/Dental Agents	1	0	0	1	0
Multivitamins	8	3	1	4	360
Musculoskeletal Therapy Agents	83	3	22	58	268
Nasal Agents - Systemic and Topical	15	0	2	13	0
Neuromuscular Agents	110	54	29	27	348
Ophthalmic Agents	88	16	14	58	150
Other*	69	21	3	45	297
Otic Agents	60	21	3	36	15
Passive Immunizing and Treatment Agents	10	0	4	6	0
Progestins	7	2	1	4	225
Psychotherapeutic and Neurological Agents - Misc.	279	88	60	131	263
Respiratory Agents - Misc.	38	18	4	16	280
Stimulants - Misc.	221	124	20	77	358
Thyroid Agents	9	0	3	6	0
Ulcer Drugs/Antispasmodics/Anticholinergics	132	19	24	89	667
Urinary Antispasmodics	79	13	11	55	622
Vaccines	2	1	0	1	239
Vaginal and Related Products	5	0	1	4	0
Vasopressors	1	0	0	1	0
Vitamins	60	2	48	10	74
Total	**10,952**	**3,658**	**1,937**	**5,357**	
Overrides					
Brand	37	18	4	15	407
Compound	17	16	0	1	12
Dosage Change	173	153	3	17	13
High Dose	2	0	0	2	0
Ingredient Duplication	2	2	0	0	87
Lost/Broken Rx	41	32	1	8	22
MAT Override	8	4	1	3	109
NDC vs Age	156	95	26	35	447
NDC vs Sex	14	12	1	1	358
Nursing Home Issue	53	42	0	11	19
Opioid MME Limit	52	11	3	38	135
Opioid Quantity	16	12	0	4	165

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Other	63	44	7	12	26
Quantity vs Days Supply	349	218	16	115	355
STBS/STBSM	6	4	0	2	131
Step Therapy Exception	4	1	2	1	358
Stolen	8	6	0	2	13
Third Brand Request	50	35	0	15	15
Overrides Total	**1,051**	**705**	**64**	**282**	
Total Regular PAs + Overrides	**12,003**	**4,363**	**2,001**	**5,639**	

Denial Reasons	
Unable to verify required trials.	5,207
Does not meet established criteria.	2,069
Lack required information to process request.	524
Other PA Activity	
Duplicate Requests	1,742
Letters	63,091
No Process	0
Helpdesk Initiated Prior Authorizations	373
PAs Missing Information	408
Pharmacotherapy	117
Changes to Existing PAs	728

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

SoonerSelect Aetna Prior Authorization Activity

4/1/2026 Through 4/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	2	0	2	0	0
Amphetamines	342	220	99	23	356
Analgesics - Anti-Inflammatory	133	72	35	26	349
Analgesics - Nonnarcotic	8	0	8	0	0
Analgesics - Opioid	126	55	48	23	164
Androgens - Anabolic	62	11	46	5	365
Anorectal and Related Products	6	0	6	0	0
Anthelmintics	9	3	5	1	9
Antianxiety Agents	41	6	9	26	199
Antiasthmatic and Bronchodilator Agents	186	41	93	52	306
Antibiotics	29	1	4	24	183
Anticoagulants	19	4	2	13	183
Anticonvulsants	63	19	16	28	290
Antidepressants	264	65	107	92	530
Antidiabetics	611	162	329	120	310
Antiemetics	34	7	4	23	121
Antifungals	2	0	1	1	0
Antihistamines	20	2	16	2	731
Antihyperlipidemics	47	6	23	18	274
Antihypertensives	42	2	0	40	365
Anti-Infective Agents - Misc.	8	1	3	4	10
Antimyasthenic/Cholinergic Agents	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	31	10	2	19	244
Anti-Obesity Agents	280	48	212	20	44
Antiparkinson and Related Therapy Agents	7	0	3	4	0
Antipsychotics/Antimanic Agents	178	42	85	51	335
Antivirals	3	0	1	2	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	99	85	14	0	761
Beta Blockers	25	2	4	19	274
Calcium Channel Blockers	15	2	2	11	365
Cardiovascular Agents - Misc.	31	11	15	5	203
Chemicals	1	1	0	0	365
Contraceptives	17	1	15	1	365
Corticosteroids	13	5	4	4	239
Dermatologicals	355	137	166	52	256
Diagnostic Products	41	23	8	10	469
Dietary Products/Dietary Management Products	1	1	0	0	365
Digestive Aids	2	0	1	1	0
Diuretics	26	1	0	25	1096
Endocrine and Metabolic Agents - Misc.	45	23	16	6	213
Estrogens	14	4	4	6	502
Gastrointestinal Agents - Misc.	107	42	58	7	278
Genitourinary Agents - Misc.	4	2	0	2	198
Gout Agents	4	1	1	2	183
Hematological Agents - Misc.	6	4	0	2	364
Hematopoietic Agents	18	3	14	1	365

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	38	6	19	13	274
Laxatives	17	1	12	4	30
Medical Devices and Supplies	101	27	49	25	501
Migraine Products	241	67	163	11	199
Minerals and Electrolytes	16	5	1	10	361
Miscellaneous Therapeutic Classes	18	16	2	0	274
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	69	3	25	41	172
Nasal Agents - Systemic and Topical	22	0	11	11	0
Neuromuscular Agents	6	4	2	0	365
Ophthalmic Agents	46	9	24	13	263
Other	12	1	1	10	365
Otic Agents	23	1	19	3	10
Progestins	3	3	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	29	12	13	4	224
Respiratory Agents - Misc.	5	3	0	2	244
Stimulants - Misc.	104	54	28	22	351
Thyroid Agents	3	0	0	3	0
Ulcer Drugs/Antispasmodics/Anticholinergics	79	7	22	50	405
Urinary Antispasmodics	13	3	7	3	304
Vaccines	2	0	2	0	0
Vaginal and Related Products	7	0	1	6	0
Vasopressors	1	0	0	1	0
Vitamins	65	10	54	1	259
****Total**	**4,300**	**1,359**	**1,936**	**1,005**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Overrides					
Brand	3	3	0	0	274
Other	1,005	0	0	1,005	0
Quantity Level Limit	22	22	0	0	250
Step Therapy Met	5	5	0	0	30
Overrides Total	**1,035**	**30**	**0**	**1,005**	

Denial Reason	
Benefit	126
Experimental/Investigational	157
Lack Required Infomation to Process Request	109
Medical Necessity	1,520
Other	24
Other PA Activity	
Duplicate Requests	28
Letters	5,409
No Process	296
Changes to existing PAs	0
PAs missing info	25

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Humana Prior Authorization Activity

4/1/2026 Through 4/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	17	5	0	12	329
Analgesics - Anti-Inflammatory	82	70	3	9	341
Analgesics - Nonnarcotic	6	1	0	5	364
Analgesics - Opioid	89	30	26	33	240
Androgens - Anabolic	91	25	53	13	198
Anorectal and Related Products	5	1	0	4	548
Anthelmintics	4	2	0	2	274
Antianxiety Agents	3	0	0	3	0
Antiasthmatic and Bronchodilator Agents	138	56	48	34	329
Antibiotics	12	0	1	11	0
Anticoagulants	1	0	0	1	0
Anticonvulsants	37	15	6	16	275
Antidepressants	72	41	9	22	421
Antidiabetics	341	111	116	114	309
Antiemetics	22	3	6	13	160
Antihistamines	6	1	1	4	122
Antihyperlipidemics	19	10	3	6	371
Antihypertensives	5	1	0	4	365
Anti-Infective Agents - Misc.	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	93	55	1	37	212
Anti-Obesity Agents	316	81	92	143	100
Antipsychotics/Antimanic Agents	8	3	0	5	213
Antivirals	3	0	1	2	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	13	9	1	3	639
Beta Blockers	5	0	0	5	0
Calcium Channel Blockers	3	2	0	1	365
Cardiovascular Agents - Misc.	37	17	3	17	388
Chemicals	1	0	0	1	0
Contraceptives	53	6	12	35	126
Corticosteroids	10	0	0	10	0
Dermatologicals	209	111	24	74	239
Diagnostic Products	19	11	4	4	487
Digestive Aids	3	1	0	2	365
Diuretics	5	4	0	1	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	1	0	0	365
Endocrine and Metabolic Agents - Misc.	46	27	5	14	244
Estrogens	7	3	0	4	365
Gastrointestinal Agents - Misc.	120	52	34	34	192
Genitourinary Agents - Misc.	2	1	0	1	365
Gout Agents	10	4	0	6	670
Hematological Agents - Misc.	6	3	0	3	304
Hematopoietic Agents	31	11	2	18	196
Hypnotics/Sedatives/Sleep Disorder Agents	10	3	0	7	304
Laxatives	1	0	0	1	0
Medical Devices and Supplies	17	11	0	6	1,068
Migraine Products	203	106	71	26	187
Miscellaneous Therapeutic Classes	11	10	0	1	267

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Multivitamins	1	0	0	1	0
Musculoskeletal Therapy Agents	30	7	8	15	228
Nasal Agents - Systemic and Topical	2	0	0	2	0
Neuromuscular Agents	43	24	5	14	259
Ophthalmic Agents	32	11	5	16	153
Other	23	0	0	23	0
Otic Agents	3	0	0	3	0
Oxytocics	1	0	0	1	0
Passive Immunizing and Treatment Agents	2	0	0	2	0
Progestins	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	44	27	4	13	238
Respiratory Agents - Misc.	15	10	0	5	297
Stimulants - Misc.	33	10	6	17	247
Thyroid Agents	1	0	0	1	0
Ulcer Drugs/Antispasmodics/Anticholinergics	17	6	4	7	246
Urinary Antispasmodics	11	0	9	2	0
Vitamins	77	5	0	72	48
Total	**2,530**	**1,004**	**563**	**963**	

Overrides					
Dosage Change	110	33	56	21	117
High Dose	1	0	0	1	0
Ingredient Duplication	175	106	36	33	181
NDC vs Age	543	374	25	144	254
Opioid MME Limit	6	4	2	0	322
Opioid Quantity	13	11	1	1	361
Other	243	84	83	76	117
Quantity vs Days Supply	234	146	44	44	247
STBS/STBSM	558	32	96	430	22
Step Therapy Exception	290	151	81	58	194
Third Brand Request	3	0	3	0	0
Overrides Total	**2,176**	**941**	**427**	**808**	
Total Regular PAs + Overrides	**4,706**	**1,945**	**990**	**1,771**	

Denial Reasons	
Alternatives Not Met	253
Medical Necessity	737

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Oklahoma Complete Health Prior Authorization Activity

4/1/2026 Through 4/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amebicides	1	0	1	0	0
Amphetamines	322	149	120	53	1,075
Analgesics - Anti-Inflammatory	125	70	28	27	890
Analgesics - Nonnarcotic	40	3	30	7	319
Analgesics - Opioid	311	125	124	62	328
Androgens - Anabolic	74	6	59	9	1,095
Anorectal and Related Products	8	1	4	3	365
Anthelmintics	4	0	4	0	0
Antianxiety Agents	40	8	25	7	528
Antiasthmatic and Bronchodilator Agents	303	113	130	60	726
Antibiotics	33	16	6	11	252
Anticoagulants	4	2	0	2	259
Anticonvulsants	116	55	41	20	775
Antidepressants	215	90	95	30	836
Antidiabetics	771	367	272	132	876
Antiemetics	25	4	14	7	335
Antifungals	6	5	1	0	276
Antihistamines	29	8	15	6	1,095
Antihyperlipidemics	32	8	17	7	990
Antihypertensives	28	24	2	2	697
Anti-Infective Agents - Misc.	11	1	0	10	5
Antimalarials	1	1	0	0	252
Antineoplastics and Adjunctive Therapies	70	35	17	18	510
Anti-Obesity Agents	278	41	131	106	361
Antiparkinson and Related Therapy Agents	3	2	1	0	258
Antipsychotics/Antimanic Agents	189	84	54	51	921
Antivirals	2	1	0	1	251
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	142	93	28	21	937
Beta Blockers	10	6	3	1	554
Calcium Channel Blockers	9	7	0	2	379
Cardiovascular Agents - Misc.	50	18	11	21	966
Chemicals	3	0	1	2	0
Contraceptives	26	8	15	3	606
Corticosteroids	15	2	1	12	179
Cough/Cold/Allergy	2	1	0	1	252
Dermatologicals	381	139	140	102	537
Diagnostic Products	47	24	15	8	728
Dietary Products/Dietary Management Products	4	0	0	4	0
Digestive Aids	3	2	0	1	1,095
Diuretics	6	3	1	2	534
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	3	0	3	0	0
Endocrine and Metabolic Agents - Misc.	58	17	29	12	918
Estrogens	9	6	2	1	259
Gastrointestinal Agents - Misc.	110	37	48	25	831
Genitourinary Agents - Misc,	1	0	1	0	0
Gout Agents	4	0	2	2	0
Hematological Agents - Misc.	7	3	2	2	674
Hematopoietic Agents	32	12	10	10	436

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

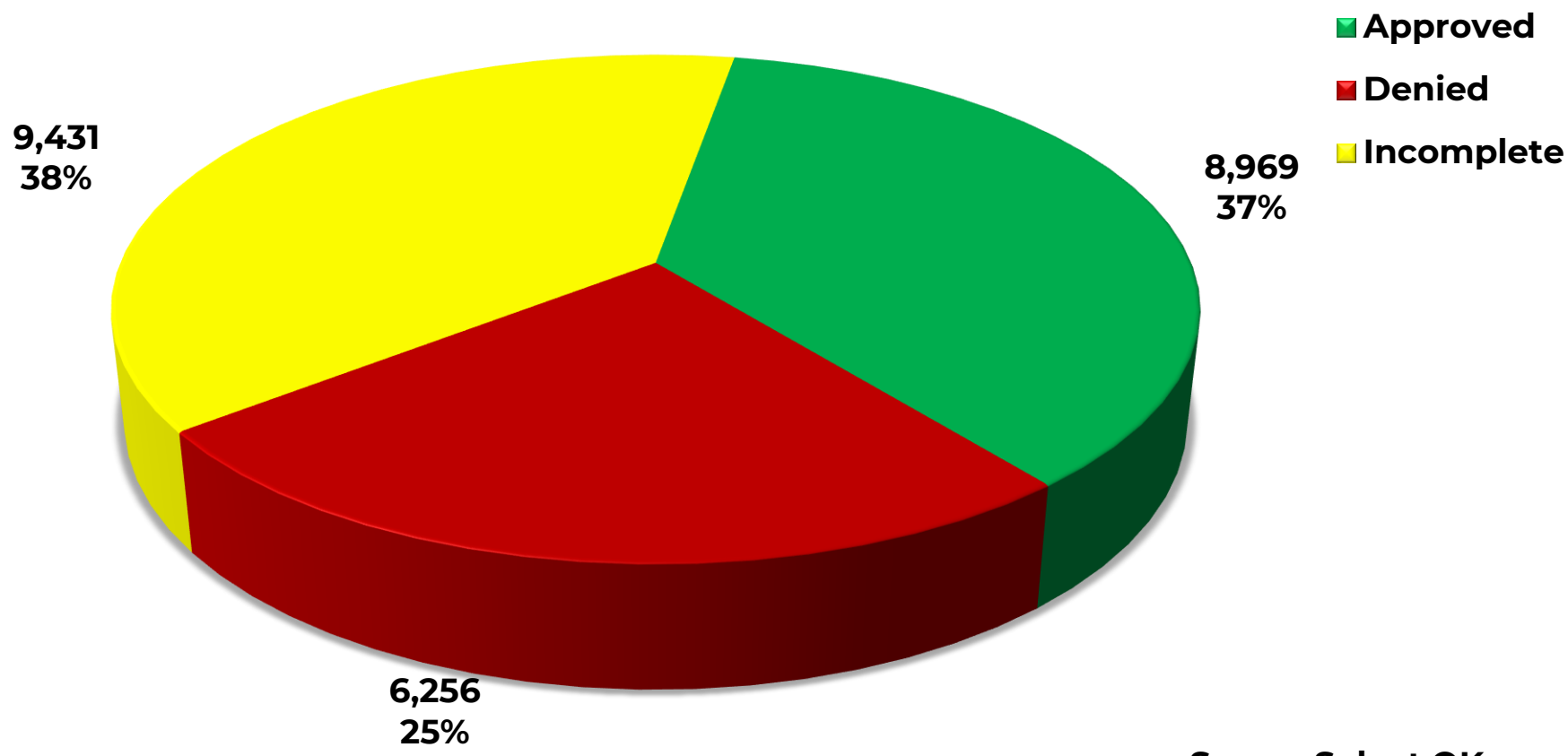
	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	21	5	10	6	262
Laxatives	28	12	5	11	260
Medical Devices and Supplies	146	89	31	26	935
Migraine Products	204	92	85	27	895
Minerals and Electrolytes	2	1	1	0	1,096
Miscellaneous Therapeutic Classes	33	20	9	4	743
Multivitamins	5	2	2	1	1,095
Musculoskeletal Therapy Agents	44	7	22	15	254
Nasal Agents - Systemic and Topical	14	2	9	3	259
Neuromuscular Agents	48	17	7	24	339
Ophthalmic Agents	50	11	24	15	445
Other	50	10	6	34	261
Otic Agents	24	6	15	3	313
Passive Immunizing and Treatment Agents	6	2	1	3	1,096
Progestins	3	0	0	3	0
Psychotherapeutic and Neurological Agents - Misc.	44	15	21	8	803
Respiratory Agents - Misc.	12	8	3	1	1,049
Stimulants - Misc.	338	266	44	28	904
Thyroid Agents	19	10	6	3	679
Ulcer Drugs/Antispasmodics/Anticholinergics	45	15	21	9	691
Urinary Antispasmodics	22	15	4	3	556
Vaccines	7	4	3	0	267
Vaginal and Related Products	7	5	1	1	278
Vasopressors	1	1	0	0	247
Vitamins	91	15	61	15	868
****Total**	**5,227**	**2,227**	**1,894**	**1,106**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

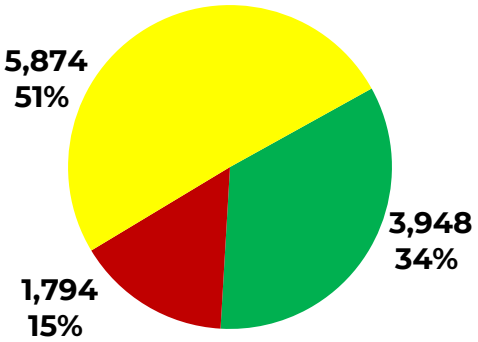
Denial Reasons	
Medical Necessity	1,894

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

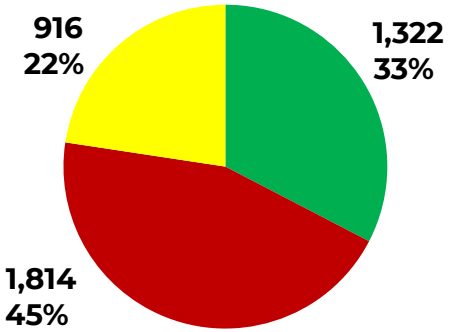
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: MAY 2026



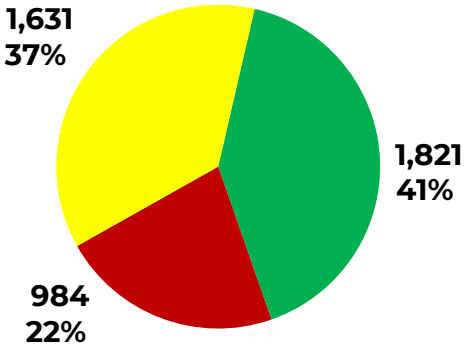
SoonerCare FFS



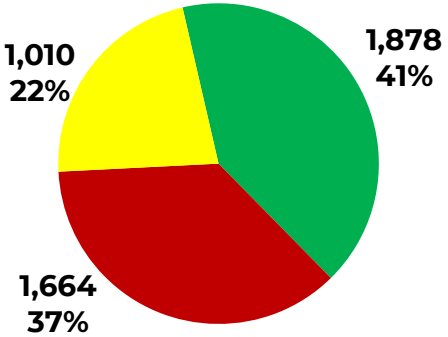
SoonerSelect Aetna



SoonerSelect Humana

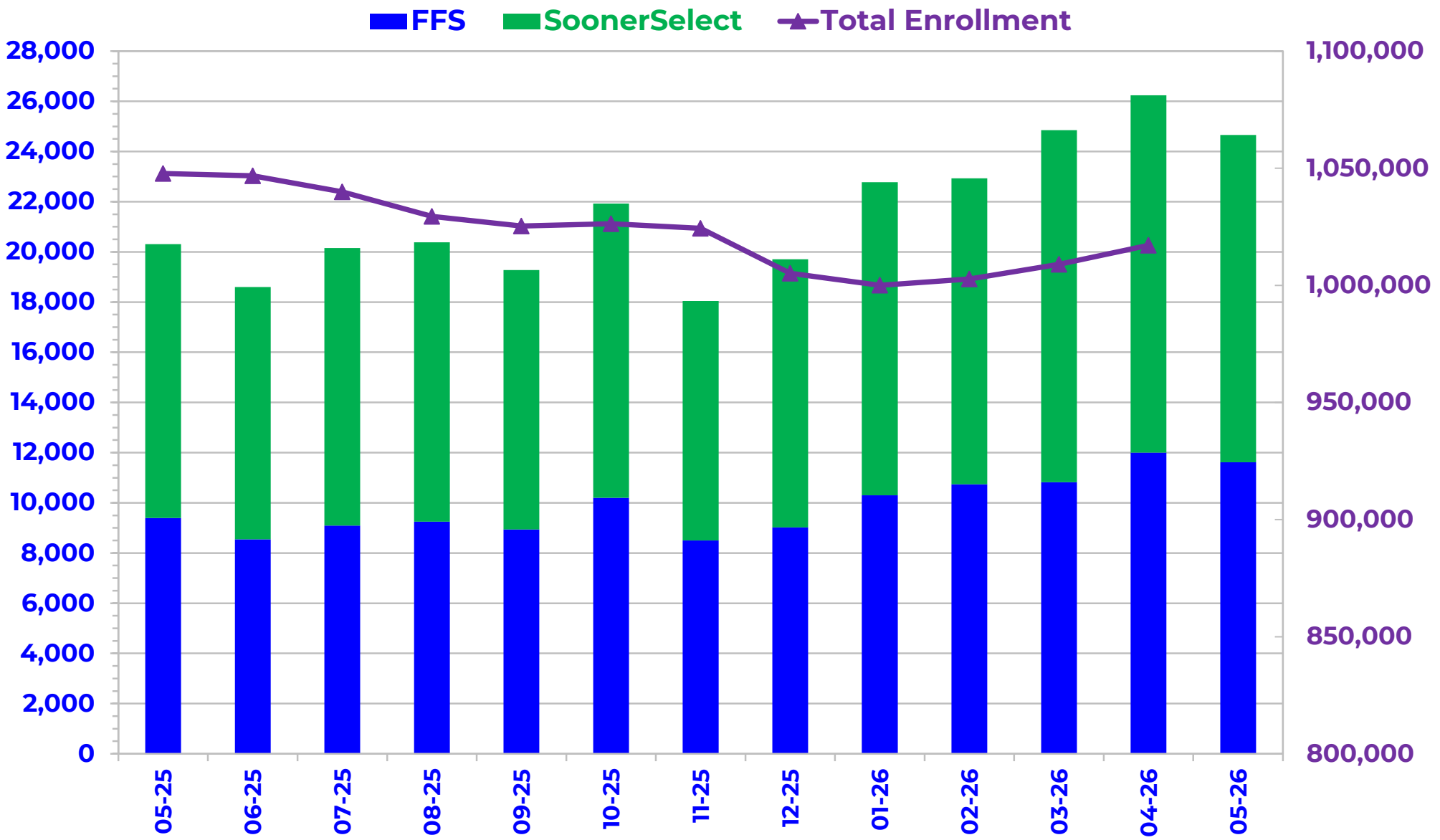


SoonerSelect OK Complete Health



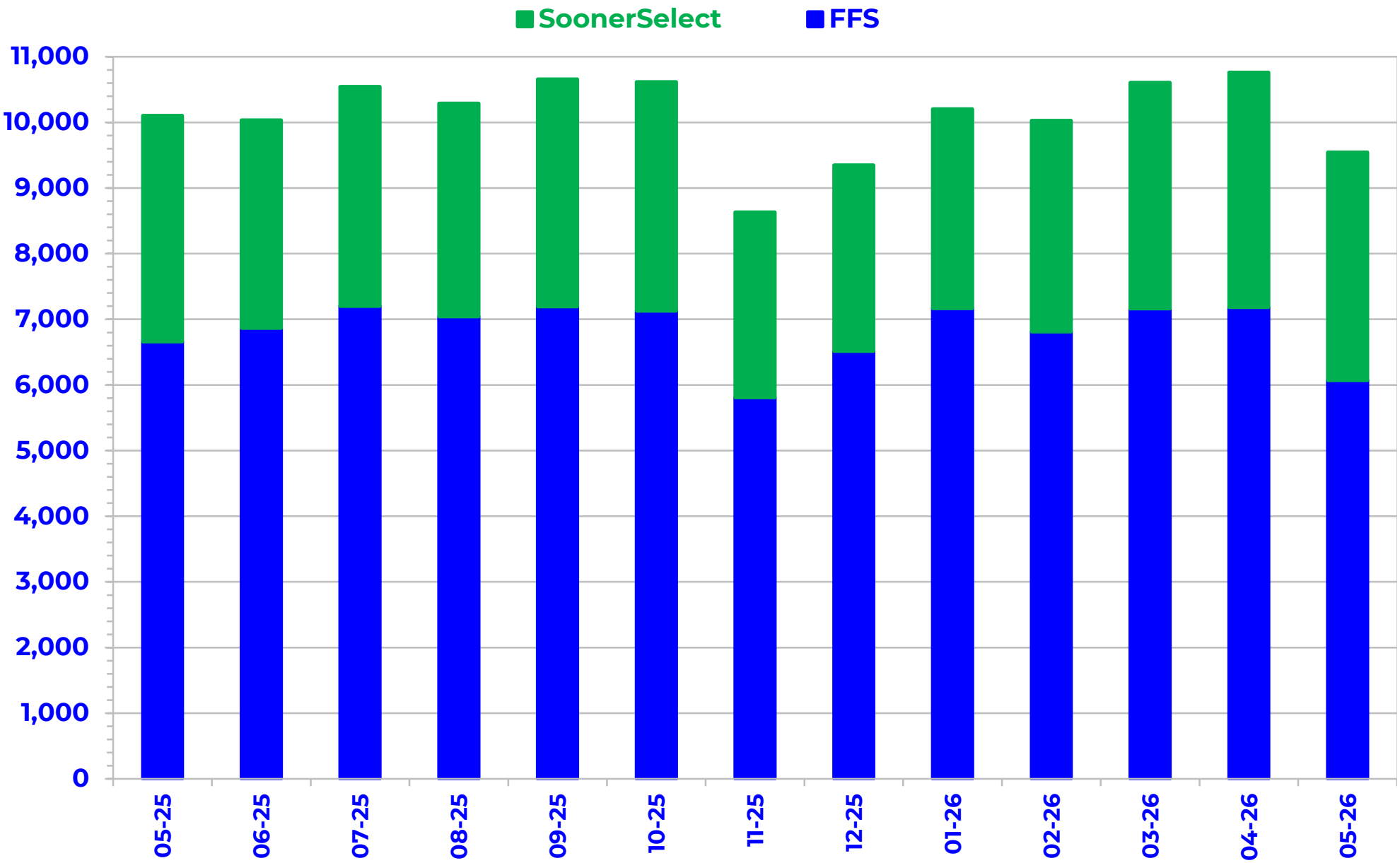
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: MAY 2025 – MAY 2026



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: MAY 2025 – MAY 2026



SoonerCare FFS Prior Authorization Activity

5/1/2026 Through 5/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	0	2	0	0
Amphetamines	948	489	88	371	355
Analgesics - Anti-inflammatory	223	78	30	115	342
Analgesics - Nonnarcotic	13	0	3	10	0
Analgesics - Opioid	424	173	40	211	139
Androgens - Anabolic	100	6	31	63	311
Anorectal and Related Products	10	0	2	8	0
Antacids	1	1	0	0	360
Anthelmintics	23	8	2	13	9
Anti-Infective Agents - Misc.	39	6	9	24	13
Anti-Obesity Agents	528	93	221	214	92
Antianxiety Agents	28	3	0	25	244
Antiarrhythmics	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	585	84	84	417	436
Antibiotics	60	18	5	37	112
Anticoagulants	16	1	2	13	360
Anticonvulsants	314	114	15	185	383
Antidepressants	308	76	45	187	453
Antidiabetics	1,812	519	270	1,023	367
Antidotes and Specific Antagonists	5	3	0	2	358
Antiemetics	40	6	6	28	113
Antifungals	8	1	0	7	87
Antihistamines	36	7	16	13	316
Antihyperlipidemics	88	23	12	53	422
Antihypertensives	36	12	1	23	785
Antimalarials	3	0	0	3	0
Antineoplastics and Adjunctive Therapies	215	137	3	75	182
Antiparkinson and Related Therapy Agents	7	2	2	3	550
Antipsychotics/Antimanic Agents	434	140	61	233	382
Antivirals	28	9	1	18	86
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	267	180	15	72	996
Beta Blockers	19	0	3	16	0
Calcium Channel Blockers	15	7	0	8	843
Cardiovascular Agents - Misc.	142	58	11	73	397
Chemicals	1	0	0	1	0
Contraceptives	56	24	5	27	350
Corticosteroids	18	4	2	12	191
Cough/Cold/Allergy	1	0	1	0	0
Dermatologicals	582	146	137	299	260
Diagnostic Products	60	17	1	42	150
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	8	6	0	2	297
Diuretics	17	4	0	13	359
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	6	0	1	5	0
Emergency PA	1	1	0	0	0

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Endocrine and Metabolic Agents - Misc.	217	90	28	99	264
Estrogens	28	1	7	20	181
Gastrointestinal Agents - Misc.	404	96	87	221	291
Genitourinary Agents - Misc.	1	1	0	0	1091
Gout Agents	7	5	0	2	359
Hematological Agents - Misc.	24	7	4	13	291
Hematopoietic Agents	42	14	8	20	130
Histamine H3-receptor Antagonist/Inverse Agonists	1	1	0	0	360
Hypnotics/Sedatives/Sleep Disorder Agents	61	4	12	45	315
Laxatives	28	12	5	11	164
Medical Devices and Supplies	381	69	85	227	293
Migraine Products	523	127	128	268	253
Minerals and Electrolytes	6	1	0	5	5
Miscellaneous Therapeutic Classes	76	29	12	35	294
Multivitamins	7	3	0	4	359
Musculoskeletal Therapy Agents	74	6	14	54	360
Nasal Agents - Systemic and Topical	13	1	3	9	360
Neuromuscular Agents	115	49	27	39	326
Ophthalmic Agents	139	27	20	92	300
Other*	74	28	5	41	215
Otic Agents	49	17	5	27	14
Passive Immunizing and Treatment Agents	62	28	2	32	264
Progestins	4	2	1	1	185
Psychotherapeutic and Neurological Agents - Misc.	274	83	48	143	234
Respiratory Agents - Misc.	33	18	2	13	329
Stimulants - Misc.	234	113	14	107	355
Thyroid Agents	8	2	2	4	725
Ulcer Drugs/Antispasmodics/Anticholinergics	146	25	20	101	728
Urinary Antispasmodics	60	9	11	40	441
Vaginal and Related Products	9	0	2	7	0
Vasopressors	2	0	0	2	0
Vitamins	81	3	61	17	268
Total	**10,712**	**3,327**	**1,740**	**5,645**	
Overrides					
Brand	17	9	2	6	134
Compound	13	11	0	2	6
Dosage Change	176	154	0	22	18
High Dose	1	0	1	0	0
Lost/Broken Rx	45	33	1	11	20
MAT Override	6	3	1	2	85
NDC vs Age	113	73	14	26	418
NDC vs Sex	8	6	0	2	358
Nursing Home Issue	78	63	5	10	12
Opioid MME Limit	46	13	4	29	168
Opioid Quantity	19	14	1	4	179
Other	33	27	1	5	23
Prescriber Temp Unlock	1	0	1	0	0

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Quantity vs Days Supply	274	171	18	85	337
STBS/STBSM	21	11	2	8	75
Step Therapy Exception	8	1	3	4	358
Stolen	12	11	0	1	22
Third Brand Request	33	21	0	12	48
Overrides Total	**904**	**621**	**54**	**229**	
Total Regular PAs + Overrides	**11,616**	**3,948**	**1,794**	**5,874**	

Denial Reasons	
Unable to verify required trials.	5,455
Does not meet established criteria.	1,832
Lack required information to process request.	578
Other PA Activity	
Duplicate Requests	1,483
Letters	55,108
No Process	1
Helpdesk Initiated Prior Authorizations	265
PAs Missing Information	310
Pharmacotherapy	80
Changes to Existing PAs	801

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

SoonerSelect Aetna Prior Authorization Activity

5/1/2026 Through 5/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Alternative Medicines	1	0	1	0	0
Amebicides	1	0	1	0	0
Amphetamines	274	169	83	22	361
Analgesics - Anti-Inflammatory	123	71	32	20	350
Analgesics - Nonnarcotic	13	1	11	1	85
Analgesics - Opioid	176	83	51	42	111
Androgens - Anabolic	76	14	61	1	365
Anorectal and Related Products	6	0	5	1	0
Anthelmintics	5	1	4	0	14
Antianginal Agents	2	0	0	2	0
Antianxiety Agents	53	12	13	28	365
Antiarrhythmics	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	163	31	92	40	339
Antibiotics	17	1	0	16	31
Anticoagulants	13	3	3	7	305
Anticonvulsants	72	27	18	27	287
Antidepressants	229	60	95	74	498
Antidiabetics	581	158	297	126	309
Antiemetics	14	2	2	10	198
Antifungals	2	0	2	0	0
Antihistamines	15	1	13	1	85
Antihyperlipidemics	52	7	24	21	311
Antihypertensives	36	1	3	32	1,096
Anti-Infective Agents - Misc.	7	2	0	5	46
Antimalarials	1	0	0	1	0
Antimyasthenic/Cholinergic Agents	1	0	1	0	0
Antineoplastics and Adjunctive Therapies	44	19	3	22	251
Anti-Obesity Agents	291	51	230	10	157
Antiparkinson and Related Therapy Agents	8	2	4	2	365
Antipsychotics/Antimanic Agents	188	51	79	58	328
Antivirals	3	1	1	1	184
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	87	62	20	5	779
Beta Blockers	15	1	1	13	365
Calcium Channel Blockers	17	0	1	16	0
Cardiovascular Agents - Misc.	29	8	18	3	342
Contraceptives	15	2	12	1	365
Corticosteroids	10	7	0	3	218
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	330	128	152	50	229
Diagnostic Products	46	25	13	8	643
Digestive Aids	6	0	0	6	0
Diuretics	30	5	1	24	302
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Endocrine and Metabolic Agents - Misc.	41	22	15	4	244
Estrogens	23	7	2	14	462
Gastrointestinal Agents - Misc.	95	35	49	11	262
Genitourinary Agents - Misc.	2	1	0	1	21
Gout Agents	3	3	0	0	365
Hematological Agents - Misc.	5	1	0	4	365
Hematopoietic Agents	12	5	7	0	305
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	1	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	43	6	27	10	133
Laxatives	19	1	10	8	92
Local Anesthetics - Parenteral	1	1	0	0	365
Medical Devices and Supplies	95	24	58	13	514
Migraine Products	188	57	112	19	235
Minerals and Electrolytes	10	0	3	7	0
Miscellaneous Therapeutic Classes	26	18	7	1	290
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	56	2	18	36	61
Nasal Agents - Systemic and Topical	24	3	10	11	320
Neuromuscular Agents	11	10	0	1	357
Nutrients	1	1	0	0	85
Ophthalmic Agents	31	7	16	8	197
Other	9	0	0	9	0
Otic Agents	14	3	7	4	107
Passive Immunizing and Treatment Agents	11	8	3	0	262
Progestins	7	4	2	1	365
Psychotherapeutic and Neurological Agents - Misc.	26	15	10	1	194
Respiratory Agents - Misc.	5	3	1	1	305
Stimulants - Misc.	95	58	22	15	362
Thyroid Agents	2	1	0	1	365
Ulcer Drugs/Antispasmodics/Anticholinergics	62	6	27	29	241
Urinary Antispasmodics	18	4	12	2	365
Vaccines	1	1	0	0	184
Vaginal and Related Products	7	0	4	3	0
Vitamins	50	7	42	1	339
****Total**	**4,052**	**1,322**	**1,814**	**916**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Overrides					
Other	916	0	0	916	0
Quantity Level Limit	42	42	0	0	287
Overrides Total	**958**	**42**	**0**	**916**	

Denial Reason	
Benefit	124
Experimental/Investigational	131
Lack Required Infomation to Process Request	141
Medical Necessity	1,416
Other	2

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

Other PA Activity	
Duplicate Requests	38
Letters	5,118
No Process	290
Changes to existing PAs	0
PAs missing info	20

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Humana Prior Authorization Activity

5/1/2026 Through 5/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	0	1	0
Amphetamines	11	0	0	11	0
Analgesics - Anti-Inflammatory	74	64	3	7	354
Analgesics - Nonnarcotic	5	2	0	3	365
Analgesics - Opioid	103	50	19	34	241
Androgens - Anabolic	73	17	39	17	217
Anorectal and Related Products	1	0	0	1	0
Anthelmintics	11	3	3	5	365
Antianxiety Agents	3	0	0	3	0
Antiasthmatic and Bronchodilator Agents	157	60	69	28	233
Antibiotics	8	4	0	4	282
Anticonvulsants	24	15	2	7	379
Antidepressants	55	25	17	13	409
Antidiabetics	428	141	164	123	180
Antiemetics	11	0	4	7	0
Antifungals	2	1	1	0	365
Antihyperlipidemics	17	7	6	4	295
Antihypertensives	5	3	0	2	274
Anti-Infective Agents - Misc.	3	0	0	3	0
Antineoplastics and Adjunctive Therapies	55	38	1	16	194
Anti-Obesity Agents	290	64	93	133	40
Antiparkinson and Related Therapy Agents	1	0	1	0	0
Antipsychotics/Antimanic Agents	5	1	1	3	122
Antivirals	3	1	1	1	47
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	17	11	1	5	584
Beta Blockers	3	1	0	2	1,461
Calcium Channel Blockers	4	2	0	2	274
Cardiovascular Agents - Misc.	38	17	1	20	391
Contraceptives	25	4	12	9	80
Corticosteroids	4	0	0	4	0
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	205	124	35	46	263
Diagnostic Products	16	6	8	2	265
Diuretics	7	5	0	2	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	0	1	0
Endocrine and Metabolic Agents - Misc.	23	15	4	4	253
Estrogens	8	3	2	3	244
Gastrointestinal Agents - Misc.	121	60	40	21	212
Genitourinary Agents - Misc.	2	0	0	2	0
Gout Agents	8	3	0	5	304
Hematological Agents - Misc.	1	1	0	0	365
Hematopoietic Agents	27	10	1	16	218
Histamine H3-Receptor Antagonist/Inverse Agonists	3	3	0	0	365
Hypnotics/Sedatives/Sleep Disorder Agents	17	3	5	9	147

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Laxatives	8	2	2	4	365
Local Anesthetics - Parenteral	1	0	0	1	0
Medical Devices and Supplies	17	9	0	8	774
Migraine Products	139	82	38	19	187
Minerals and Electrolytes	3	0	1	2	0
Miscellaneous Therapeutic Classes	16	11	0	5	322
Multivitamins	5	4	0	1	183
Musculoskeletal Therapy Agents	34	12	11	11	335
Nasal Agents - Systemic and Topical	1	0	1	0	0
Neuromuscular Agents	45	30	1	14	299
Ophthalmic Agents	30	11	3	16	230
Other	2	1	0	1	184
Otic Agents	2	0	0	2	0
Passive Immunizing and Treatment Agents	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	31	20	2	9	261
Respiratory Agents - Misc.	17	10	0	7	320
Stimulants - Misc.	27	9	8	10	313
Ulcer Drugs/Antispasmodics/Anticholinergics	26	8	6	12	233
Urinary Antispasmodics	13	3	7	3	609
Vaginal and Related Products	7	1	1	5	37
Vitamins	84	6	0	78	196
Total	**2,386**	**983**	**614**	**789**	
Overrides					
Dosage Change	107	39	51	17	113
Ingredient Duplication	182	105	42	35	173
NDC vs Age	508	332	14	162	240
NDC vs Sex	7	5	0	2	313
Opioid MME Limit	7	6	0	1	365
Opioid Quantity	6	6	0	0	386
Other	188	56	74	58	109
Quantity vs Days Supply	228	145	42	41	243
STBS/STBSM	617	35	90	492	21
Step Therapy Exception	200	109	57	34	199
Overrides Total	**2,050**	**838**	**370**	**842**	
Total Regular PAs + Overrides	**4,436**	**1,821**	**984**	**1,631**	
Denial Reasons					
Alternatives Not Met					260
Medical Necessity					724

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Oklahoma Complete Health Prior Authorization Activity

5/1/2026 Through 5/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	317	160	103	54	1,054
Analgesics - Anti-Inflammatory	96	45	25	26	897
Analgesics - Nonnarcotic	9	1	5	3	1,095
Analgesics - Opioid	297	128	123	46	255
Androgens - Anabolic	63	7	44	12	1,095
Anorectal And Related Products	6	0	3	3	0
Anorexiants Non-Amphetamine	3	0	0	3	0
Anthelmintics	7	2	4	1	273
Antianxiety Agents	28	11	11	6	334
Antiasthmatic and Bronchodilator Agents	276	106	122	48	672
Antibiotics	26	13	6	7	341
Anticoagulants	6	2	2	2	666
Anticonvulsants	90	38	29	23	662
Antidepressants	174	62	77	35	842
Antidiabetics	732	360	229	143	819
Antidiarrheal/Probiotic Agents	1	0	1	0	0
Antiemetics	12	3	5	4	290
Antifungals	5	2	3	0	298
Antihistamines	20	5	15	0	919
Antihyperlipidemics	27	3	18	6	1,096
Antihypertensives	15	11	3	1	575
Anti-Infective Agents - Misc.	5	1	0	4	239
Antineoplastics and Adjunctive Therapies	67	38	10	19	510
Anti-Obesity Agents	252	46	98	108	654
Antiparkinson and Related Therapy Agents	9	2	2	5	1,095
Antipsychotics/Antimanic Agents	190	84	68	38	872
Antivirals	1	0	1	0	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	110	65	22	23	1,050
Beta Blockers	13	9	3	1	603
Calcium Channel Blockers	5	4	0	1	225
Cardiovascular Agents - Misc.	47	10	15	22	999
Chemicals	2	0	0	2	0
Contraceptives	34	9	17	8	453
Corticosteroids	9	1	2	6	90
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	349	135	119	95	480
Diagnostic Products	23	11	9	3	707
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	1	0	0	1	0
Diuretics	7	5	1	1	880
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	3	0	3	0	0
Endocrine and Metabolic Agents - Misc.	48	19	20	9	1,046
Estrogens	18	8	8	2	548
Gastrointestinal Agents - Misc.	98	31	50	17	735

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Genitourinary Agents - Misc.	3	0	1	2	0
Gout Agents	8	2	3	3	1,095
Hematological Agents - Misc.	7	4	2	1	519
Hematopoietic Agents	18	4	8	6	196
Hypnotics/Sedatives/Sleep Disorder Agents	20	6	10	4	209
Laxatives	22	11	3	8	264
Medical Devices and Supplies	181	108	36	37	883
Migraine Products	200	73	98	29	654
Miscellaneous Therapeutic Classes	31	14	7	10	700
Multivitamins	6	2	2	2	1,095
Musculoskeletal Therapy Agents	35	8	16	11	384
Nasal Agents - Systemic and Topical	15	4	9	2	227
Neuromuscular Agents	37	21	8	8	600
Nutrients	1	0	0	1	0
Ophthalmic Agents	58	26	22	10	435
Other	25	3	2	20	453
Otic Agents	34	11	19	4	309
Passive Immunizing and Treatment Agents	7	4	1	2	650
Progestins	1	1	0	0	226
Psychotherapeutic and Neurological Agents - Misc.	35	14	9	12	740
Respiratory Agents - Misc.	7	3	1	3	1,095
Stimulants - Misc.	117	63	33	21	990
Thyroid Agents	15	10	2	3	902
Ulcer Drugs/Antispasmodics/Anticholinergics	37	14	16	7	807
Urinary Antispasmodics	19	6	9	4	663
Vaccines	3	1	2	0	90
Vaginal and Related Products	3	2	1	0	299
Vasopressors	4	4	0	0	231
Vitamins	100	22	68	10	1,095
****Total**	**4,552**	**1,878**	**1,664**	**1,010**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Denial Reasons	
Medical Necessity	1,663
Benefit	1

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

Appendix C

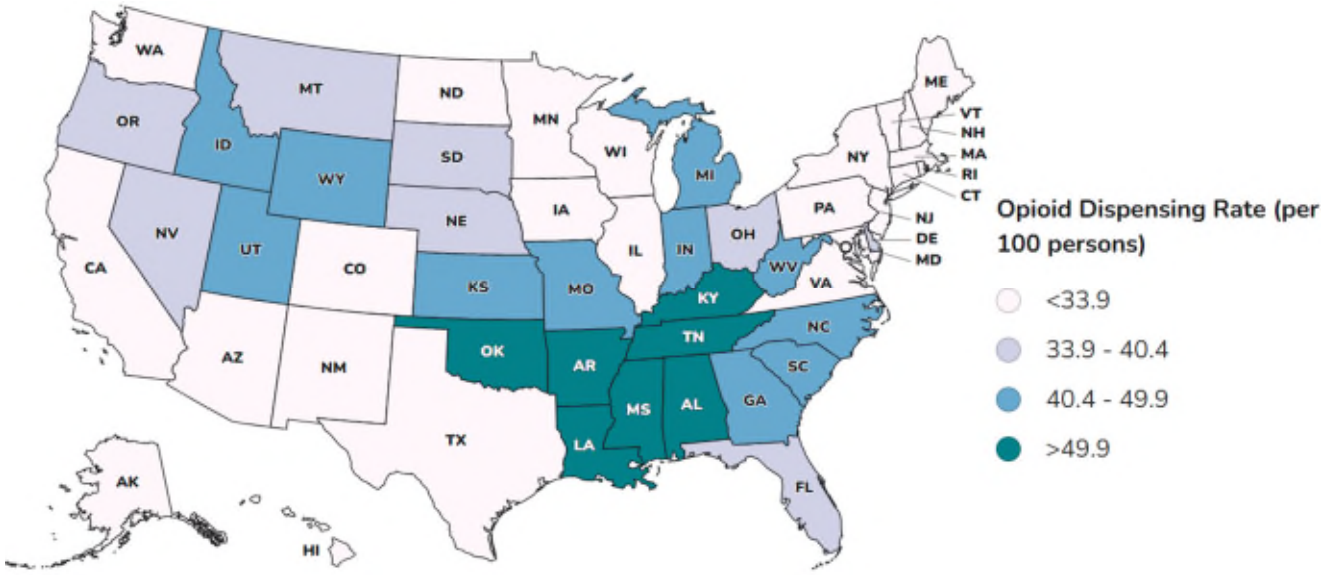
Evaluation of Pediatric Opioid Prescribing in SoonerCare Beneficiaries

Oklahoma Health Care Authority
June 2026

Introduction[1,2,3,4]

Opioid-related hospitalizations place a substantial burden on the healthcare system and Medicaid programs. Data from the Oklahoma State Department of Health (2020–2024) show approximately $231 million in inpatient, nonfatal discharges and 4,460 opioid-related overdose discharges across all ages. Among individuals younger than 15 years of age, spending accounted for approximately $2 million, with 115 discharges in this age group.[1] These findings highlight a meaningful burden of opioid-related utilization among younger populations. Prescribing practices represent an important opportunity to reduce unnecessary opioid exposure. Additionally, the map below (Figure 1) from the Centers for Disease Control and Prevention (CDC) demonstrates substantial geographic variation in opioid prescribing rates from 2024, with higher rates concentrated in the southern United States, including Oklahoma.[2]

Figure 1: State Opioid Dispensing Rates in 2024[2]



Clinical Practice Guidance for Pediatric Opioid Prescribing[3,4]

In this context, evaluating postoperative prescribing patterns, particularly following the release of clinical practice guidelines in 2024, may help identify

opportunities to improve clinically appropriate pediatric opioid use across the state. Postoperative prescribing is a common starting point for opioid exposure and a key area where changes may reduce unnecessary health care utilization and associated costs over time. The objectives of this retrospective drug utilization review (retroDUR) were to evaluate opioid prescribing in pediatric SoonerCare members using currently available evidence-based guidelines and to assess opioid necessity based on post-operative expert recommendations.

The American Academy of Pediatrics (AAP) Clinical Practice Guideline for Opioid Prescribing for Acute Pain Management in Children and Adolescents in Outpatient Settings and the Guidelines for Opioid Prescribing in Children and Adolescents After Surgery, an Expert Panel Opinion published in the *Journal of the American Medical Association (JAMA) Surgery* were used to evaluate opioid prescribing patterns in the Oklahoma SoonerCare pediatric population. The AAP provides guidance for safe opioid prescribing practices, while separate expert recommendations were used to classify surgical procedures into non-opioid recommended (NOR) and non-opioid possible (NOP) categories based on the expected need for opioid medications following the procedure. Key elements of these guidelines are summarized below in Table 1.

Table 1: Clinical Practice Guidance for Pediatric Opioid Prescribing

Pediatric Postoperative Opioid Prescribing Recommendations (*JAMA Surgery Expert Panel Opinion*, 2021)
NOR Surgeries: ▪ Circumcision ▪ Myringotomy ▪ Inguinal hernia repair (<5 years of age) ▪ Testicular procedures (e.g., suspension of testis) **NOP Surgeries:** ▪ Tonsillectomy ▪ Adenoidectomy
Pediatric Outpatient Opioid Prescribing Guidelines (*AAP Clinical Practice Guideline*, 2024)
▪ Primary healthcare providers (PHCPs) should treat acute pain using a multimodal approach that includes the appropriate use of nonpharmacologic therapies, nonopioid medications, and, when needed, opioid medications ▪ When prescribing opioids for acute pain, PHCPs should provide immediate-release opioid formulations and start with the lowest dose per patient weight

- Initial duration of opioids for acute pain should be ≤5 days, unless the pain is related to trauma or surgery requiring a longer duration
- In children and adolescents younger than 12 years of age, pediatricians and other PHCPs should not prescribe codeine or tramadol
- Pediatricians and other PHCPs should provide naloxone and counsel patients and families on the signs of opioid overdose and on how to respond to an overdose

Provider Mailing[5]

In October 2025 and March 2026, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) distributed educational letters to 147 and 120 providers, respectively. The pediatric opioid mailings included data only for members in the SoonerCare fee-for-service (FFS) population. Members covered by other health plans were excluded from the mailing. Pediatric patients ≤17 years of age with paid opioid claims were included. The pediatric opioid mailings included an educational section, highlighting key recommendations from the AAP opioid prescribing guideline, as well as examples of surgical procedures classified as NOR and NOP for postoperative pain management. The second section of the letter included an individualized prescriber summary of provider opioid prescribing patterns and identified risk indicators, including elevated morphine milligram equivalents (MME) ≥50, opioid refill activity resulting in cumulative days' supply (DS) >5 days, prescriptions exceeding DS >5 and/or >7 days, long-acting opioid use for acute pain, concurrent benzodiazepine (BZD) or antipsychotic (AP) overlap, and naloxone co-prescribing patterns.

All providers associated with opioid prescribing for NOR procedures were selected for the mailing, independent from other prescribing parameters. Additional providers were included based on the criteria above. The criteria were stratified and then applied to identify providers with higher-risk opioid prescribing patterns. Providers were prioritized for inclusion if >80% of their opioid prescribing claims contained risk indicators and they had ≥1 major clinical risk indicator (MME ≥50, opioid refill activity, BZD overlap, or AP overlap). Providers with low patient counts and isolated DS concerns without additional high-risk indicators were generally not prioritized for the mailing. This approach was designed to prioritize providers with the greatest potential for intervention.

Table 2 summarizes the paid opioid claim population included in each evaluation period. In addition to total opioid claims, unique member counts and member overlap between periods were evaluated to better understand population characteristics and determine the extent to which the same members contributed to prescribing patterns across evaluation periods.

Table 2: Member and Claim Summary by Evaluation Period

Period	Total Opioid Claims	Unique Members	Members Appearing in Both Periods (n)	Unique Members Appearing in Both Periods (%)
Period 1 (4/1/2025 to 9/30/2025)	783	722	409	57%
Period 2 (11/1/2025 to 4/30/2026)	522	454	356	78%

Data Analysis

SoonerCare pharmacy and medical claims data was analyzed prior to and following the initial provider mailing noted above. Figure 2 compares retroDUR Evaluation Period 1 (4/1/2025 to 9/30/2025) and Evaluation Period 2 (11/1/2025 to 4/30/2026) opioid DS duration outcomes by surgical status. Percentages were calculated using the total opioid claims within each surgical status category (surgical vs. non-surgical) and the evaluation period as the denominator.

Among surgical opioid claims, 253 of 423 claims (59.81%) in Period 1 exceeded 5 DS compared to 118 of 168 claims (70.24%) in Period 2, while claims exceeding 7 DS remained relatively stable [15/423 (3.55%) vs. 6/168 (3.57%)]. Although the number of surgical claims exceeding prolonged DS thresholds decreased between periods, the total surgical opioid claim volume also declined substantially from 423 claims in Period 1 to 168 claims in Period 2.

In contrast, among non-surgical opioid claims, 252 of 360 claims (70.00%) in Period 1 exceeded 5 DS compared to 227 of 354 claims (64.12%) in Period 2, while claims exceeding 7 DS increased slightly from 30 of 360 claims (8.33%) to 32 of 354 claims (9.04%). Surgical claims had higher proportions exceeding 5 DS in Period 2, but non-surgical claims consistently demonstrated higher proportions exceeding 7 DS across both periods. These findings suggest persistent opportunities to improve provider awareness and opioid stewardship among non-surgical prescribing patterns despite targeted educational outreach and pediatric guideline implementation.

Figure 2: Opioid Days' Supply (DS) Duration by Surgical Status

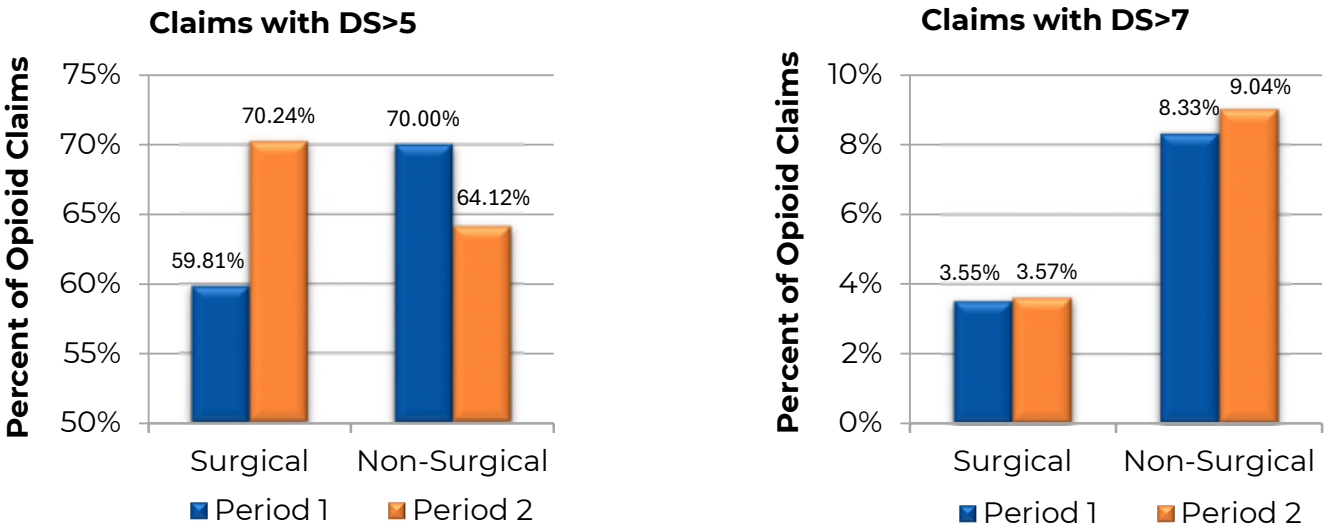
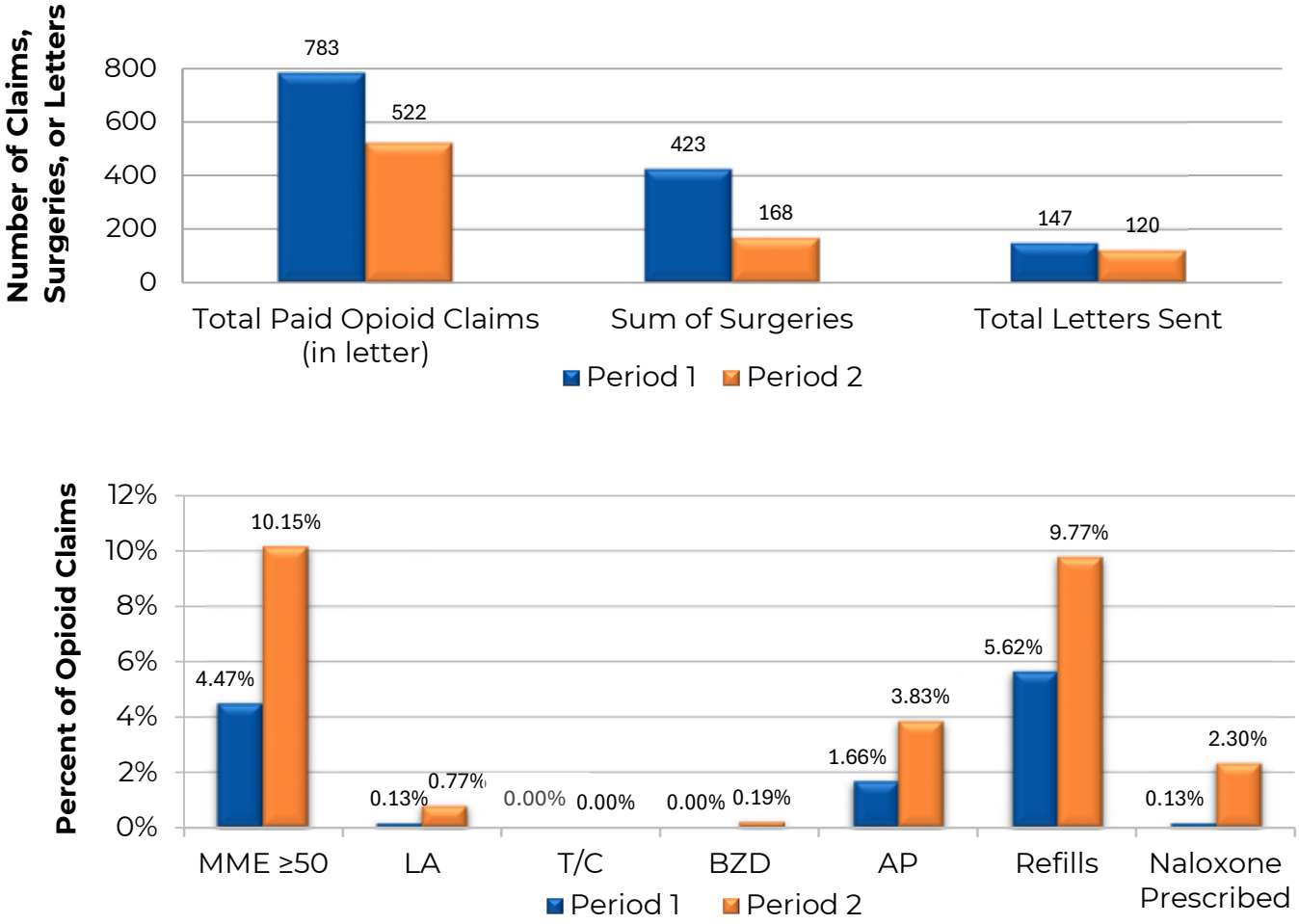


Figure 3 compares prescribing patterns between Period 1 and Period 2 using the proportion of opioid claims meeting stratified prescribing and safety indicators. Percentages were calculated using the total paid opioid claims within each evaluation period as the denominator. Opioid claims with MME ≥50 increased from 35 claims (4.47%) in Period 1 to 53 claims (10.15%) in Period 2, indicating a higher proportion of opioid claims meeting elevated opioid dosing thresholds during Period 2. Refill activity, defined as cumulative refill DS >5 days, increased from 44 claims (5.62%) to 51 claims (9.77%).

Naloxone co-prescribing remained low overall but increased from 1 claim (0.13%) in Period 1 to 12 claims (2.30%) in Period 2. Concurrent benzodiazepine overlap remained minimal across both evaluation periods, increasing slightly from 0 claims (0.00%) to 1 claim (0.19%). Concurrent antipsychotic overlap increased from 13 claims (1.66%) to 20 claims (3.83%). Long-acting opioid prescribing remained uncommon overall, increasing from 1 claim (0.13%) in Period 1 to 4 claims (0.77%) in Period 2. Overall opioid claim volume declined from 783 claims in Period 1 to 522 claims in Period 2. These findings highlight continued opportunities to improve provider awareness of elevated opioid dosing thresholds, refill activity, and concurrent sedating medication use in pediatric opioid prescribing, while increased naloxone co-prescribing may reflect greater awareness of opioid safety and overdose prevention strategies following provider education and guideline implementation.

Figure 3: Changes in Postoperative Opioid Prescribing Following Targeted Provider Outreach



MME = Morphine Milligram Equivalents; LA = long-acting opioids; T/C = tramadol and codeine; BZD = benzodiazepine; AP = antipsychotic

Guideline-based evaluation of NOR and NOP procedures was also performed. Figure 4 evaluates opioid prescribing associated with NOR procedures between evaluation periods. NOR procedures are defined in the literature as surgeries where opioid-free postoperative analgesia is recommended for most patients under most circumstances. Among NOR procedures associated with opioid prescribing, opioid use following circumcisions decreased from 8 claims in Period 1 to 5 claims in Period 2, while opioid use following myringotomies decreased from 3 claims to 0 claims. Overall, NOR-associated opioid claims decreased from 11 to 5 between evaluation periods. These findings may reflect increased provider awareness of procedures where opioid prescribing is generally not recommended based on current pediatric postoperative prescribing guidance.

Figure 4: Opioid Prescribing Associated with Guideline-Classified NOR Procedures

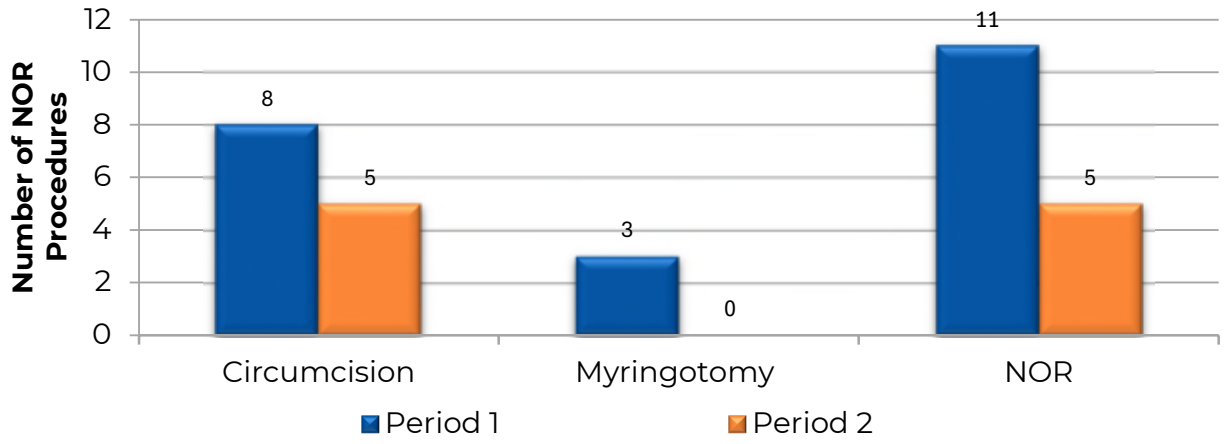
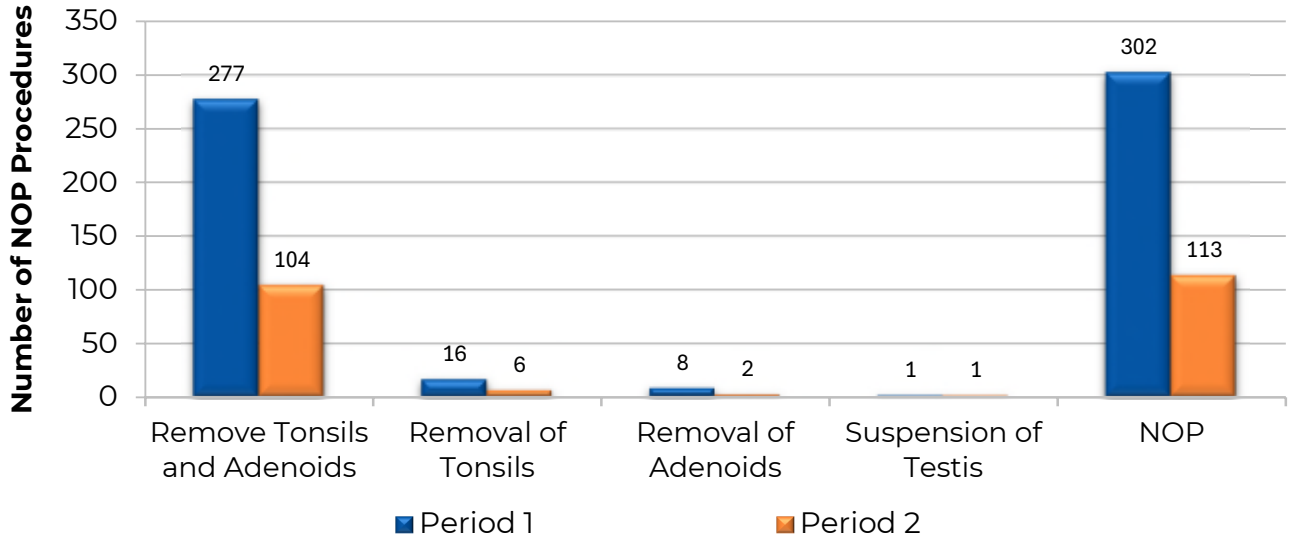


Figure 5 evaluates opioid prescribing associated with NOP procedures between evaluation periods. NOP procedures are defined in the literature as surgeries where opioid-free postoperative analgesia may be feasible for some patients under appropriate circumstances. Among NOP procedures associated with opioid prescribing, claims involving opioid use following the removal of tonsils and adenoids decreased from 277 to 104. Claims involving opioid use following the removal of tonsils alone decreased from 16 to 6, and claims involving opioid use following the removal of adenoids alone decreased from 8 to 2 between periods. Overall, NOP-associated opioid claims decreased from 302 in Period 1 to 113 in Period 2. These reductions were consistent with the overall decrease in post-surgical opioid claim volume observed during Period 2. These findings highlight continued opportunities to improve provider awareness of procedures where opioid use may not be necessary or where opioid-free postoperative pain management strategies may be appropriate.

Figure 5: Opioid Prescribing Associated with Guideline-Classified NOP Procedures



Conclusions

Overall, pediatric opioid prescribing in the Oklahoma Sooner Care population generally aligned with guideline-recommended prescribing practices. However, extended days' supply >5 DS and >7 DS remain important opportunities for improvement, particularly among non-surgical opioid claims. Naloxone co-prescribing remained infrequent among higher-risk claims, although prescribing increased from 1 claim (0.13%) in Period 1 to 12 claims (2.30%) in Period 2, representing a 12-fold increase between evaluation periods and potentially reflecting increased provider awareness of opioid safety and overdose prevention strategies following provider education and guideline implementation. This data does not reflect members who obtained naloxone from other sources, which could include the following: over-the-counter (OTC) products, provided by the provider's office, and OK I'm Ready – mail order provided by the Oklahoma Department of Mental Health and Substance Abuse Services (ODMHSAS). These findings also highlight opportunities to improve consistency in postoperative prescribing practices. The high volume of procedures classified as NOP suggests a meaningful opportunity for continued provider awareness and education regarding procedures where opioid use may potentially be reduced or avoided. Future COP and OHCA efforts may include additional educational mailings, prescribing guidance, or postoperative pain management recommendations to support provider decision-making in these situations. For procedures where opioid use may be uncertain, prescribing shorter initial durations with reassessment for refills based on clinical need may help reduce unnecessary opioid exposure while maintaining appropriate acute pain management.

This retroDUR has several limitations that should be considered when interpreting the findings. First, this intervention was primarily educational and awareness-based, designed to provide providers with prescribing pattern feedback and guideline-based pediatric opioid prescribing recommendations rather than enforce specific prescribing changes. Additionally, this analysis was based solely on paid pharmacy claims data and did not include access to complete clinical documentation, diagnosis information, provider rationale, pain severity, or patient-specific clinical discussions that may have influenced prescribing decisions. As a result, certain opioid prescriptions or prolonged durations may have been clinically appropriate based on factors not captured within claims data alone. For example, non-surgical opioid claims demonstrated longer durations overall, but associated diagnoses and clinical justification were not available within this analysis.

Because this analysis was based on paid claims data, prescribing patterns may have been influenced by factors not fully captured within the evaluation period, including delayed surgical claims submission, differences in surgical volume between periods, patient-specific clinical considerations, and diagnoses or provider-patient discussions not available within claims data. Total paid opioid claims also include multiple claims per patient and do not represent unique patient counts. Additionally, the March 2026 educational mailing occurred during Evaluation Period 2 (11/1/2025–4/30/2026). As a result, a portion of Period 2 claims occurred before provider outreach was distributed. However, changes in prescribing behavior may require time for providers to review educational materials, implement practice changes, and subsequently generate prescribing claims. Therefore, the full impact of the educational intervention may not be fully reflected within the evaluation period. Despite these limitations, this retroDUR provides insight into pediatric opioid prescribing patterns and identifies potential opportunities for continued provider awareness, opioid stewardship, and guideline-concordant prescribing practices within the Oklahoma SoonerCare population.

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Appendix D

Vote to Prior Authorize Voyxact® (Sibeprenlimab-szsi) and Update the Approval Criteria for the Primary Immunoglobulin A Nephropathy (IgAN) Medications

Oklahoma Health Care Authority
June 2026

Market News and Updates[1,2,3,4,5]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **August 2025:** The FDA approved changes to the Filspari® (sparsentan) Risk Evaluation and Mitigation Strategy (REMS) program to remove the requirements related to embryofetal toxicity (EFT) based on an analysis of human pregnancy data compiled from the use of endothelin receptor antagonist (ERA) medications for 2 decades. The FDA determined the warning within the label was enough to ensure the benefits of ERA medication outweigh the risks and the REMS program was no longer necessary. However, the REMS program is still in place for hepatotoxicity risk with Filspari®.
- **November 2025:** The FDA granted accelerated approval to Voyxact® (sibeprenlimab-szsi) for the reduction of proteinuria in adults with primary IgAN at risk for disease progression.
- **April 2026:** The FDA approved Filspari® to reduce proteinuria in adult and pediatric patients 8 years of age and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome. The approval was based on data from the Phase 3 DUPLEX trial, which compared Filspari® to irbesartan in 371 patients with biopsy-proven or genetic FSGS. The primary endpoint was the rate of change in estimated glomerular filtration rate (eGFR) from baseline to week 108. The results of the overall study population did not reach statistical significance for the primary endpoint; however, in a subgroup analysis of patients without nephrotic syndrome, the percent reduction in urine protein-to-creatine ratio (UPCR) at week 108 relative to baseline was 48% in the Filspari® treated group versus 27% in the irbesartan treated group with a treatment difference of 29% [95% confidence interval (CI): 9%, 44%]. Conversely, in the patients with nephrotic syndrome, the percent reduction in UPCR at week 108 was similar at 39% in the Filspari® treated group versus 37% in the irbesartan treated group. Additionally, with this new approval, the drug interactions for antacids and proton pump inhibitors (PPIs) were removed based on new clinical data showing no clinically significant difference was observed in the

pharmacokinetics of Filspari® when co-administered with esomeprazole.

Guideline Update(s):

- **Kidney Disease Improving Global Outcomes (KDIGO) Guideline Update:** KDIGO released a clinical practice update for the *Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV)* clinical practice guideline in October 2025, which replaced the guidelines from October 2021. Some of the key updates for IgAN included:
  - A diagnosis of IgAN can only be confirmed by a kidney biopsy and should be considered in all adults with proteinuria ≥0.5g/day (or equivalent) with a suspicion of IgAN. Once IgAN is confirmed, the patient should be assessed for secondary causes of IgAN.
  - The definition of a patient at risk of progressive loss of kidney function was changed from the prior definition of proteinuria (previously defined as >0.75 to 1g/day despite ≥90 days of optimized supportive care). The update now defines at risk patients as having proteinuria ≥0.5g/day (or equivalent), while on or off treatment for IgAN, and recommends treatment/additional treatment should be started in all cases.
  - The treatment goal is to reduce the rate of loss of kidney function <1mL/min per year for the rest of a patient's life. Urine protein excretion is the only validated biomarker to help guide clinical decision making and should be maintained at <0.5g/day (or equivalent), ideally at <0.3g/day (or equivalent), and multiple treatment strategies may be needed to achieve this goal.
  - The focus of management for most patients should be simultaneously to prevent or reduce IgA immune complex formation and immune complex-mediated glomerular injury [i.e., treatment with Tarpeyo® (budesonide delayed-release capsule)] as well as to manage the consequences of existing IgAN-induced nephron loss [i.e., treatment with lifestyle modifications, renin-angiotensin system inhibitors (RASi), and sodium-glucose cotransporter-2 (SGLT-2) inhibitors].

Voyxact® (Sibeprenlimab-szsi) Product Summary[6]

Therapeutic Class: A PRoliferation-Inducing Ligand (APRIL) blocker

Indication(s): To reduce proteinuria in adults with primary IgAN at risk of disease progression

- This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Voyxact® slows kidney function decline over the long-term in patients with IgAN.

Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

How Supplied: 400mg/2mL (200mg/mL) single-dose prefilled syringe

Dosing and Administration:

- The recommended dose of Voyxact® is 400mg injected subcutaneously (sub-Q) once every 4 weeks.

Efficacy: The efficacy of Voyxact® was studied in a randomized, double-blind, placebo-controlled, multicenter Phase 3 VISIONARY clinical trial.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Biopsy confirmed IgAN
  - eGFR ≥30mL/min/1.73m^2
  - Proteinuria [defined as either UPCR based on 24-hour urine collections ≥0.75g/g or urine protein ≥1.0g/day]
  - Stable dose of maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) and/or angiotensin receptor blocker (ARB) with or without an SGLT-2 inhibitor
- Intervention: Randomized 1:1 to receive either Voyxact® or placebo injected sub-Q once every 4 weeks
- Primary Outcome: The primary endpoint was the percent reduction in UPCR at 9 months compared to baseline.
- Results: Voyxact® showed a 51% reduction in UPCR compared to placebo (96.5% CI: 43%, 58%; P<0.0001) at 9 months.

Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days	Cost Per Year
Voyxact® (sibeprenlimab-szsi) 400mg/2mL inj	**$15,000.00**	**$30,000.00**	**$390,000.00¥**
Fabhalta® (iptacopan) 200mg tablet	$799.31	$44,761.36	$581,897.68*

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet; inj = injection
¥Cost is based on the FDA approved dosing of 400mg/2mL injection sub-Q once every 4 weeks.
*Cost is based on the FDA approved dosing of 1 tablet twice daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Voyxact® (sibeprenlimab-szsi) with the following criteria (shown in red):

Voyxact® (Sibeprenlimab-szsi) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent); and
6. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver will be trained by a health care provider on proper administration and storage of Voyxact®; and
7. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

The College of Pharmacy also recommends adding approval criteria for Filspari® (sparsentan) based on the new FDA approved indication of FSGS and recommends updating the IgAN approval criteria for clarity, based on clinical practice, and recent FDA label updates (changes shown in red):

Filspari® (Sparsentan) Approval Criteria [Focal Segmental Glomerulosclerosis (FSGS) Diagnosis]:

1. An FDA approved indication to reduce proteinuria in members with FSGS; and
2. Member must be 8 years of age or older; and
3. The diagnosis of FSGS must be confirmed by 1 of the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); or
   b. A genetic mutation known to cause FSGS (results of genetic testing must be submitted); and
4. Member must not have nephrotic syndrome; and
5. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
6. Member must have previously tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and

7. Prescriber must verify the member will not use other renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) concurrently with Filspari®; and
8. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Filspari®; and
9. Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 2 weeks after the last dose of Filspari®; and
10. Prescriber, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
11. Quantity limits will apply as follows:
    a. 200mg tablets: A quantity limit of 30 tablets per 30 days will apply; and
    b. 400mg tablets: A quantity limit of 60 tablets per 30 days will apply.

Filspari® (Sparsentan) Approval Criteria [Immunoglobulin A Nephropathy (IgAN) Diagnosis]:

1. An FDA approved indication to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy (can refer to a recent or historical biopsy); and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent)~~, despite 3 months of maximal supportive care~~; and
6. ~~Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and~~
7. Member must have previously tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
8. Prescriber must verify the member will ~~discontinue~~ not use ~~of~~ other renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin

receptor antagonists (ERAs) ~~prior to initiating treatment~~ concurrently with Filspari®; and

~~9. Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari®; and~~

~~10. Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs) concomitantly with Filspari®; and~~

~~11. If member is using antacids, they must agree to separate antacid and Filspari® administration by 2 hours; and~~

12. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Filspari®; and
13. Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 2 weeks after the last dose of Filspari®; and
14. Prescriber, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
15. A quantity limit of 30 tablets per 30 days will apply.

The College of Pharmacy also recommends updating the Vanrafia® (atrasentan) approval criteria for clarity and based on clinical practice (changes shown in red):

Vanrafia® (Atrasentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent)~~, despite 3 months of maximal supportive care~~; and

~~6. Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and~~

7. Member must have previously tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months alone, and member must agree to continue the use of an ACE or an ARB with Vanrafia™, unless contraindicated or intolerant; and
8. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Vanrafia®; and
9. Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 2 weeks after the last dose of Vanrafia®; and
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Lastly, the College of Pharmacy recommends updating the Tarpeyo® (budesonide delayed release capsule) approval criteria based on guideline updates and clinical practice (changes shown in red):

Tarpeyo® [Budesonide Delayed Release (DR) Capsule] Approval Criteria:

1. An FDA approved indication to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent); and
6. ~~Member must be on a stable dose of a maximally-tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and~~
7. Approval duration will be for 9 months. The safety and efficacy of Tarpeyo® have not been established beyond 9 months of treatment. For continued authorization consideration after 9 months of treatment, a patient-specific, clinically significant reason why a longer treatment duration is medically necessary for the member must be provided; and
8. A quantity limit of 120 capsules per 30 days will apply.

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[5] Kidney Diseases: Improving Global Outcomes (KDIGO). KDIGO 2025 Clinical Practice Guidelines for the Management of Immunoglobin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Available online at: https://www.kidney-international.org/article/S0085-2538(25)00279-0/fulltext. Issued 10/2025. Last accessed 05/07/2026.
[6] Voyxact® (Sibeprenlimab-szsi) Prescribing Information. Otsuka Pharmaceutical Co., Ltd. Available online at: https://otsuka-us.com/media/static/VOYXACT-PI.pdf. Last revised 11/2025. Last accessed 05/07/2026.

Appendix E

Vote to Prior Authorize Arynta™ (Lisdexamfetamine Oral Solution) and Atoncy™ (Atomoxetine Oral Solution) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications

Oklahoma Health Care Authority
June 2026

Market News and Updates[1,2,3,4]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **June 2025:** The FDA approved Arynta™ (lisdexamfetamine oral solution) through the 505(b)(2) pathway based on prior studies utilizing Vyvanse® (lisdexamfetamine) capsules. A pharmacokinetic study demonstrated comparable bioavailability between Arynta™ and lisdexamfetamine capsules. Azurity Pharmaceuticals has announced that Arynta™ will be available in mid-2026.
- **March 2026:** The FDA approved Atoncy™ (atomoxetine oral solution) through the 505(b)(2) pathway based on prior studies utilizing Strattera® (atomoxetine) capsules. No clinically significant differences in pharmacokinetics of atomoxetine were observed after administration of Atoncy™ and atomoxetine capsules under fasted conditions.

Arynta™ (Lisdexamfetamine Oral Solution) Product Summary[5,6]

Therapeutic Class: Central nervous system (CNS) stimulant

Indication(s):

- Treatment of ADHD in adults and pediatric patients 6 years and older
- Treatment of moderate to severe binge eating disorder (BED) in adults
- **Limitation(s) of Use:**
  - Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
  - Arynta™ is not indicated or recommended for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of Arynta™ for the treatment of obesity have not been established.

How Supplied: 10mg/mL oral solution in a 30mL, 60mL, 90mL, 100mL, or 120mL bottle

Dosing and Administration:

- The recommended dosing is the same as the recommended dosing for Vyvanse® (lisdexamfetamine) capsules and chewable tablets. The recommended initial dose is 30mg and the maximum recommended dose is 70mg regardless of indication.
- Arynta™ should be taken orally once daily in the morning, with or without food, using the oral dosing syringe and bottle adapter provided. Afternoon doses should be avoided because of the potential for insomnia.
- Any remaining medication should be discarded 30 days after first opening the bottle.

Efficacy: The efficacy of Arynta™ was based primarily on the existing data from studies utilizing lisdexamfetamine capsules. Arynta™ was determined to have comparable bioavailability to lisdexamfetamine capsules.

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Arynta™ (lisdexamfetamine) 10mg/mL sol - 120mL bottle	**$2.75**	**$577.50**	**$6,930.00**
Vyvanse® (lisdexamfetamine) 70mg cap	$12.36	$370.80	$4,449.60
Vyvanse® (lisdexamfetamine) 60mg chewable tab	$12.35	$370.50	$4,446.00
lisdexamfetamine 60mg chewable tab (generic)	$4.09	$122.70	$1,472.40
lisdexamfetamine 70mg cap (generic)	$2.97	$89.10	$1,069.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the use of 1 capsule/tablet daily or 7mL (70mg) daily for the solution.
Unit = each capsule, tablet, or mL
cap = capsule; sol = solution; tab = tablet

Atoncy™ (Atomoxetine Oral Solution) Product Summary[7]

Therapeutic Class: Selective norepinephrine reuptake inhibitor (SNRI)

Indication(s): Treatment of ADHD in adults and pediatric patients 6 years of age and older as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with ADHD

How Supplied: 4mg/mL grape-flavored oral solution in a 100mL bottle

Dosing and Administration:

- The recommended dosing for Atoncy™ is the same as the recommended dosing for Strattera® (atomoxetine) capsules.
- Atoncy™ may be administered either as a single daily dose in the morning or as evenly divided doses in the morning and late afternoon/early evening.

- Pediatric patients weighing <70kg:
  - The recommended starting dose is 0.5mg/kg/day.
  - The maximum recommended dose is 1.4mg/kg/day or 100mg/day, whichever is less.
- Pediatric patients weighing ≥70kg and adults:
  - The recommended starting dose is 40mg/day.
  - The maximum recommended dose is 100mg/day.
- Atoncy™ may be taken with or without food. Only the supplied syringe and bottle adapter should be used to measure and take Atoncy™.
- Any remaining medication should be discarded 45 days after first opening the bottle.

Efficacy: The efficacy of Atoncy™ was based primarily on the existing data from studies utilizing atomoxetine capsules. No clinically significant differences in pharmacokinetics of atomoxetine were observed after administration of Atoncy™ and atomoxetine capsules under fasted conditions.

Cost: The cost of Atoncy™ is not yet available.

Recommendations

The College of Pharmacy recommends the following changes to the ADHD and Narcolepsy Medications Product Based Prior Authorization (PBPA) category (changes noted in red in the following PBPA Tier chart and approval criteria):

1. Prior authorization of Arynta™ (lisdexamfetamine oral solution) and Atoncy™ (atomoxetine oral solution) and placement into the Special PA Tier with the additional criteria shown below; and
2. Separating the existing lisdexamfetamine binge eating disorder (BED) approval criteria and making additional updates to apply to all formulations and Tiers of lisdexamfetamine with the changes shown below; and
3. Moving Daytrana® [methylphenidate extended-release (ER)] patch from Tier-2 to Tier-3 based on net cost; and
4. Updating the Qelbree® (viloxazine) approval criteria regarding drug interactions for clarity.

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine (Evekeo®)Δ amphetamine ODT (Evekeo ODT®)Δ amphetamine/ dextroamphetamine ER (Mydayis®)Δ dextroamphetamine (Dexedrine®)Δ dextroamphetamine soln (ProCentra®)Δ dextroamphetamine (Xelstrym®)Δ dextroamphetamine (Zenzedi®)Δ **lisdexamfetamine soln (Arynta™)Δ** methamphetamine (Desoxyn®)Δ methylphenidate ER 72mgΔ methylphenidate ER ODT (Cotempla XR-ODT®)Δ methylphenidate ER (Relexxii®)Δ methylphenidate chew tab (Methylin®)Δ methylphenidate ER chew tab (QuilliChew ER®)Δ
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®)	dextroamphetamine ER (Dexedrine Spansules®) lisdexamfetamine cap (Vyvanse®)+	amphetamine ER ODT (Adzenys XR-ODT®)Δ amphetamine ER susp and tab (Dyanavel® XR)Δ lisdexamfetamine chew tab (Vyvanse®)Δ	
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®)Δ methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) methylphenidate ER (Concerta®) methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin SR®)	methylphenidate ER (Aptensio XR®) ~~**methylphenidate ER (Daytrana®)Δ**~~ methylphenidate ER susp (Quillivant XR®)Δ methylphenidate ER (Ritalin LA®)	**methylphenidate ER (Daytrana®)Δ** methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	
Non-Stimulants			
atomoxetine (Strattera®)	clonidine ER (Kapvay®)Δ	clonidine ER susp (Onyda™ XR)Δ	**atomoxetine soln (Atoncy™)Δ**

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
guanfacine ER (Intuniv®)			viloxazine (Qelbree®)[Δ]

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
[+]Unique criteria applies for the diagnosis of binge eating disorder (BED). Other tier trial requirements do not apply for a diagnosis of BED.
[Δ]Unique criteria applies in addition to tier trial requirements.
ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Tier-2 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 180 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
3. ~~For Daytrana® patches, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and~~
4. For Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
5. Kapvay® Approval Criteria:
    a. An FDA approved diagnosis; and
    b. A previously failed trial (within the last 180 days) with a long-acting Tier-1 stimulant or non-stimulant unless contraindicated, that did not yield adequate results.
6. ~~Vyvanse® Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:~~
    ~~a. An FDA approved diagnosis of moderate-to-severe BED; and~~
    ~~b. Member must be 18 years of age or older; and~~
    ~~c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and~~
    ~~d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone.~~

~~The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and~~

~~e. A quantity limit of 30 capsules per 30 days will apply; and~~

~~f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.~~

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and
3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
    a. Trials should have been within the last 365 days; and
    b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
    c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
4. For Adzenys XR-ODT® and Dyanavel® XR oral suspension, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
5. For Daytrana® patches, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
6. Onyda™ XR Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 years of age or older; and
    c. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
    d. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Kapvay® (clonidine ER tablet) must be provided.
7. ~~For~~ Vyvanse® Chewable Tablet Approval Criteria:
    a. For a diagnosis of binge eating disorder (BED), the member must meet the unique BED approval criteria; or
    b. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when

opened and mixed with yogurt, water, or orange juice must be provided; and

c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Arynta™ Approval Criteria:
   a. For a diagnosis of binge eating disorder (BED), the member must meet the unique BED approval criteria; or
   b. An FDA approved diagnosis; and
   c. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
   d. A patient-specific, clinically significant reason why the member cannot use lisdexamfetamine chewable tablets must be provided; and
   e. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Atoncy™ Approval Criteria:
   a. An FDA approved diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all lower-tiered stimulant and non-stimulant medications, including generic atomoxetine capsules, must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
3. Cotempla XR-ODT®, Evekeo ODT®, QuilliChew ER®, and Xelstrym® Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Desoxyn®, Dexedrine®, Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
   a. A covered diagnosis; and

b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.

5. Methylin® Chewable Tablets Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
6. Mydayis® Approval Criteria:
   a. A covered diagnosis; and
   b. Member must be 13 years of age or older; and
   c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
7. Qelbree® Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 years of age or older; and
   c. Previously failed trial (within the last 180 days) with atomoxetine or any ADHD medication, unless contraindicated, that did not yield adequate results; and
      i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or any ADHD medications within the past 180 days of claims history; and
   ~~d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and~~
   ~~e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and~~
   f. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment; and
   g. Quantity limits will apply based on FDA-approved dosing.

Arynta™ (Lisdexamfetamine Oral Solution) and Vyvanse® (Lisdexamfetamine Capsule or Chewable Tablet) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe BED; and
2. Member must be 18 years of age or older; and
3. ~~Vyvanse®~~ Lisdexamfetamine for the diagnosis of BED must be prescribed by a psychiatrist; and

4. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of ~~Vyvanse®~~ lisdexamfetamine for the treatment of obesity have not been established; and
5. For Vyvanse® chewable tablet:
    a. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
    b. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
6. For Arynta™:
    a. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
    b. A patient-specific, clinically significant reason why the member cannot use lisdexamfetamine chewable tablets must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
~~7. A quantity limit of 30 capsules per 30 days will apply; and~~
8. A maximum dose of 70mg per day will apply; and
9. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of ~~Vyvanse®~~ lisdexamfetamine.

[1] U.S. Food and Drug Administration (FDA). Arynta™ NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/219847Orig1s000ltr.pdf. Issued 06/16/2025. Last accessed 05/20/2026.
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[4] Atoncy™ (Atomoxetine) – New Drug Approval. *OptumRx*®. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval-atoncy-032425.pdf. Issued 03/20/2026. Last accessed 05/20/2026.
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[7] Atoncy™ (Atomoxetine Oral Solution) Prescribing Information. Validus Pharmaceuticals LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220320orig1s000correctedlbl.pdf. Last revised 03/2026. Last accessed 05/20/2026.

Appendix F

Vote to Prior Authorize Itvisma® (Onasemnogene Abeparvovec-brve) and Update the Approval Criteria for the Spinal Muscular Atrophy (SMA) Medications

Oklahoma Health Care Authority
June 2026

Market News and Updates[1,2]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **November 2025:** The FDA approved Itvisma® (onasemnogene abeparvovec-brve), an adeno-associated virus (AAV) vector-based gene therapy, for the treatment of SMA in patients 2 years of age and older with confirmed mutation in the *survival motor neuron 1* (*SMN1*) gene. Itvisma® contains the same active ingredient as Zolgensma® (onasemnogene abeparvovec-xioi), which is FDA approved for use in patients younger than 2 years of age. Itvisma® is administered as a one-time intrathecal injection at a fixed dose, while Zolgensma® is administered one-time intravenously at a weight-based dose.

Itvisma® (Onasemnogene Abeparvovec-brve) Product Summary[3,4]

Therapeutic Class: AAV vector-based gene therapy

Indication(s): Treatment of SMA in adult and pediatric patients 2 years of age and older with confirmed mutation in *survival motor neuron 1 (SMN1)* gene

How Supplied: Single-dose vial containing 1.2 x 10^{14} vector genomes (vg) of onasemnogene abeparvovec in 3mL of suspension

Dosing and Administration:

- Patients previously treated with Zolgensma® should not be treated with Itvisma®.
- Baseline testing for the presence of anti-AAV9 antibodies should be performed.
- The recommended dose is 1.2 x 10^{14} vg in 3mL of suspension administered as an intrathecal bolus injection over approximately 1 to 2 minutes.
- Administration should be postponed in patients with infections until the infection has resolved and the patient is clinically stable.
- Beginning 1 day prior to Itvisma® administration, systemic corticosteroids (equivalent to oral prednisolone at 1mg/kg of body weight per day) should be administrated for a total of 30 days.

        - At the end of the 30-day period, liver function should be evaluated by clinical examination and laboratory testing.
            - For patients with unremarkable findings, the corticosteroid dose should be tapered gradually over 28 days.
            - Alternatively, if liver function abnormalities persist, corticosteroids should be continued until findings become unremarkable and then tapered gradually over 28 days or longer.
    - Liver function should be evaluated weekly for the month after Itvisma® administration and during the corticosteroid taper period; liver function should be monitored every other week for another month after the corticosteroid taper period ends.
    - Platelet counts should be monitored weekly for the first month and as clinically indicated until platelet counts return to baseline.

Efficacy: The safety and efficacy of Itvisma® were evaluated in a randomized, double-blind, sham-controlled trial.

- Key Inclusion Criteria:
    - Confirmed diagnosis of SMA
    - Onset of clinical signs and symptoms at ≥6 months of age
    - Treatment-naïve for all survival motor neuron (SMN)-targeting therapies
    - Able to sit but never able to walk independently
- Key Exclusion Criteria:
    - Elevated baseline serum anti-AAV9 antibody titer >1:50
    - Requiring invasive or noninvasive ventilation or requiring tracheostomy
- Intervention(s): Patients were stratified by age and pre-treatment Hammersmith Functional Motor Scale – Expanded (HFMSE) and then randomized 3:2 to receive Itvisma® 1.2×10^{14} vg by single lumbar intrathecal injection or sham procedure.
- Primary Endpoint(s): Change in baseline in HFMSE total score at the end of follow-up, defined as the average of week 48 and week 52 assessments
- Results:
    - The mean change from baseline in HFMSE total score at the end of follow-up was 2.39 [standard error of the mean (SEM): 0.439] for the Itvisma® group (N=75) and 0.51 (SEM: 0.532) for the sham group (N=51), with a treatment difference of 1.88 [95% confidence interval (CI): 0.51, 3.25; P=0.0074].

Cost: The Wholesale Acquisition Cost (WAC) of Itvisma® is $2.59 million per 1-time treatment.

Recommendations

The College of Pharmacy recommends the prior authorization of Itvisma® (onasemnogene abeparvovec-brve) with the following criteria (shown in red):

Itvisma® (Onasemnogene Abeparvovec-brve) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and
2. Member must be 2 years of age or older; and
3. Molecular genetic testing confirming biallelic mutations in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
4. Member must be able to sit without support and is unable to walk without assistance (i.e., unable to walk without assistive devices); and
5. Must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests and platelet counts at baseline and as directed by the package labeling; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Itvisma® infusion and continuing as recommended in the package labeling based on member's liver function; and
9. Itvisma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the package labeling; and
10. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam) or Spinraza® (nusinersen) following Itvisma® infusion (current authorizations for risdiplam or nusinersen will be discontinued upon Itvisma® approval); and
11. Member must not have previously received Zolgensma® (onasemnogene abeparvovec-xioi); and
12. Only 1 Itvisma® infusion will be approved per member per lifetime.

The College of Pharmacy also recommends updating the Evrysdi® (risdiplam) and Zolgensma® (onasemnogene abeparvovec-xioi) approval criteria based on the FDA approval of Itvisma® (changes shown in red):

Evrysdi® (Risdiplam) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1 (SMN1)* gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for

>21 days in the absence of an acute, reversible illness or a perioperative state); and

4. Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. For the tablet formulation, the member must be 2 years of age or older and weigh ≥20kg (recent weight measured within the last 3 months must be submitted); and
6. Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and
7. Pharmacy must confirm Evrysdi® oral solution will be constituted by a pharmacist prior to dispensing and must confirm Evrysdi® oral solution will be shipped via cold chain supply to adhere to the storage and handling requirements in the package labeling; and
8. Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® formulations prior to administration of the first dose; and
9. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
10. Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and
11. Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and
12. Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and
13. Member must not have previously received treatment with Itvisma® (onasemnogene abeparvovec-brve) or Zolgensma® (onasemnogene abeparvovec-xioi); and
14. A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Upper Limb Module (ULM) Test]; and
15. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is compliant with Evrysdi® and responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pre-treatment baseline status using the same exam as performed at baseline assessment; and

16. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
17. A quantity limit of 240mL per 36 days will apply.
18. For the oral solution, a quantity limit of 240mL per 36 days will apply and for the tablets, a quantity limit of 30 tablets per 30 days will apply.

Zolgensma® (Onasemnogene Abeparvovec-xioi) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) in pediatric members younger than 2 years of age; and
2. Member must have reached full-term gestational age prior to Zolgensma® infusion; and
3. Molecular genetic testing to confirm biallelic mutations in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
4. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
5. Zolgensma® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
6. Member must have baseline anti-AAV9 antibody titers ≤1:50; and
7. Prescriber must agree to monitor liver function tests and platelet counts at baseline and as directed by the package labeling; and
8. Prescriber must agree to administer systemic corticosteroids starting 1 day prior to the Zolgensma® infusion and continuing as recommended in the package labeling based on member's liver function; and
9. Zolgensma® must be shipped to the facility where the member is scheduled to receive treatment and must adhere to the storage and handling requirements in the package labeling; and
10. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam), Itvisma® (onasemnogene abeparvovec-brve), or Spinraza® (nusinersen) following Zolgensma® infusion (current authorizations for risdiplam or nusinersen will be discontinued upon Zolgensma® approval); and
11. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
12. Only 1 Zolgensma® infusion will be approved per member per lifetime.

Lastly, the College of Pharmacy recommends updating the Spinraza® (nusinersen) approval criteria to be consistent with the other SMA medications' approval criteria and based on the FDA approval of Itvisma® (changes shown in red):

Spinraza® (Nusinersen) Approval Criteria:

1. An FDA approved ~~D~~diagnosis of spinal muscular atrophy (SMA)~~:~~; and
   ~~a. Type 1; or~~
   ~~b. Type 2; or~~
   ~~c. Type 3 with symptoms; and~~
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1* (*SMN1*) gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Member must not have previously received treatment with Itvisma® (onasemnogene abeparvovec-brve) or Zolgensma® (onasemnogene abeparvovec-xioi); and
6. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam); and
7. Prescriber must verify platelet count, coagulation laboratory testing, and quantitative spot urine protein testing have been assessed at baseline, levels are acceptable to the prescriber, and levels will be monitored prior to each dose; and
8. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
   a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
9. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
   a. Hammersmith Infant Neurological Exam (HINE); or
   b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
   c. Upper Limb Module (ULM) Test; or
   d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
10. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment:
    a. HINE; or
    b. CHOP-INTEND; or
    c. ULM Test; or

d. HFMSE; and

11. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. Only (1) 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

[1] Novartis. Novartis Receives FDA Approval for Itvisma®, the Only Gene Replacement Therapy for Children 2 Years and Older, Teens, and Adults with Spinal Muscular Atrophy (SMA). Available online at: https://www.novartis.com/news/media-releases/novartis-receives-fda-approval-itvisma-only-gene-replacement-therapy-children-two-years-and-older-teens-and-adults-spinal-muscular-atrophy-sma. Issued 11/24/2025. Last accessed 05/27/2026.

[2] U.S. Food and Drug Administration (FDA). FDA Approves Gene Therapy for Treatment of Spinal Muscular Atrophy. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-gene-therapy-treatment-spinal-muscular-atrophy. Issued 11/24/2025. Last accessed 05/27/2026.

[3] Itvisma® (Onasemnogene Abeparvovec-brve) Prescribing Information. Novartis Gene Therapies. Available online at: https://www.fda.gov/media/189857/download?attachment. Last revised 11/2025. Last accessed 05/27/2026.

[4] Efficacy and Safety of Intrathecal OAV101 (AVXS-101) in Pediatric Patients with Type 2 Spinal Muscular Atrophy (SMA) (STEER). *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT05089656. Last revised 01/13/2026. Last accessed 05/27/2026.

Appendix G

Vote to Prior Authorize Jascayd ® (Nerandomilast) and Update the Approval Criteria for the Interstitial Lung Disease (ILD) Medications

Oklahoma Health Care Authority
June 2026

Market News and Updates[1,2]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **October 2025:** The FDA approved Jascayd® (nerandomilast) for the treatment of the signs and symptoms of idiopathic pulmonary fibrosis (IPF) in adult patients.
- **February 2026:** The FDA approved Jascayd® (nerandomilast) for the treatment of progressive pulmonary fibrosis (PPF) in adult patients.

Jascayd® (Nerandomilast) Product Summary[3,4,5,6]

Therapeutic Class: Phosphodiesterase-4B enzyme (PDE4) inhibitor

Indication(s): Treatment of IPF and PPF in adult patients

How Supplied: 9mg or 18mg oral tablets

Dosing and Administration:

- The recommended dose is 18mg twice daily with or without food.
- Jascayd® tablets should be swallowed whole and should not be crushed or chewed.
- If needed, the tablet may be placed into 3 to 4 ounces of room temperature water until fragmented to create a mixture. Jascayd® will not fully dissolve.
- The dosage should be reduced to 9mg twice daily with concomitant use of strong CYP3A inhibitors or for those unable to tolerate 18mg twice daily.
- The dosage should not be reduced to 9mg twice daily with concomitant use of pirfenidone. The clinical study FIBRONEER-IPF showed a 50% decrease in steady state of Jascayd® in combination with pirfenidone. Target dosing with this combination is 18mg twice daily.

Efficacy: The efficacy of Jascayd® for IPF was evaluated in 2 randomized, double-blind, placebo-controlled trials, FIBRONEER-IPF and Trial 2, in adults with IPF with or without background antifibrotic therapy. The efficacy of Jascayd® for PPF was evaluated in a randomized, double-blind, placebo-controlled trial, FIBRONEER-ILD, with or without background treatment with nintedanib.

- Key Inclusion Criteria:
  - FIBRONEER-IPF and Trial 2:
    - 40 years of age or older
    - Confirmed IPF diagnosis
    - FVC at least 45% of predicted
    - Carbon monoxide diffusing capacity [(DLCO), corrected for hemoglobin] at least 25% of predicted
  - FIBRONEER-ILD:
    - 18 years of age or older
    - Fibrosis with more than 10% fibrotic features
    - Clinical signs of progression with:
      - FVC decline ≥10%; or
      - FVC decline ≥5% and <10% with worsening of respiratory symptoms or imaging; or
      - Worsening of respiratory symptoms and worsening imaging all in the 24 months prior to screening
    - FVC at least 45% of predicted
    - DLCO (corrected for hemoglobin) at least 25% of predicted
    - On stable dosing of nintedanib for at least 12 weeks, had discontinued treatment for at least 8 weeks, or treatment naïve
- Intervention(s):
  - FIBRONEER-IPF and FIBRONEER-ILD: Patients were randomized 1:1:1 to receive Jascayd® 9mg twice daily, Jascayd® 18mg twice daily, or placebo twice daily until the last patient completed 52 weeks of treatment.
  - Trial 2: Patients were randomized 2:1 to receive Jascayd® 18mg twice daily or placebo twice daily for 12 weeks.
- Primary Endpoint(s):
  - FIBRONEER-IPF and FIBRONEER-ILD: Absolute change from baseline in FVC at week 52
  - Trial 2: Change from baseline in FVC at week 12
- Results:
  - Jascayd® 18mg twice daily: Mean change from baseline in FVC was:
    - FIBRONEER-IPF: -106mL vs. -170mL in the placebo group [treatment difference: 64mL; 95% confidence interval (CI): 25, 102]
    - FIBRONEER-ILD: -86mL vs. -152mL in the placebo group (treatment difference: 65mL; 95% CI: 30, 101)
  - Jascayd® 9mg twice daily: Mean change from baseline in FVC was:
    - FIBRONEER-IPF: -122mL vs. -170mL in the placebo group (treatment difference: 48mL; 95% CI: 10, 86)

    - FIBRONEER-ILD: -69mL vs. -152mL in the placebo group (treatment difference: 83 mL; 95% CI: 48, 118)
- Trial 2 (Jascayd® 18mg twice daily): Change from baseline in FVC was -91mL compared to placebo (95% CI: 44, 138)

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Jascayd® (nerandomilast) 18mg tablets	**$270.33**	**$16,219.80**	**$194,637.60**
Ofev® (nintedanib) 150mg capsules	$229.78	$13,786.80	$165,441.60
Esbriet® (pirfenidone) 801mg tablets	$116.10	$10,449.00	$125,388.00
pirfenidone 801mg tablets (generic)	$2.76	$248.40	$2,980.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = each capsule or tablet
*Cost per 30 days based on the maximum FDA approved dose for each product: 18mg twice daily for Jascayd®, 150mg twice daily for Ofev®, and 801mg three times daily for Esbriet® and generic pirfenidone.

Recommendations

The College of Pharmacy recommends the prior authorization of Jascayd® (nerandomilast) with the following criteria (shown in red):

Jascayd® (Nerandomilast) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Idiopathic pulmonary fibrosis (IPF); or
    b. Progressive pulmonary fibrosis (PPF); and
2. Member must be 18 years of age or older; and
3. Medication must be prescribed by a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
4. Requests must indicate if Jascayd® will be used as monotherapy or in combination with nintedanib or pirfenidone; and
    a. If combination therapy is being requested, a patient-specific, clinically significant reason why the member requires combination therapy must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Ofev® (nintedanib) and generic pirfenidone must be provided; and
6. A quantity limit of 60 tablets per 30 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Ofev® (nintedanib) based on clinical practice and net costs (changes shown in red):

Ofev® (Nintedanib) Approval Criteria:

1. An FDA approved indication of 1 of the following:

a. Treatment of idiopathic pulmonary fibrosis (IPF); or
b. Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype; or
c. To slow the rate of decline in pulmonary function in members with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and

2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Ofev® treatment, at regular intervals during the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
4. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 3 months after therapy completion; and
5. Medication must be prescribed by, or in consultation with, a pulmonologist, ~~or~~ pulmonary specialist, or rheumatologist (or an advanced care practitioner with a supervising physician who is a pulmonologist, ~~or~~ pulmonary specialist, or rheumatologist); and
6. A patient-specific, clinically significant reason why the member cannot use generic pirfenidone must be provided; and
7. A quantity limit of 60 capsules per 30 days will apply.

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[1] Boehringer Ingelheim. Boehringer Ingelheim Announces U.S. FDA Approves Boehringer's Jascayd® (Nerandomilast Tablets) as First New Treatment Option for Adults with IPF in Over a Decade. Available online at: https://www.boehringer-ingelheim.com/human-health/lung-diseases/pulmonary-fibrosis/fda-approves-jascayd-nerandomilast-first-new-treatment-ipf-over-decade. Issued 09/10/2025. Last accessed 05/19/2026.

[2] Boehringer Ingelheim. Boehringer Ingelheim Announces U.S. FDA Approves Jascayd® (Nerandomilast) Tablets for the Treatment of Progressive Pulmonary Fibrosis in Adults. Available online at: https://www.boehringer-ingelheim.com/human-health/lung-diseases/pulmonary-fibrosis/us-fda-approves-jascayd-nerandomilast-progressive-pulmonary-fibrosis. Issued 12/19/2025. Last accessed 05/19/2026.

[3] Jascayd® (Nerandomilast Tablets) Prescribing Information. Boehringer Ingelheim Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218764s000lbl.pdf. Last revised 10/2025. Last accessed 05/19/2026.

[4] Richeldi L, Azuma A, Cottin, V, et al. Nerandomilast in Patients with Idiopathic Pulmonary Fibrosis. *N Engl J Med* 2025; 392(22):2193-2202. doi: 10.1056/NEJMoa2414108.

[5] Richeldi L, Azuma A, Cottin, V, et al. Trial of a Preferential Phosphodiesterase 4B Inhibitor for Idiopathic Pulmonary Fibrosis. *N Engl J Med* 2022; 386(23):2178-2187. doi: 10.1056/NEJMoa2201737.

[6] Boehringer Ingelheim. Boehringer Ingelheim Announces Global Phase III Trials Demonstrate That Nerandomilast Slowed Lung Function Decline in IPF and PPF, with Similar Discontinuation Rates to Placebo. Available online at: https://www.boehringer-ingelheim.com/human-health/lung-diseases/pulmonary-fibrosis/phase-3-trials-nerandomilast-slowed-lung-function-decline-ipf-and-ppf. Issued 05/19/2025. Last accessed 05/19/2026.

Appendix H

Vote to Prior Authorize Rethymic® (Allogeneic Processed Thymus Tissue–agdc)

Oklahoma Health Care Authority
June 2026

Market News and Updates[1]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **October 2021:** The FDA approved Rethymic®, an allogeneic thymus tissue-based treatment. It is indicated for immune reconstitution in pediatric patients with congenital athymia (CA).

Rethymic® (Allogeneic Processed Thymus Tissue–agdc) Product Summary[1]

Therapeutic Class: Allogeneic thymus tissue-based treatment

Indication(s): Immune reconstitution in pediatric patients with CA

- **Limitation(s) of Use:** Not indicated for the treatment of patients with severe combined immunodeficiency (SCID)

How Supplied: Yellow to brown slices of processed thymus tissues with varying thickness and shape

Dosing and Administration:

- Rethymic® is administered by a surgical procedure.
- The recommended dose range is 5,000 to 22,000mm^2 of Rethymic® per m^2 of recipient's body surface area (BSA).
- Immunosuppressive therapy is recommended for patients receiving Rethymic® based on disease phenotype and phytohemagglutinin (PHA) levels.

Efficacy: The efficacy and safety of Rethymic® were evaluated in 105 pediatric patients across 10 open-label, prospective, single-center clinical trials, with a follow-up of up to 25.5 years. The primary efficacy analysis included 95 patients [median age at time of treatment: 9 months (range: 1 to 36 months of age)].

- Key Inclusion Criteria:
  - Pediatric patients with CA
- Key Exclusion Criteria:
  - Pediatric patients with SCID
  - Pre-existing cytomegalovirus (CMV) infection
  - Pre-existing renal impairment

- Intervention(s): Patients received a single surgical implantation of Rethymic® with dosing based on BSA (approximately 4,900 to 24,000 mm^2 per m^2), along with concomitant immunosuppressive therapy as clinically indicated based on disease phenotype and pre-treatment immune function.
- Primary Endpoint(s): Overall survival at 1 year post-treatment
- Results:
  - Kaplan-Meier estimated survival was 77% at 1 year [95% confidence interval (CI): 67.0%, 84.1%] and 76% at 2 years (95% CI: 65.8%, 83.2%).
  - Among patients alive at 1 year post-treatment, 94% remained alive long-term with a median follow-up of 10.7 years.
  - Survival was significantly improved compared to natural history, where untreated patients with CA typically die by age 2–3 years.
  - Treatment resulted in the development of functional naïve T cells, indicating immune reconstitution.
  - Treatment resulted in a significant reduction in infections over time, including a 38% decrease in the number of patients with an infection event 6–12 months post-treatment and a mean reduction of 2.9 infection events per patient at 2 years (P<0.001).

Cost: The Wholesale Acquisition Cost (WAC) of Rethymic® is $2.8 million for the one-time dose (not including procedural costs).

Recommendations

The College of Pharmacy recommends the prior authorization of Rethymic® (allogeneic processed thymus tissue–agdc) with the following criteria (shown in red):

Rethymic® (Allogeneic Processed Thymus Tissue-agdc) Approval Criteria:

1. An FDA approved indication for immune reconstitution in pediatric patients with congenital athymia (CA). Diagnosis must be confirmed by the following (supporting documentation must be submitted):
   a. Flow cytometry documenting <50 naïve T-cells/mm^3 (CD45RA+, CD62L+) in the peripheral blood or <5% of total T-cells being naïve in phenotype; and
   b. Clinical, genetic, and/or immunologic findings, including evaluation to exclude severe combined immunodeficiency (SCID); and
2. Member must be younger than 18 years of age; and
3. Member must not have SCID; and
4. Member must not have a pre-existing cytomegalovirus (CMV) infection or pre-existing renal impairment; and
5. Rethymic® must be prescribed by a specialist with expertise in CA and in the administration of Rethymic®; and

6. Prescriber must attest that the member will not receive immunizations until immune function is established; and
7. Documentation of anti-human leukocyte antigen (HLA) antibody screening; and
    a. If the member is positive for anti-HLA antibodies, prescriber must verify the member will receive Rethymic® from a donor who does not express those HLA alleles; and
8. If the member has received a hematopoietic cell transplant (HCT) or a solid organ transplant, the following will be required:
    a. HLA matching; and
    b. Member will receive Rethymic® HLA matched to recipient alleles that were not expressed in the HCT donor to minimize the risk of graft-versus-host disease (GVHD); and
9. Verification that the member will be monitored and the member and/or caregiver will be counseled on all the following after treatment with Rethymic®, as per package labeling:
    a. Lymphoproliferative disorders; and
    b. Transmission of infectious disease; and
    c. Development of autoimmune disorders; and
    d. Development of GVHD; and
    e. Infection control measures and immune prophylaxis; and
10. Prescriber attestation that Rethymic® will be prescribed with immunosuppressive therapy based on disease phenotype and phytohemagglutinin levels; and
11. Member has no history of receiving a previous thymus tissue implantation in their lifetime; and
12. Approval will be for 1 treatment per member per lifetime.

[1] Rethymic® (Allogeneic Processed Thymus Tissue–agdc) Prescribing Information. Sumitomo Pharma America, Inc. Available online at: https://www.rethymic.com/RETHYMIC_Prescribing_Information_English.pdf. Last revised 10/2024. Last accessed 05/18/2026.

Appendix I

Vote to Prior Authorize Eydenzelt® (Aflibercept-boav) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications

Oklahoma Health Care Authority
June 2026

Market News and Updates[1,2]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **October 2025:** The FDA approved Eydenzelt® (aflibercept-boav) as a biosimilar to Eylea® (aflibercept). The cost is not available at this time.

Recommendations

The College of Pharmacy recommends the prior authorization of Eydenzelt® (aflibercept-boav) with the same criteria as the other aflibercept biosimilar products (changes shown in red):

Eydenzelt® (Aflibercept-boav), Enzeevu® (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use Eylea®/Eylea® HD (aflibercept) or Pavblu® (aflibercept-ayyh) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

[1] Celltrion. Celltrion Receives U.S. FDA Approval for Eydenzelt® (Aflibercept-boav), Biosimilar Referencing Eylea® (Aflibercept). Available online at: https://www.celltrionusa.com/board/newslist/44. Issued 10/13/2025. Last accessed 05/07/2026.
[2] Eydenzelt® (Aflibercept-boav) Prescribing Information. Celltrion, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761377s000lbl.pdf. Last revised 10/2025. Last accessed 05/07/2026.

Appendix J

Vote to Prior Authorize Avgemsi™ (Gemcitabine), Emrelis™ (Telisotuzumab Vedotin-tllv), Ensacove™ (Ensartinib), Hernexeos® (Zongertinib), Hyrnuo® (Sevabertinib), Ibtrozi™ (Taletrectinib), and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) and Update the Approval Criteria for the Lung Cancer Medications

Oklahoma Health Care Authority
June 2026

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16]

New U.S. Food and Drug Administration (FDA) Approval(s):

- **December 2024:** The FDA approved Ensacove™ (ensartinib) for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test who have not previously received an ALK-inhibitor. According to the FDA's National Drug Code (NDC) Directory, Ensacove™ began being marketed in April 2025.
- **May 2025:** The FDA granted accelerated approval to Emrelis™ (telisotuzumab vedotin-tllv) for the treatment of adult patients with locally advanced or metastatic non-squamous NSCLC with high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.
- **June 2025:** The FDA approved Ibtrozi™ (taletrectinib) for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive NSCLC.
- **June 2025:** The FDA approved Avgemsi™ (gemcitabine) through the 505(b)(2) pathway based on prior studies utilizing Gemzar® (gemcitabine). Avgemsi™ is supplied as a solution for intravenous (IV) use in multiple-dose vials available in 1g/26.3mL and 2g/52.6mL strengths.
- **August 2025:** The FDA granted accelerated approval to Hernexeos® (zongertinib) for the treatment of adult patients with unresectable or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy. In February 2026, the FDA granted accelerated approval for an updated

indication for Hernexeos®, removing the requirement that patients have received prior systemic therapy.

- **October 2025:** The FDA approved Tecentriq® (atezolizumab) and Tecentriq Hybreza® (atezolizumab/hyaluronidase-tqjs), in combination with Zepzelca® (lurbinectedin), for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with atezolizumab or atezolizumab/hyaluronidase-tqjs, and carboplatin plus etoposide.
- **November 2025:** The FDA granted accelerated approval to Hyrnuo® (sevabertinib) for the treatment of adult patients with locally advanced or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.
- **November 2025:** The FDA approved an age expansion for Tecentriq Hybreza® (atezolizumab/hyaluronidase-tqjs) for the treatment of pediatric patients 12 years of age and older who weigh ≥40kg with unresectable or metastatic alveolar soft part sarcoma (ASPS). Previously, Tecentriq Hybreza® was only FDA approved for this indication in adults.
- **November 2025:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) chemotherapy as neoadjuvant and adjuvant treatment, followed by single agent durvalumab, for the treatment of adult patients with resectable gastric or gastroesophageal junction (GEJ) adenocarcinoma.
- **December 2025:** The FDA approved Rybrevant Faspro™ (amivantamab/hyaluronidase-lpuj), a new subcutaneous (sub-Q) formulation of amivantamab, for adult patients with NSCLC for all the same indications as the IV formulation of amivantamab.
- **May 2026:** The FDA approved Tecentriq® (atezolizumab) and Tecentriq Hybreza® (atezolizumab/hyaluronidase-tqjs) for a new indication as adjuvant treatment of adult patients with muscle invasive bladder cancer (MIBC) after cystectomy who have circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test.
- **May 2026:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with Bacillus Calmette-Guérin (BCG), for the treatment of adult patients with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC).

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for NSCLC allow for the use of erlotinib in patients with metastatic disease

who have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as a single agent or in combination with ramucirumab (if T790M mutation negative).

Emrelis™ (Telisotuzumab Vedotin-tllv)) Product Summary[17]

Therapeutic Class: C-Met-directed antibody and microtubule inhibitor conjugate

Indication(s): Treatment of adult patients with locally advanced or metastatic non-squamous NSCLC with high c-Met protein overexpression [≥50% of tumor cells with strong (3+) staining], as determined by an FDA-approved test, who have received a prior systemic therapy.

- This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied: Lyophilized powder in 20mg and 100mg single-dose vials (SDVs)

Dosing and Administration:

- The recommended dose is 1.9mg/kg (up to a maximum of 190mg for patients weighing ≥100kg) every 2 weeks until disease progression or unacceptable toxicity.
- Each dose should be administered as an IV infusion over 30 minutes.

Cost: The Wholesale Acquisition Cost (WAC) is $13,980 per 100mg SDV and $2,796 per 20mg SDV. For a member weighing 80kg, this would result in an estimated cost of $44,736 per 28 days or $581,568 per year based on recommended dosing. At maximum dose, this would result in an estimated cost of $55,920 per 28 days or $726,960 per year.

Ensacove™ (Ensartinib) Product Summary[18]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with ALK-positive locally advanced or metastatic NSCLC as detected by an FDA-approved test who have not previously received an ALK-inhibitor.

How Supplied: 25mg and 100mg oral capsules

Dosing and Administration:

- The recommended dose is 225mg orally once daily with or without food, continued until disease progression or unacceptable toxicity.

Cost: The WAC is $310.52 per 100mg capsule and $77.60 per 25mg capsule. This would result in an estimated cost of $20,959.20 per month or $251,510.40 per year based on recommended dosing.

Hernexeos® (Zongertinib) Product Summary[19]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with unresectable or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-authorized test.

- This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

How Supplied: 60mg oral tablets

Dosing and Administration: The recommended dosage is based on body weight, as follows:

- <90kg: 120mg once daily with or without food
- ≥90kg: 180mg once daily with or without food
- Dosing should continue until disease progression or unacceptable toxicity.
- Dosage adjustments may be necessary based on adverse reactions or drug interactions. If concomitant use with strong CYP3A4 inducers cannot be avoided, increased doses up to 360mg once daily may be required.

Cost: The WAC is $361.12 per tablet. For a member weighing <90kg, this would result in an estimated cost of $21,667.20 per month or $260,006.40 per year based on recommended dosing. For a member weighing ≥90kg, this would result in an estimated cost of $32,500.80 per month or $390,009.60 per year.

Hyrnuo® (Sevabertinib) Product Summary[20]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with locally advanced or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.

- This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

How Supplied: 10mg oral tablets

Dosing and Administration:

- The recommended dose is 20mg orally twice daily with food, continued until disease progression or unacceptable toxicity.

Cost: The WAC is $200 per tablet. This would result in an estimated cost of $24,000 per month or $288,000 per year based on recommended dosing.

Ibtrozi™ (Taletrectinib) Product Summary[21]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of adult patients with locally advanced or metastatic *ROS1*-positive NSCLC

How Supplied: 200mg oral capsules

Dosing and Administration:

- The recommended dosage is 600mg [using (3) 200mg capsules] orally once daily on an empty stomach (no food intake at least 2 hours before and 2 hours after taking Ibtrozi™) until disease progression or unacceptable toxicity.

Cost: The WAC is $347.30 per capsule. This would result in an estimated cost of $31,257 per month or $375,084 per year based on recommended dosing.

Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) Product Summary[22]

Therapeutic Class: Combination of amivantamab, a bispecific EGFR-directed and MET receptor-directed antibody, and hyaluronidase, an endoglycosidase

Indication(s): Indicated for all of the same all of the same indications for NSCLC as the IV formulation of Rybrevant®

How Supplied: Available as SDVs in the following combinations:

- 1,600mg amivantamab/20,000 units hyaluronidase per 10mL solution
- 2,240mg amivantamab/28,000 units hyaluronidase per 14mL solution
- 2,400mg amivantamab/30,000 units hyaluronidase per 15mL solution
- 3,520mg amivantamab/44,000 units hyaluronidase per 22mL solution

Dosing and Administration:

- Rybrevant Faspro™ should be administered as a sub-Q injection in the abdomen over approximately 5 minutes.
- The recommended dose and frequency depends on whether Rybrevant Faspro™ is used in combination with carboplatin and pemetrexed, in combination with lazertinib, or as a single agent.

- Rybrevant Faspro™ should be continued until disease progression or unacceptable toxicity.
- Please see the full *Prescribing Information* for specific dosing information.

Cost: The WAC is $1,238.27 per mL. For a member weighing 80kg and receiving 2,240mg/28,000 units (14mL) every 2 weeks, this would result in an estimated cost of $34,671.56 per 28 days or $450,730.28 per year.

Cost Comparison: Gemcitabine Products

Product	Cost Per 200mg	Cost Per 21 Days*	Cost Per Year
Avgemsi™ (gemcitabine) (J9184)	**$410.44**	**$9,029.68**	**$153,504.56**
gemcitabine (Accord) (J9196)	$5.29	$116.38	$1,978.46
gemcitabine (generic Gemzar®) (J9201)	$3.24	$71.28	$1,211.76

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS).
*Cost per 21 days based on a dose of 1,250mg/m^2 on days 1 and 8 of each 21-day cycle for a member with a body surface area (BSA) of 1.73m^2 (using a total of 2,200mg per dose).

Recommendations

The College of Pharmacy recommends the prior authorization of Emrelis™ (telisotuzumab vedotin-tllv), Ensacove™ (ensartinib), Hernexeos® (zongertinib), Hyrnuo® (sevabertinib), and Ibtrozi™ (taletrectinib) based on recent FDA approval with the following criteria (shown in red):

Emrelis™ (Telisotuzumab Vedotin-tllv) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of recurrent, advanced, or metastatic non-squamous NSCLC; and
2. Disease with high c-Met/MET protein overexpression, defined as ≥50% of tumor cells with strong staining [immunohistochemistry (IHC) 3+]; and
3. Epidermal growth factor receptor (EGFR) wild-type; and
4. Member has received prior systemic therapy; and
5. ECOG performance status of 0-2; and
6. Used as a single agent; and
7. Member must be 18 years of age or older.

Ensacove™ (Ensartinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positive; and
3. Used as a single agent; and

4. Member has not previous received an ALK inhibitor.

Hernexeos® (Zongertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of non-squamous NSCLC; and
2. Disease is unresectable or metastatic; and
3. Disease is positive for HER2 (ERBB2) tyrosine kinase domain activating mutation; and
4. Member must be 18 years of age or older.

Hyrnuo® (Sevabertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of non-squamous NSCLC; and
2. Disease is locally advanced or metastatic; and
3. Disease is positive for HER2 (ERBB2) tyrosine kinase domain activating mutations; and
4. Member has received prior systemic therapy; and
5. Member is 18 years of age or older.

Ibtrozi™ (Taletrectinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
2. Disease is locally advanced or metastatic; and
3. Disease is positive for *ROS1* rearrangements; and
4. Members is 18 years of age or older.

Next, the College of Pharmacy also recommends the prior authorization of Rybrevant Faspro™ (amivantamab/hyaluronidase-lpuj) with criteria similar to Rybrevant® (amivantamab-vmjw) with the following changes (shown in red):

Rybrevant® (Amivantamab-vmjw) and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
    a. As first-line therapy in combination with carboplatin and pemetrexed; or
    b. As a single agent in disease that has progressed on or after platinum-based chemotherapy; or
3. Tumor exhibits EGFR exon 19 deletion or exon 21 L858R mutations; and
    a. As first-line therapy in combination with lazertinib; or
    b. As subsequent therapy in combination with carboplatin and pemetrexed after progression on an EGFR tyrosine kinase inhibitor.

The College of Pharmacy also recommends the prior authorization of Avgemsi™ (gemcitabine) based on net costs with the following criteria (shown in red):

Avgemsi™ (Gemcitabine; J9184) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Gemzar® (gemcitabine – J9201) and other preferred gemcitabine products (J9196 – Accord) that do not require prior authorization must be provided.

Next, the College of Pharmacy recommends updating the Imfinzi® (durvalumab), Tecentriq® (atezolizumab), Tecentriq Hybreza® (atezolizumab/hyaluronidase-tqjs), and Zepzelca® (lurbinectedin) approval criteria based on new FDA approvals (changes shown in red):

Imfinzi® (Durvalumab) Approval Criteria [Bladder Cancer Diagnosis]:

1. Diagnosis of muscle invasive bladder cancer; and
   a. Used in combination with gemcitabine and cisplatin as neoadjuvant treatment for 4 cycles; and
   b. Followed by single-agent adjuvant treatment following radical cystectomy for up to 8 additional cycles; or
2. Diagnosis of high-risk, non-muscle-invasive bladder cancer (NMIBC); and
   a. Used in combination with Bacillus Calmette-Guerin (BCG); and
   b. Member has not received BCG previously; and
   c. Approval will be for a maximum of 13 cycles.

Imfinzi® (Durvalumab) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of gastric or GEJ adenocarcinoma; and
2. Disease is resectable; and
3. Disease is positive for programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1 or tumor area positivity (TAP) ≥1%; and
4. Used as perioperative treatment, where:
   a. Used in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) chemotherapy as neoadjuvant and adjuvant treatment; and
   b. Used as single agent maintenance therapy following combination therapy with FLOT chemotherapy; and
5. Member is 18 years of age or older.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Alveolar Soft Part Sarcoma (ASPS) Diagnosis]:

1. Diagnosis of unresectable or metastatic ASPS; and
2. Member must be 2 years of age or older for Tecentriq®; or
3. Member must be ~~18~~ 12 years of age or older and weigh ≥40kg for Tecentriq Hybreza®.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Muscle Invasive Bladder Cancer (MIBC) Diagnosis]:

1. Diagnosis of MIBC; and
2. Used as adjuvant treatment after cystectomy; and
3. Presence of circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test; and
4. Used as a single agent.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza® (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. A diagnosis of SCLC; and
2. ~~First-line therapy; and~~
3. Extensive-stage disease; and
4. ~~Atezolizumab must be used in combination with carboplatin and etoposide; and~~
5. Used in 1 of the following settings:
    a. Used as primary treatment in combination with carboplatin and etoposide; or
    b. Used as first-line maintenance treatment for disease that has not progressed on or after first-line induction therapy with atezolizumab or atezolizumab/hyaluronidase, carboplatin, and etoposide; and
        i. Maintenance treatment is given in combination with lurbinectedin or as a single agent; and
6. Member must be 18 years of age or older.

Zepzelca® (Lurbinectedin) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. A diagnosis of ~~metastatic~~ SCLC; and
2. Used in 1 of the following settings:
    a. Disease is metastatic; and
        i. Used as subsequent therapy following disease progression on or after platinum-based chemotherapy; or
    b. Disease is extensive-stage; and

i. Used as first-line maintenance treatment for disease that has not progressed on or after first-line induction therapy with atezolizumab or atezolizumab/hyaluronidase, carboplatin, and etoposide; and
ii. Maintenance treatment is given in combination with atezolizumab or atezolizumab/hyaluronidase; and

3. Member must be 18 years of age or older.

Next, the College of Pharmacy recommends updating the Tarceva® (erlotinib) approval criteria based on NCCN guideline recommendations (changes shown in red):

Tarceva® (Erlotinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of NSCLC; and
2. Recurrent or metastatic disease; and
3. Epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation detected; and
4. As a single agent ~~only.~~; or
5. In combination with ramucirumab (if T790M mutation negative).

[1] U.S. Food and Drug Administration (FDA). FDA Approves Ensartinib for ALK-Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-ensartinib-alk-positive-locally-advanced-or-metastatic-non-small-cell-lung-cancer. Issued 12/18/2024. Last accessed 05/20/2026.
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[3] U.S. FDA. FDA Grants Accelerated Approval to Telisotuzumab Vedotin-tllv for NSCLC with High C-Met Protein Overexpression. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-telisotuzumab-vedotin-tllv-nsclc-high-c-met-protein-overexpression. Issued 05/14/2025. Last accessed 05/20/2026.
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drugs/fda-grants-accelerated-approval-zongertinib-non-squamous-nsclc-her2-tkd-activating-mutations. Issued 08/08/2025. Last accessed 05/20/2026.

[8] U.S. FDA. FDA Grants Accelerated Approval to Zongertinib for Unresectable or Metastatic Non-Squamous Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-zongertinib-unresectable-or-metastatic-non-squamous-non-small-cell. Issued 02/26/2026. Last accessed 05/20/2026.

[9] U.S. FDA. FDA Approves Lurbinectedin in Combination with Atezolizumab or Atezolizumab and Hyaluronidase-tqjs for Extensive-Stage Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-lurbinectedin-combination-atezolizumab-or-atezolizumab-and-hyaluronidase-tqjs-extensive. Issued 10/02/2025. Last accessed 05/20/2026.

[10] U.S. FDA. FDA Grants Accelerated Approval to Sevabertinib for Non-Squamous Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-sevabertinib-non-squamous-non-small-cell-lung-cancer. Issued 11/19/2025. Last accessed 05/20/2026.

[11] U.S. FDA. Tecentriq Hybreza® Supplement Approval/Fulfillment of Postmarketing Requirement Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/761347Orig1s004ltr.pdf. Issued 11/24/2025. Last accessed 05/20/2026.

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[13] U.S. FDA. FDA Approves Amivantamab and Hyaluronidase-lpuj for Subcutaneous Injection. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-amivantamab-and-hyaluronidase-lpuj-subcutaneous-injection. Issued 12/17/2025. Last accessed 05/20/2026.

[14] U.S. FDA. FDA Approves Atezolizumab for Adjuvant Treatment of Muscle Invasive Bladder Cancer in Patients with Molecular Residual Disease. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-adjuvant-treatment-muscle-invasive-bladder-cancer-patients-molecular. Issued 05/15/2026. Last accessed 05/20/2026.

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[20] Hyrnuo® (Sevabertinib) Prescribing Information. Byer HealthCare Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219972s000lblCorrected.pdf. Last revised 11/2025. Last accessed 05/20/2026.

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[22] Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) Prescribing Information. Janssen Biotech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761484Orig1s000correctedlbl.pdf. Last revised 02/2026. Last accessed 05/20/2026.

Appendix K

Fiscal Year 2025 Annual Review of Zokinvy® (Lonafarnib)

Oklahoma Health Care Authority
June 2026

Current Prior Authorization Criteria

Zokinvy® (Lonafarnib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. To reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS); or
   b. Treatment of processing-deficient Progeroid Laminopathies (PL) with either:
      i. Heterozygous *LMNA* mutation with progerin-like protein accumulation; or
      ii. Homozygous or compound heterozygous *ZMPSTE24* mutations; and
2. Member must have confirmatory mutational analysis showing mutation in the *LMNA* gene; and
3. Zokinvy® will not be approved for other progeroid syndromes or processing-proficient PL (based upon its mechanism of action, Zokinvy® would not be effective in these populations); and
4. Member must be 1 year of age or older; and
5. Member must have a body surface area (BSA) ≥0.39m^2; and
6. Member must have clinical signs of progeria (e.g., characteristic facial features, growth deficiency, atherosclerosis); and
7. Zokinvy® must be prescribed by, or in consultation with, a specialist with expertise in treating HGPS or PL (or an advanced care practitioner with a supervising physician who is a specialist in treating HGPS or PL); and
8. Member must not be taking any of the following medications: strong/moderate CYP3A inhibitors, CYP2C9 inhibitors, midazolam, lovastatin, simvastatin, atorvastatin, or loperamide if younger than 2 years of age; and
9. Prior to and during treatment, the potential for drug interactions should be considered, concomitant medications reviewed, and members should be monitored for adverse reactions; and
10. Member should have ophthalmological evaluations performed at regular intervals and at the onset of any new visual changes; and
11. Prescriber must verify the member will be monitored for changes in electrolytes, complete blood counts, renal function, and liver enzymes; and

12. Member's recent BSA must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
13. The maximum approvable dose of Zokinvy® is 300mg/m^2 per day; and
14. Initial approvals will be for 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as a positive response to treatment including no new or worsening heart failure and no stroke incidence, will be required for continued approval. Subsequent approvals will be for 12 months and compliance and documentation of a positive response to Zokinvy® therapy will be required on each continuation request.

Utilization of Zokinvy® (Lonafarnib): Fiscal Year 2025

There was no SoonerCare utilization of Zokinvy® (lonafarnib) during fiscal year 2025 (07/01/2024 to 06/30/2025).

Prior Authorization of Zokinvy® (Lonafarnib)

There were no prior authorization requests submitted for Zokinvy® (lonafarnib) during fiscal year 2025 (07/01/2024 to 06/30/2025).

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Zokinvy® (lonafarnib): July 2029

New U.S. Food and Drug Administration (FDA) Approval(s):

- **March 2024:** The FDA approved label updates for Zokinvy® (lonafarnib) regarding drug interactions with concomitant administration of Zokinvy® and inhibitors of CYP3A or CYP2C9. These updates were based on the results of a postmarketing study. Additionally, a new warning was added about QTc prolongation with Zokinvy®.

Recommendations

The College of Pharmacy recommends updating the Zokinvy® (lonafarnib) prior authorization criteria based on the FDA label updates and clinical practice (changes shown in red):

Zokinvy® (Lonafarnib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. To reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS); or
   b. Treatment of processing-deficient Progeroid Laminopathies (PL) with either:

i. Heterozygous *LMNA* mutation with progerin-like protein accumulation; or
ii. Homozygous or compound heterozygous *ZMPSTE24* mutations; and

2. Member must have confirmatory mutational analysis showing mutation in the *LMNA* and/or *LMPSTE24* gene (results of the genetic testing must be submitted); and
3. Zokinvy® will not be approved for other progeroid syndromes or processing-proficient PL (based upon its mechanism of action, Zokinvy® would not be effective in these populations); and
4. Member must be 1 year of age or older; and
5. Member must have a body surface area (BSA) ≥0.39m^2; and
6. Member must have clinical signs of progeria (e.g., characteristic facial features, growth deficiency, atherosclerosis); and
7. Zokinvy® must be prescribed by, or in consultation with, a specialist with expertise in treating HGPS or PL (or an advanced care practitioner with a supervising physician who is a specialist in treating HGPS or PL); and
8. ~~Member must not be taking any of the following medications: strong/moderate CYP3A inhibitors, CYP2C9 inhibitors, midazolam, lovastatin, simvastatin, atorvastatin, or loperamide if younger than 2 years of age; and~~
9. Prior to and during treatment, the potential for drug interactions should be considered, concomitant medications reviewed, and members should be monitored for adverse reactions; and
10. Member should have ophthalmological evaluations performed at regular intervals and at the onset of any new visual changes; and
11. Prescriber must verify the member will be monitored for changes in electrolytes, complete blood counts, renal function, and liver enzymes; and
12. Member's recent BSA must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
13. The maximum approvable dose of Zokinvy® is 300mg/m^2 per day; and
14. Initial approvals will be for 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as a positive response to treatment including no new or worsening heart failure and no stroke incidence, will be required for continued approval. Subsequent approvals will be for 12 months and compliance and documentation of a positive response to Zokinvy® therapy will be required on each continuation request.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 05/2026. Last accessed 05/07/2026.
[2] U.S. FDA. Zokinvy® sNDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/213969Orig1s002,%20s003ltr.pdf. Issued 03/21/2024. Last accessed 05/07/2026.
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Appendix L

Fiscal Year 2025 Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Inlexzo™ (Gemcitabine Intravesical System), Kyxata™ (Carboplatin), Lifyorli™ (Relacorilant), and Zusduri™ (Mitomycin Intravesical Solution)

Oklahoma Health Care Authority
June 2026

Current Prior Authorization Criteria

Utilization data for Bavencio® (avelumab), Keytruda® (pembrolizumab), Keytruda Qlex™ (pembrolizumab/berahyaluronidase alfa-pmph), Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), Opdivo® (nivolumab), Opdivo Qvantig™ (nivolumab/hyaluronidase-nvhy), and Yervoy® (ipilimumab) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the December 2025 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki) and Talzenna® (talazoparib) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the September 2025 DUR Board packet. These medications and criteria are reviewed annually with the breast cancer medications. Utilization data for Imfinzi® (durvalumab) and Tarceva® (erlotinib) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the April 2026 DUR Board packet. These medications and criteria are reviewed annually with the lung cancer medications.

Adstiladrin® (Nadofaragene Firadenovec-vncg) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC with carcinoma in situ (CIS) with or without papillary tumors; and
2. High-risk disease that was unresponsive to prior Bacillus Calmette-Guérin (BCG) therapy.

Afinitor® (Everolimus) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Hormone receptor (HR) positive; and
4. Used in combination with exemestane, fulvestrant, or tamoxifen; and

5. Member must have failed treatment with, have a contraindication to, or be intolerant to letrozole or anastrozole.

Afinitor® (Everolimus) Approval Criteria [Neuroendocrine Tumors (NET) of Pancreatic (PNET), Gastrointestinal, or Lung Origin Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic NET of pancreatic (PNET), gastrointestinal, or lung origin; and
2. Progressive disease from a previous treatment.

Afinitor® (Everolimus) Approval Criteria [Renal Angiomyolipoma (AML) and Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Diagnosis of renal AML and TSC; and
2. Not requiring immediate surgery; and
3. Used in pediatric and adult members 1 year of age and older.

Afinitor® (Everolimus) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Failure of treatment with sunitinib or sorafenib; and
3. Everolimus may also be approved to be used in combination with lenvatinib for advanced RCC.

Afinitor® (Everolimus) Approval Criteria [Subependymal Giant Cell Astrocytoma (SEGA) with Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Diagnosis of SEGA with TSC; and
2. Requires therapeutic intervention but cannot be curatively resected.

Afinitor® (Everolimus) Approval Criteria [Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures Diagnosis]:

1. Diagnosis of TSC-associated partial-onset seizures; and
2. Initial prescription must be written by a neurologist or neuro-oncologist; and
3. Failure of ≥3 other medications commonly used for seizures; and
4. Must be used as adjunctive treatment; and
5. Member must not be taking any P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin) concurrently with Afinitor®; and
6. Member must not be taking St. John's wort concurrently with Afinitor®; and
7. Prescriber must verify that Afinitor® trough levels and adverse reactions (e.g., non-infectious pneumonitis, stomatitis, hyperglycemia, dyslipidemia, thrombocytopenia, neutropenia, febrile neutropenia) will be monitored and dosing changes or discontinuations will correspond with recommendations in the package labeling; and

8. Prescriber must verify that female members are not pregnant and will use contraception while receiving Afinitor® therapy and for 8 weeks after the last dose of Afinitor® and that male members with female partners of reproductive potential will use contraception while receiving Afinitor® therapy and for 4 weeks after the last dose of Afinitor®; and
9. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Akeega® (Niraparib/Abiraterone Acetate) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Presence of deleterious or suspected deleterious BRCA mutation based upon an FDA-approved test; and
3. Used in conjunction with prednisone; and
4. Used in conjunction with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

Anktiva® (Nogapendekin Alfa Inbakicept-pmln) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC with carcinoma in situ (CIS); and
2. Cancer is unresponsive to initial Bacillus Calmette-Guerin (BCG) therapy; and
3. Will be used in conjunction with BCG; and
4. Initial approval will be for 6 induction doses; and
5. Subsequent requests must indicate if the member has had a complete response to induction dosing; and
    a. A second induction course (6 doses) may be approved if a complete response is not achieved at month 3; and
6. If complete response is achieved, maintenance dosing may be approved in 6-month intervals up to a maximum of 37 months of treatment.

Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) Approval Criteria [Ovarian Cancer Diagnosis]:

1. Diagnosis of low-grade serous ovarian cancer; and
2. Disease is recurrent; and
3. Member has KRAS-mutation; and
4. Member has received prior systemic therapy; and
5. Member is 18 years of age or older.

Balversa® (Erdafitinib) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Tumor positive for *FGFR3* genetic mutation; and
3. Disease has progressed on or after at least 1 line of systemic therapy; and
    a. Member has received prior treatment with a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor.

Bavencio® (Avelumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Must be used as first-line treatment; and
3. Must be used in combination with axitinib.

Bavencio® (Avelumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Disease has progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; or
3. Used as maintenance therapy for members not progressing on first-line platinum-containing regimen.

Cabometyx® (Cabozantinib) Approval Criteria:

1. For cabozantinib monotherapy:
    a. Diagnosis of advanced renal cell carcinoma (RCC); or
    b. Diagnosis of advanced hepatocellular carcinoma (HCC); and
        i. Member has previously received sorafenib; or
    c. Diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) in adults and pediatric members 12 years of age and older; and
        i. Disease has progressed following prior vascular endothelial growth factor (VEGF)-targeted therapy; and
        ii. Disease is radioactive iodine-refractory or member is ineligible for radioactive iodine; or
    d. Diagnosis of locally advanced, unresectable or metastatic well-differentiated pancreatic neuroendocrine tumors (pNET) or extrapancreatic neuroendocrine tumors (epNET) in adults and pediatric members 12 years of age and older; and
        i. As second line or subsequent therapy; or
2. For cabozantinib in combination with nivolumab:
    a. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
    b. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

Camcevi® (Leuprolide) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of advanced prostate cancer; and
2. A patient-specific, clinically significant reason why the member cannot use Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication].

Elahere® (Mirvetuximab Soravtansine-gynx) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. Tumor is folate receptor alpha (FRα) positive; and
3. Member has received 1 to 3 prior systemic treatment regimens.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Cervical, Endometrial, Ovarian, Vaginal, or Vulvar Cancer Diagnosis]:

1. Diagnosis of advanced, recurrent, or metastatic cervical, endometrial, ovarian, vaginal, or vulvar cancer; and
2. Human epidermal receptor type 2 (HER2)-positive with immunohistochemistry (IHC) 2+ or 3+; and
3. Used as a single agent.

Erleada® (Apalutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of non-metastatic CRPC; or
2. Castration-resistant or disease progression while on androgen deprivation therapy (ADT); and
3. Prostate specific antigen doubling time of ≤10 months; and
4. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Erleada® (Apalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Fotivda® (Tivozanib) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or refractory advanced RCC; and
2. Member has received at least 2 prior systemic therapies; and
3. As a single agent.

Imfinzi® (Durvalumab) Approval Criteria [Bladder Cancer Diagnosis]:

1. Diagnosis of muscle invasive bladder cancer; and

2. Used in combination with gemcitabine and cisplatin as neoadjuvant treatment for 4 cycles; and
3. Followed by single-agent adjuvant treatment following radical cystectomy for up to 8 additional cycles.

Imfinzi® (Durvalumab) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Diagnosis of primary advanced (FIGO measurable stage III/newly diagnosed stage IV) or recurrent endometrial cancer; and
2. Mismatch repair deficient (dMMR); and
3. Used in combination with carboplatin and paclitaxel followed by single-agent maintenance.

Jelmyto® (Mitomycin) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of non-metastatic upper urinary tract tumor; and
2. Must be a single, residual, low-grade, low-volume (5 to 15mm) tumor; and
3. Member is not a candidate for nephroureterectomy; and
4. Initial approvals will be for the duration of 6 weeks. With documentation from the prescriber of complete response 3 months after initial treatment, subsequent approvals may be authorized for once monthly use for up to 11 additional instillations.

Jemperli (Dostarlimab-gxly) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Used as a single agent; and
    a. Diagnosis of advanced, recurrent, or metastatic endometrial cancer; and
    b. Mismatch repair deficient (dMMR) disease; and
    c. Disease has progressed on or following prior treatment with a platinum-containing regimen; or
2. Used in combination with carboplatin and paclitaxel; and
    a. Diagnosis of primary advanced or recurrent endometrial cancer.

Jemperli (Dostarlimab-gxly) Approval Criteria [Mismatch Repair Deficient (dMMR) Solid Tumor Diagnosis]:

1. Diagnosis of recurrent or advanced solid tumors that are dMMR; and
2. Disease has progressed on or following prior treatment; and
3. There are no satisfactory treatment alternatives for the member.

Jevtana® (Cabazitaxel) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Previous treatment with a docetaxel-containing regimen; and
3. Used in combination with prednisone.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Bladder Cancer Diagnosis]:

1. For non-muscle invasive bladder cancer (NMIBC):
    a. Diagnosis of high-risk NMIBC; and
    b. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
    c. Member must be ineligible for or has elected not to undergo cystectomy; or
2. For muscle invasive bladder cancer (MIBC):
    a. Used as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment; and
    b. Used in combination with enfortumab vedotin; and
    c. Member is ineligible for cisplatin-containing chemotherapy.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
    a. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and
    b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
        i. Disease progression on or after chemotherapy; or
        ii. As first-line therapy in combination with chemotherapy, with or without bevacizumab; or
        iii. As second line or subsequent therapy as a single agent; or
2. Diagnosis of FIGO 2014 Stage III-IVA cervical cancer; and
    a. Used in combination with concomitant chemotherapy and radiation.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Endometrial Cancer Diagnosis]:

1. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo (nivolumab)]; and
2. Disease progression following prior systemic therapy; and
    a. Member is not a candidate for curative surgery or radiation; and
    b. Used in 1 of the following settings:
        i. In combination with lenvatinib for advanced endometrial cancer that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); or
        ii. As a single agent for advanced endometrial cancer that is MSI-H or dMMR; or

3. Primary advanced (newly diagnosed stage III/IVA or stage IVB) or recurrent endometrial cancer; and
    a. Used in combination with carboplatin and paclitaxel followed by single-agent maintenance pembrolizumab.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of new or recurrent stage 4 clear-cell RCC; and
    a. Member has not received previous systemic therapy for advanced disease; and
    b. Must be used in combination with axitinib or lenvatinib; and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or
2. Diagnosis of RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

Keytruda® (Pembrolizumab) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Member must have 1 of the following:
    a. As a single agent for locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
    b. As a single agent within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
    c. As a single agent frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy or any platinum-containing chemotherapy; and
        i. Cisplatin ineligibility is defined as:
            1. Baseline creatinine clearance of <60mL/min; or
            2. ECOG performance status of 2; or
            3. Class III heart failure; or
            4. Grade 2 or greater peripheral neuropathy; or
            5. Grade 2 or greater hearing loss; or
    d. In combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Lenvima® (Lenvatinib) Approval Criteria [Differentiated Thyroid Cancer (DTC) Diagnosis]:

1. Locally recurrent or metastatic disease; and

2. Disease progression on prior treatment; and
3. Radioactive iodine-refractory disease.

Lenvima® (Lenvatinib) Approval Criteria [Endometrial Carcinoma Diagnosis]:

1. Advanced disease with progression on prior systemic therapy; and
2. Member is not a candidate for curative surgery or radiation; and
3. Disease is mismatch repair proficient (pMMR) or is not microsatellite instability-high (MSI-H); and
4. Used in combination with pembrolizumab.

Lenvima® (Lenvatinib) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Unresectable disease; and
2. First-line treatment.

Lenvima® (Lenvatinib) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
    a. Used in combination with pembrolizumab; or
    b. Following 1 prior anti-angiogenic therapy; and
        i. Used in combination with everolimus.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cervical, Vaginal, or Vulvar Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical, vaginal, or vulvar cancer; and
2. Used as second-line or subsequent therapy; and
3. Used as a single agent; and
4. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab), Yervoy® (ipilimumab)].

Lynparza® (Olaparib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-negative, high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy; and
    a. Used in the adjuvant setting; and
    b. Positive test for a germline BRCA-mutation (gBRCAm); and
    c. Maximum treatment duration of 1 year; or
2. Diagnosis of metastatic breast cancer; and
    a. Member must have shown progression on previous chemotherapy; and

b. Members with hormone receptor positive disease must have failed prior endocrine therapy or are considered to not be a candidate for endocrine therapy.

Lynparza® (Olaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Used in 1 of the following settings:
    a. Member must have failed previous first-line therapy; and
        i. Used as a single agent except for the following:
            1. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
        ii. Disease must be positive for a mutation in a homologous recombination gene; or
    b. Used in combination with abiraterone and prednisone (or prednisolone); and
        i. Disease must be positive for a deleterious or suspected deleterious BRCA mutation.

Lynparza® (Olaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Maintenance treatment of advanced disease:
    a. Disease must be in a complete or partial response to primary chemotherapy; and
        i. Used as a single agent in members with a diagnosis of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) or somatic BRCA-mutated (sBRCAm), advanced ovarian cancer; or
        ii. Used in combination with bevacizumab following a primary therapy regimen that included bevacizumab; or
    b. Complete or partial response to second-line or greater platinum-based chemotherapy (no mutation required); and
    c. A quantity limit based on FDA approved dosing will apply.

Lynparza® (Olaparib) Approval Criteria [Pancreatic Cancer Diagnosis]:

1. Diagnosis of metastatic pancreatic adenocarcinoma with known germline BRCA1/BRCA2 mutation; and
2. Maintenance therapy as a single agent; and
3. In members who have not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

Mekinist® (Trametinib) Approval Criteria [Serous Ovarian Cancer Diagnosis]:

1. Diagnosis of persistent disease or recurrent low-grade serous carcinoma; and
2. Meets 1 of the following:
    a. Used in combination with dabrafenib; and
        i. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
        ii. Progression on primary, maintenance, or recurrence therapy; or
        iii. Stable or persistent disease (if not on maintenance therapy); or
        iv. Complete remission and relapse after completing chemotherapy; or
    b. Used as a single agent for platinum-sensitive or platinum-resistant recurrence.

Nubeqa® (Darolutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of non-metastatic CRPC; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Nubeqa® (Darolutamide) Approval Criteria [Metastatic Castration-Sensitive Prostate Cancer (mCSPC) Diagnosis]:

1. Diagnosis of mCSPC; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
3. Used in combination with docetaxel or as a single agent.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
2. Used in 1 of the following settings:
    a. For nivolumab monotherapy:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease; and
        ii. Failed prior therapy with 1 of the following medications:
            1. Sunitinib; or
            2. Sorafenib; or
            3. Pazopanib; or
            4. Axitinib; or
    b. For nivolumab use in combination with ipilimumab:

i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or

c. For nivolumab use in combination with cabozantinib:
   i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and
   ii. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and

3. Member must be 18 years of age or older for Opdivo Qvantig™; and
4. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Opdivo® (Nivolumab) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. Diagnosis of urothelial carcinoma; and
   a. Member has undergone radical resection; and
   b. Disease is at high risk of recurrence; or
2. Diagnosis of metastatic or unresectable locally advanced disease; and
   a. Used as second-line or greater therapy; and
   b. Previous failure of a platinum-containing regimen; and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; or
3. Diagnosis of metastatic or unresectable urothelial carcinoma; and
   a. Used as first-line therapy; and
   b. In combination with cisplatin and gemcitabine; and
   c. Followed by maintenance treatment with nivolumab for a maximum duration of 24 months of therapy; and
4. Member must be 18 years of age or older for Opdivo Qvantig™; and
5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

Orgovyx® (Relugolix) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of advanced prostate cancer; and
2. A patient-specific, clinically significant reason why the member cannot use Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication]; and
3. A quantity limit of 30 tablets per 30 days will apply. Upon meeting approval criteria, a quantity limit override will be approved for the day 1 loading dose of 360mg.

Padcev® (Enfortumab Vedotin-ejfv) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial cancer; and
2. Used in 1 of the following settings:

a. As a single agent and member has previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting; or
b. As a single agent and member has received at least 1 prior therapy and is ineligible for cisplatin-containing chemotherapy; or
c. Used in combination with pembrolizumab.

Pluvicto® (Lutetium Lu-177 Vipivotide Tetraxetan) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC); and
2. Member must have been treated with androgen receptor pathway inhibitor (ARPI) therapy; and
3. Member must meet 1 of the following:
   a. Considered appropriate to delay taxane-based chemotherapy; or
   b. Has received prior taxane-based chemotherapy.

Provenge® (Sipuleucel-T) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Asymptomatic or minimally symptomatic; and
3. No hepatic metastases; and
4. Life expectancy of >6 months; and
5. ECOG performance status of 0 or 1; and
6. Approvals will be for 1 treatment course (3 doses) per member per lifetime.

Rubraca® (Rucaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Member must have failed previous first-line therapy; and
3. Used as a single agent except for the following:
   a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Disease must be positive for a mutation in BRCA1 or BRCA2.

Rubraca® (Rucaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Maintenance treatment of recurrent disease:
   a. Diagnosis of recurrent disease; and
   b. Disease must be in a complete or partial response to platinum-based chemotherapy; and
   c. Positive for a BRCA mutation; and
   d. Used as a single agent.

Talzenna® (Talazoparib) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of metastatic, castration-resistant prostate cancer; and
2. Disease is homologous recombination repair (HRR) gene-mutated; and
3. Used in combination with enzalutamide.

Tarceva® (Erlotinib) Approval Criteria [Kidney Cancer Diagnosis]:

1. Diagnosis of advanced papillary renal cell carcinoma; and
2. Non-clear cell histology; and
3. Relapsed disease or surgically unresectable stage IV disease; and
4. Used in combination with bevacizumab.

Tivdak® (Tisotumab Vedotin-tftv) Approval Criteria [Cervical Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical cancer; and
2. Disease has progressed on or after chemotherapy.

Welireg® (Belzutifan) Approval Criteria [Pheochromocytoma or Paraganglioma (PPGL) Diagnosis]:

1. Diagnosis of locally advanced, unresectable, or metastatic PPGL; and
2. Member must be 12 years of age or older; and
3. As a single agent.

Welireg® (Belzutifan) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC with a clear cell component; and
2. Member has received at least 2 lines of systemic therapy, including a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI); and
3. As a single agent.

Welireg® (Belzutifan) Approval Criteria [von Hippel-Landau (VHL) Disease Diagnosis]:

1. Diagnosis of VHL disease; and
2. Diagnosis of either renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumor; and
3. Does not require immediate surgery.

Xofigo® (Radium-223 Dichloride) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Symptomatic bone metastases; and
3. No known visceral metastatic disease; and
4. Prescriber must verify radium-223 dichloride will not be used in combination with chemotherapy; and

5. Absolute neutrophil count ≥1.5 x 10^9/L, platelet count ≥100 x 10^9/L, and hemoglobin ≥10g/dL; and
6. Approvals will be for the duration of 6 months at which time additional authorization may be granted if the prescriber documents the following:
    a. The member has not shown evidence of progressive disease while on radium-223 dichloride therapy; and
    b. Member must have an absolute neutrophil count ≥1 x 10^9/L, platelet count ≥100 x 10^9/L (radium-223 dichloride should be delayed 6 to 8 weeks otherwise).

Xtandi® (Enzalutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of CRPC.

Xtandi® (Enzalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC; or
2. Diagnosis of non-metastatic CSPC with biochemical recurrence at high risk for metastasis (high-risk BCR).

Yervoy® (Ipilimumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or surgically unresectable stage IV disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; and
2. Used in combination with nivolumab; and
3. Member has not previously failed programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Dose as follows: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks.

Yonsa® (Abiraterone Acetate) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Zejula® (Niraparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Maintenance treatment of advanced disease:
    a. Diagnosis of advanced or recurrent disease; and

b. Disease must be in a complete or partial response to platinum chemotherapy; and
c. If used for maintenance following recurrence:
    i. Must be positive for a BRCA mutation (this does not apply if used after first-line therapy); and
d. Used as a single agent.

Zytiga® (Abiraterone) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Zytiga® (Abiraterone) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic, high-risk, CSPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Oncology Medications Additional Criteria:

1. Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and
    a. Unless otherwise specified in a medication's approval criteria, continuation requests will be approved for the duration of 6 months if there is no evidence of disease progression or adverse drug reactions; and
2. The following situations require the request to be reviewed by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician:
    a. Any request for an oncology medication which does not meet approval criteria; or
    b. Any continuation request if the member has evidence of disease progression or adverse drug reactions while on the requested medication; or
    c. Any level-1 appeal request for an oncology medication; or
    d. Any peer-to-peer request for an oncology medication.

Utilization of Genitourinary and Gynecologic Cancer Medications: Fiscal Year 2025

The following utilization data includes medications indicated for genitourinary and gynecologic cancers; however, the data does not differentiate between genitourinary cancer, gynecologic cancer, and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	142	770	$9,115,519.39	$11,838.34	$400.82	60,961	22,742
Aetna	8	22	$185,652.72	$8,438.76	$317.36	2,160	585
Humana	23	51	$620,823.97	$12,173.02	$414.99	4,552	1,496
OCH	13	32	$368,444.49	$11,513.89	$393.22	2,512	937
2024 Total	**152**	**875**	**$10,290,440.57**	**$11,760.50**	**$399.47**	**70,185**	**25,760**
Fiscal Year 2025							
FFS	94	501	$7,254,661.56	$14,480.36	$489.55	36,847	14,819
Aetna	21	118	$1,092,174.45	$9,255.72	$309.92	10,058	3,524
Humana	37	176	$2,212,149.42	$12,569.03	$429.96	14,147	5,145
OCH	24	125	$1,581,143.92	$12,649.15	$428.38	10,290	3,691
2025 Total	**156**	**920**	**$12,140,129.35**	**$13,195.79**	**$446.67**	**71,342**	**27,179**
% Change	**2.60%**	**5.10%**	**18.00%**	**12.20%**	**11.80%**	**1.60%**	**5.50%**
Change	**4**	**45**	**$1,849,688.78**	**$1,435.29**	**$47.20**	**1,157**	**1,419**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

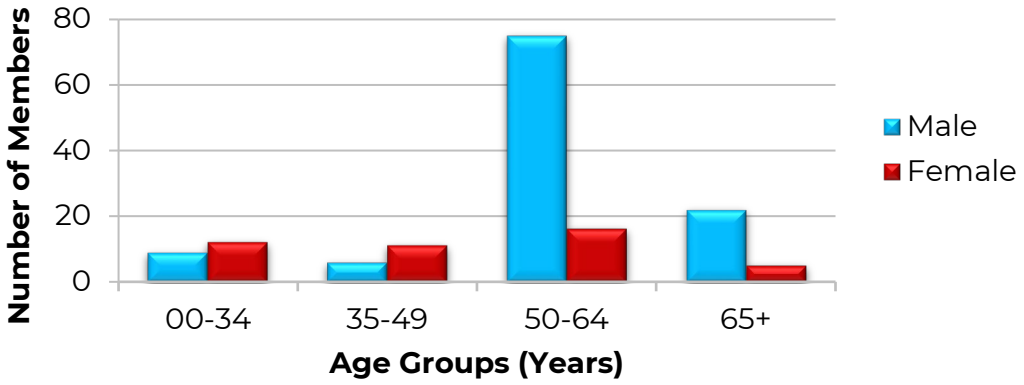
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	312	1,301	$1,381,048.25	$1,061.53	4.17
Aetna	17	43	$758.60	$17.64	2.53
Humana	21	50	$1,403.76	$28.08	2.38
OCH	25	62	$49,794.44	$803.14	2.48
2024 Total	**348**	**1,456**	**$1,433,005.05**	**$984.21**	**4.18**
Fiscal Year 2025					
FFS	187	675	$1,288,224.41	$1,908.48	3.61
Aetna	45	155	$90,814.80	$585.90	3.44
Humana	42	134	$232,941.64	$1,738.37	3.19
OCH	54	165	$92,636.57	$561.43	3.06
2025 Total	**303**	**1,129**	**$1,704,617.42**	**$1,509.85**	**3.73**
% Change	**-12.93%**	**-22.46%**	**18.95%**	**53.41%**	**-10.77%**
Change	**-45**	**-327**	**$271,612.37**	**$525.64**	**-0.45**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

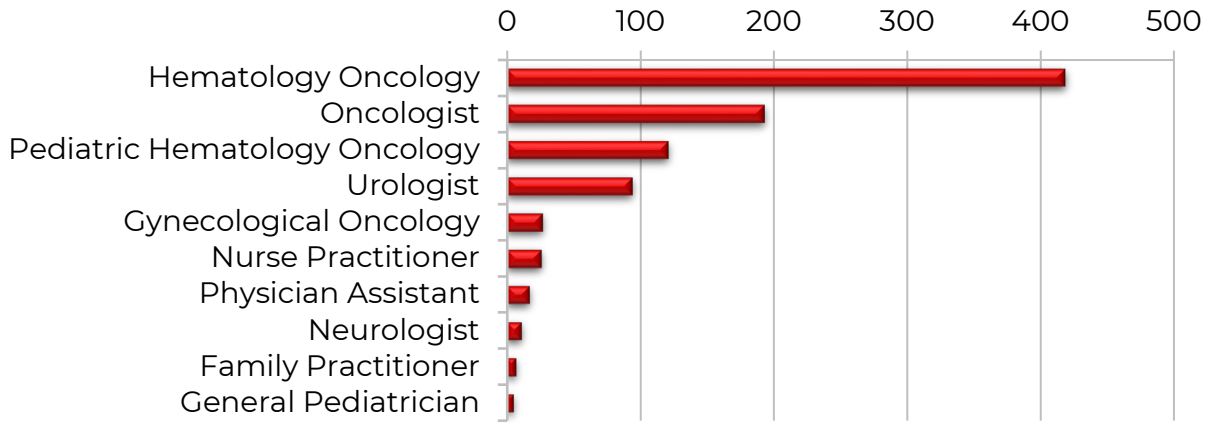
- Aggregate drug rebates collected during fiscal year 2025 for genotourinary and gynecologic cancer medications totaled $5,336,061.92.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Genitourinary and Gynecologic Cancer Medications: Pharmacy Claims (All Plans)



[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

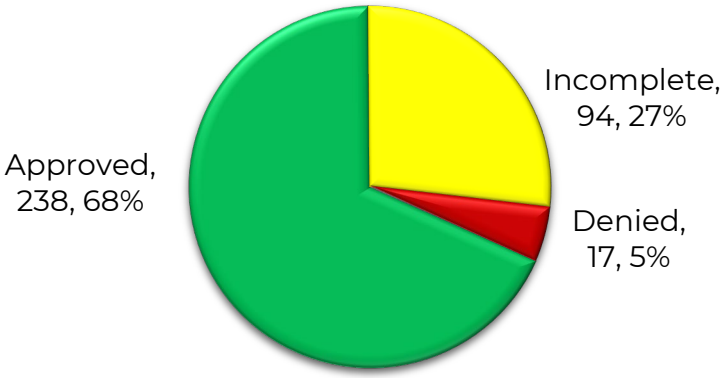
Top Prescriber Specialties of Genitourinary and Gynecologic Cancer Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Genitourinary and Gynecologic Cancer Medications

There were 349 prior authorization requests submitted for genitourinary and gynecologic cancer medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	177	69%	72	28%	6	2%	**255**
Aetna	29	81%	3	8%	4	11%	**36**
Humana	17	89%	0	0%	2	11%	**19**
OCH	15	38%	19	49%	5	13%	**39**
Total	**238**	**68%**	**94**	**27%**	**17**	**5%**	**349**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9]

Anticipated Patent Expiration(s):

- Afinitor® (everolimus): July 2028
- Jelmyto® (mitomycin): January 2031
- Zusduri™ (mitomycin intravesical solution): January 2031
- Jevtana® (cabazitaxel): April 2031
- Cabometyx® (cabozantinib): July 2033
- Yonsa® (abiraterone acetate): May 2034
- Inlexzo™ (gemcitabine intravesical system): August 2034
- Rubraca® (rucaparib): August 2035
- Xtandi® (enzalutamide): February 2037
- Orgovyx® (relugolix): September 2037
- Balversa® (erdafitinib): February 2038
- Akeega® (niraparib/abiraterone): March 2038
- Lenvima® (lenvatinib): November 2038
- Zejula® (niraparib): January 2039
- Camcevi® (leuprolide mesylate): January 2039
- Fotivda® (tivozanib): November 2039
- Erleada® (apalutamide): January 2041
- Pluvicto® (lutetium Lu-177 vipivotide tetraxetan): September 2041
- Lynparza® (olaparib): October 2041
- Lifyorli™ (relacorilant): December 2041
- Nubeqa® (darolutamide): June 2042
- Welireg® (belzutifan): June 2042
- Avmapki™ Fakzynja™ Co-Pack (avutometinib and defactinib): December 2042
- Kyxata™ (carboplatin): April 2045

New U.S. Food and Drug Administration (FDA) Approval(s):

- **June 2025:** The FDA approved Zusduri™ (mitomycin intravesical solution) for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (NMIBC).
- **August 2025:** The FDA approved Kyxata™ (carboplatin) through the 505(b)(2) pathway based on prior studies utilizing carboplatin. Kyxata™ is supplied as a solution for intravenous (IV) use in multiple-dose vials available in 20mg/2mL, 80mg/8mL, and 500mg/50mL strengths.
- **September 2025:** The FDA approved Inlexzo™ (gemcitabine intravesical system) for the treatment of adult patients with Bacillus Calmette-Guerin (BCG)-unresponsive NMIBC with carcinoma *in situ* (CIS) with or without papillary tumors.
- **November 2025:** The FDA approved Padcev® (enfortumab vedotin-ejfv) for a new indication, in combination with pembrolizumab or pembrolizumab/berahyaluronidase alfa-pmph, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment,

for the treatment of adult patients with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy.
- **December 2025:** The FDA approved Akeega® (niraparib/abiraterone) for a new indication for the treatment of adult patients with deleterious or suspected deleterious *BRCA2*-mutated metastatic castration-sensitive prostate cancer (CSPC).
- **March 2026:** The FDA approved Lifyorli™ (relacorilant), in combination with nab-paclitaxel, for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens, at least 1 of which included bevacizumab.

Guideline Update(s):
- The National Comprehensive Cancer Network (NCCN) guidelines for neuroendocrine and adrenal tumors allow for the use of everolimus in patients with unresectable, locally advanced, or metastatic neuroendocrine tumors (NET) of pancreatic (PNET), gastrointestinal, or lung origin and no functional carcinoid tumors.
- The NCCN guidelines for prostate cancer allow for the use of the following:
  - Enzalutamide in the treatment of non-metastatic and metastatic castration-resistant prostate cancer (CRPC) as a single agent or in combination with talazoparib; and
  - Enzalutamide in the treatment of metastatic CSPC as a single agent; and
  - Abiraterone in the treatment of metastatic CRPC in combination with methylprednisolone; and
  - Niraparib in the treatment of CRPC with suspected and/or deleterious *BRCA* mutation in conjunction with prednisone or methylprednisolone in patients who have not progressed on prior abiraterone therapy; and
  - Niraparib in the treatment of metastatic CSPC with high-volume metastases and suspected and/or deleterious BRCA mutation in conjunction with prednisone or methylprednisolone in patients who have not progressed on prior abiraterone therapy.

Inlexzo™ (Gemcitabine Intravesical System) Product Summary[10]

Therapeutic Class: Nucleoside metabolic inhibitor-containing intravesical system

Indication(s): Treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors

How Supplied: 1 single-dose 225mg gemcitabine intravesical system consisting of a flexible bi-oval shaped tube

Dosing and Administration: The recommended dosage is 1 intravesical system (225mg of gemcitabine) inserted into the bladder once every 3 weeks for up to 6 months (8 doses), followed by once every 12 weeks for up to 18 months (6 doses), or until persistent or recurrent NMIBC, disease progression, or unacceptable toxicity. Inlexzo™ should be removed after each 3-week indwelling period.

Cost: The Wholesale Acquisition Cost (WAC) is $69,000 per intravesical system. This would result in an estimated cost of $552,000 for the initial 6 months of treatment.

Lifyorli™ (Relacorilant) Product Summary[11]

Therapeutic Class: Glucocorticoid receptor antagonist

Indication(s): Treatment, in combination with nab-paclitaxel, of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens, at least 1 of which included bevacizumab

How Supplied: 25mg and 100mg oral capsules

Dosing and Administration:

- The recommended dose is 150mg orally once on the day before, the day of, and the day after each nab-paclitaxel infusion until disease progression or unacceptable toxicity.
- A dose reduction to 125mg may be required for adverse reactions.
- The recommended dosing of nab-paclitaxel for this indication is 80mg/m^2 as an intravenous infusion on days 1, 8, and 15 of each 28-day cycle until disease progression or unacceptable toxicity.

Cost: The WAC is $1,403.70 per capsule, and the recommended 150mg dose would require a total of 27 capsules for each 28-day cycle. This would result in an estimated cost of $37,899.90 per 28 days or $492,698.70 per year based on recommended dosing.

Zusduri™ (Mitomycin Intravesical Solution) Product Summary[12]

Therapeutic Class: Alkylating drug

Indication(s): Treatment of adult patients with recurrent low-grade intermediate-risk NMIBC

How Supplied: Supplied as a kit containing the following:

- (2) 40mg single-dose vials of mitomycin for intravesical solution; and

- (1) vial of 60mL sterile hydrogel for reconstitution

Dosing and Administration:

- The recommended dose is 75mg (56mL) instilled once weekly for 6 weeks into the bladder via a urinary catheter.
- Zusduri™ is for intravesical instillation only and should not be administered by pyelocalyceal instillation or by any other route.

Cost: The WAC is $21,500 per kit. This would result in an estimated cost of $129,000 for the recommended 6 weeks of treatment.

Cost Comparison: Carboplatin Products

Product	Cost Per mg	Cost Per 21 Days*	Cost Per Year
Kyxata™ (carboplatin) (J9278)	**$5.24**	**$3,406.00**	**$57,902.00**
carboplatin (generic) (J9045)	$0.06	$39.00	$663.00

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS).
*Cost per 21 days based on a dose of area under the curve (AUC) 5 on day 1 of each 21-day cycle for a member with normal renal function with creatinine clearance capped at 125mL/min (using a total of 650mg per dose).

Recommendations

The College of Pharmacy recommends the prior authorization of Inlexzo™ (gemcitabine intravesical system), Lifyorli™ (relacorilant), and Zusduri™ (mitomycin intravesical solution) with the following criteria (shown in red):

Inlexzo™ (Gemcitabine Intravesical System) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC with carcinoma in situ (CIS), with or without papillary tumors; and
2. Disease is unresponsive to Bacillus Calmette-Guérin (BCG) treatment; and
3. Member must be 18 years of age or older; and
4. Used for intravesical administration only; and
5. Initial approvals will be for 6 months for 8 doses administered every 3 weeks; and
6. Subsequent approvals will be for 6 months for 2 doses administered every 12 weeks; and
7. Approval will be limited to a maximum total of 14 doses.

Lifyorli™ (Relacorilant) Approval Criteria [Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer; and

2. Disease is platinum resistant; and
3. Member has received a prior systemic treatment regimen that included bevacizumab; and
4. Used in combination with nab-paclitaxel; and
5. Member must be 18 years of age or older.

Zusduri™ (Mitomycin Intravesical Solution) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC; and
2. Disease is low-grade, intermediate-risk; and
3. Disease is recurrent; and
4. Administered by intravesical instillation only; and
5. Member must be 18 years of age or older; and
6. Approval will be limited to a total of 6 weekly instillations.

The College of Pharmacy also recommends the prior authorization of Kyxata™ (carboplatin) based on net costs with the following criteria (shown in red):

Kyxata™ (Carboplatin; J9278) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use generic carboplatin products (J9045), which are available without prior authorization, must be provided.

Next, the College of Pharmacy recommends updating the approval criteria for Padcev® (enfortumab vedotin-ejfv) based on recent FDA approvals (changes and new criteria noted in red):

Padcev® (Enfortumab Vedotin-ejfv) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of muscle invasive bladder cancer (MIBC); and
    a. Used as neoadjuvant treatment and continued as adjuvant treatment after cystectomy; and
    b. Used in combination with pembrolizumab or pembrolizumab berahyaluronidase alfa-pmph; and
    c. Member is ineligible for cisplatin-containing chemotherapy; or
2. Diagnosis of locally advanced or metastatic urothelial cancer; and
    a. Used in 1 of the following settings:
        i. As a single agent and member has previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting; or

ii. As a single agent and member has received at least 1 prior therapy and is ineligible for cisplatin-containing chemotherapy; or
iii. Used in combination with pembrolizumab.

Next, the College of Pharmacy recommends updating the approval criteria for Akeega® (niraparib/abiraterone acetate) based on recent FDA approvals and NCCN recommendations (changes and new criteria noted in red):

Akeega® (Niraparib/Abiraterone Acetate) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC with high-volume metastasis; and
   a. High-volume defined as presence of visceral metastasis or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis; and
2. Presence of deleterious or suspected deleterious *BRCA2* mutation based upon an FDA-approved test; and
3. Used in conjunction with prednisone; and
4. Used in conjunction with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

Next, the College of Pharmacy recommends updating the Afinitor® (everolimus), Xtandi® (enzalutamide), Yonsa® (abiraterone acetate), Zejula® (niraparib), and Zytiga® (abiraterone) approval criteria based on NCCN guideline recommendations and net cost (changes shown in red):

Afinitor® (Everolimus) Approval Criteria [Neuroendocrine Tumors (NET) of Pancreatic (PNET), Gastrointestinal, or Lung Origin Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic NET of pancreatic (PNET), gastrointestinal, or lung origin; and
~~2. Progressive disease from a previous treatment.~~
3. Member does not have functional carcinoid tumor.

Xtandi® (Enzalutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of non-metastatic CRPC; and
   a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
   b. PSA doubling time (PSADT) is ≤10 months; or
2. Diagnosis of metastatic CRPC; and
   a. Concomitant treatment with a GnRH analog or prior history of bilateral orchiectomy; or
   b. Disease is homologous recombination repair (HRR) gene-mutated; and
      i. Used in combination with talazoparib; and

ii. Concomitant treatment with a GnRH analog or prior history of bilateral orchiectomy.

Xtandi® (Enzalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC; ~~or~~ and
   a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; or
2. Diagnosis of non-metastatic CSPC with biochemical recurrence at high risk for metastasis (high-risk BCR).

Yonsa® (Abiraterone Acetate) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with ~~a corticosteroid~~ methylprednisolone; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. A patient-specific, clinically significant reason why the member cannot use generic abiraterone tablets must be provided.

Zejula® (Niraparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
3. Used in combination with abiraterone and prednisone or abiraterone acetate and methylprednisolone; and
4. Used in combination with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

Zejula® (Niraparib) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC with high-volume metastases; and
   a. High-volume defined as presence of visceral metastasis or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis; and
2. Presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
3. Used in combination with abiraterone and prednisone or abiraterone acetate and methylprednisolone; and

4. Used in combination with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

Zytiga® (Abiraterone) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Zytiga® (Abiraterone) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic, high-risk, CSPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Lastly, the College of Pharmacy recommends removing the prior authorization requirement for Camcevi® (leuprolide) and updating the Orgovyx® (relugolix) approval criteria based on net cost (changes shown in red):

~~**Camcevi® (Leuprolide) Approval Criteria [Prostate Cancer Diagnosis]:**~~

~~1. Diagnosis of advanced prostate cancer; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication].~~

Orgovyx® (Relugolix) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of advanced prostate cancer; and

2. A patient-specific, clinically significant reason why the member cannot use Camcevi® (leuprolide), Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication]; and
3. A quantity limit of 30 tablets per 30 days will apply. Upon meeting approval criteria, a quantity limit override will be approved for the day 1 loading dose of 360mg.

Utilization Details of Genitourinary and Gynecologic Cancer Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ENZALUTAMIDE PRODUCTS						
XTANDI TAB 40MG	71	13	$1,005,257.96	$14,158.56	5.46	8.28%
XTANDI CAP 40MG	61	11	$886,968.98	$14,540.48	5.55	7.31%
XTANDI TAB 80MG	44	8	$613,266.50	$13,937.88	5.5	5.05%
SUBTOTAL	**176**	**32**	**$2,505,493.44**	**$14,235.76**	**5.5**	**20.64%**
EVEROLIMUS PRODUCTS						
EVEROLIMUS TAB 5MG	45	6	$759,574.57	$16,879.43	7.5	6.26%
EVEROLIMUS TAB 5MG	40	7	$51,949.91	$1,298.75	5.71	0.43%
EVEROLIMUS TAB 2MG	32	4	$645,114.12	$20,159.82	8	5.31%
EVEROLIMUS TAB 7.5MG	29	6	$52,621.50	$1,814.53	4.83	0.43%
EVEROLIMUS TAB 10MG	19	6	$19,557.54	$1,029.34	3.17	0.16%
EVEROLIMUS TAB 2.5MG	3	1	$2,650.74	$883.58	3	0.02%
AFINITOR DIS TAB 3MG	2	1	$36,793.06	$18,396.53	2	0.30%
EVEROLIMUS TAB 3MG	2	1	$26,071.10	$13,035.55	2	0.21%
SUBTOTAL	**172**	**32**	**$1,594,332.54**	**$9,269.38**	**5.38**	**13.13%**
ABIRATERONE PRODUCTS						
ABIRATERONE TAB 250MG	102	22	$11,525.33	$112.99	4.64	0.09%
ABIRATERONE TAB 500MG	22	5	$19,205.31	$872.97	4.4	0.16%
SUBTOTAL	**124**	**27**	**$30,730.64**	**$247.83**	**4.59**	**0.25%**
DAROLUTAMIDE PRODUCTS						
NUBEQA TAB 300MG	109	18	$1,509,307.69	$13,846.86	6.06	12.43%
SUBTOTAL	**109**	**18**	**$1,509,307.69**	**$13,846.86**	**6.06**	**12.43%**
APALUTAMIDE PRODUCTS						
ERLEADA TAB 60MG	66	9	$897,662.43	$13,600.95	7.33	7.39%
ERLEADA TAB 240MG	20	3	$303,506.69	$15,175.33	6.67	2.50%
SUBTOTAL	**86**	**12**	**$1,201,169.12**	**$13,967.08**	**7.17**	**9.89%**
CABOZANTINIB PRODUCTS						
CABOMETYX TAB 40MG	57	12	$1,486,880.04	$26,085.61	4.75	12.25%
CABOMETYX TAB 60MG	13	5	$337,765.58	$25,981.97	2.6	2.78%
CABOMETYX TAB 20MG	11	2	$282,975.27	$25,725.02	5.5	2.33%
SUBTOTAL	**81**	**19**	**$2,107,620.89**	**$26,020.01**	**4.26**	**17.36%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LENVATINIB PRODUCTS						
LENVIMA CAP 20 MG	19	7	$464,677.79	$24,456.73	2.71	3.83%
LENVIMA CAP 10 MG	14	3	$346,977.74	$24,784.12	4.67	2.86%
LENVIMA CAP 4MG	13	2	$319,059.83	$24,543.06	6.5	2.63%
LENVIMA CAP 8 MG	11	2	$269,809.01	$24,528.09	5.5	2.22%
LENVIMA CAP 14 MG	4	3	$99,962.64	$24,990.66	1.33	0.82%
LENVIMA CAP 12MG	3	2	$74,983.23	$24,994.41	1.5	0.62%
LENVIMA CAP 24 MG	2	1	$25,005.82	$12,502.91	2	0.21%
LENVIMA CAP 18 MG	1	1	$24,262.91	$24,262.91	1	0.20%
SUBTOTAL	**67**	**21**	**$1,624,738.97**	**$24,249.84**	**3.19**	**13.38%**
OLAPARIB PRODUCTS						
LYNPARZA TAB 150MG	44	16	$678,130.83	$15,412.06	2.75	5.59%
LYNPARZA TAB 100MG	7	3	$76,683.24	$10,954.75	2.33	0.63%
SUBTOTAL	**51**	**19**	**$754,814.07**	**$14,800.28**	**2.68**	**6.22%**
RELUGOLIX PRODUCTS						
ORGOVYX TAB 120MG	26	5	$71,064.67	$2,733.26	5.2	0.59%
SUBTOTAL	**26**	**5**	**$71,064.67**	**$2,733.26**	**5.2**	**0.59%**
BELZUTIFAN PRODUCTS						
WELIREG TAB 40MG	13	3	$384,444.43	$29,572.65	4.33	3.17%
SUBTOTAL	**13**	**3**	**$384,444.43**	**$29,572.65**	**4.33**	**3.17%**
NIRAPARIB PRODUCTS						
ZEJULA TAB 100MG	8	2	$147,250.36	$18,406.30	4	1.21%
ZEJULA TAB 200MG	1	1	$18,334.07	$18,334.07	1	0.15%
SUBTOTAL	**9**	**3**	**$165,584.43**	**$18,398.27**	**3**	**1.36%**
TIVOZANIB PRODUCTS						
FOTIVDA CAP 1.34MG	6	2	$190,828.46	$31,804.74	3	1.57%
SUBTOTAL	**6**	**2**	**$190,828.46**	**$31,804.74**	**3**	**1.57%**
TOTAL	**920**	**156***	**$12,140,129.35**	**$13,195.79**	**5.9**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DIS = Disperz (oral tablet for suspension); TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
CARBOPLATIN J9045	953	284	$39,321.61	$41.26	3.36
PADCEV J9177	112	13	$868,094.21	$7,750.84	8.62
TIVDAK J9273	43	6	$538,715.00	$12,528.26	7.17
JEMPERLI J9272	13	3	$179,703.00	$13,823.31	4.33
JEVTANA J9043	8	2	$78,783.60	$9,847.95	4
TOTAL	**1,129**	**303**	**$1,704,617.42**	**$1,509.85**	**3.73**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix M

Fiscal Year 2025 Annual Review of the SoonerCare Pharmacy Benefit

Oklahoma Health Care Authority
June 2026

Summary[1]

During fiscal year (FY) 2025 (07/01/2024 to 06/30/2025), prescription drugs accounted for $1.26 billion of the approximately $11.76 billion in total SoonerCare spending. The FY 2023 through FY 2025 average monthly enrollment and prescription drugs utilization details are noted below in Table 1.

In July 2021, the SoonerCare benefit expanded across the state to include the Healthy Adult Program (HAP). The expanded population is included in the FY 2023, FY 2024, FY 2025 data. The federal public health emergency (PHE) declared in March 2020 due to the COVID-19 pandemic ended in May 2023. After the PHE ended, state Medicaid agencies were allowed to go through an unwinding process to disenroll members who no longer qualified for services but were enrolled during the PHE. The unwinding process for SoonerCare members was completed by December 2023.

Following an increase in average monthly enrollment as a result of Oklahoma Medicaid expansion and the COVID-19 federal PHE, average monthly enrollment then decreased from FY 2023 to FY 2024 (16.1%) and from FY 2024 to FY 2025 (7.3%) as a result of the unwinding process that followed the end of the PHE.

Similar to the decrease in average monthly enrollment, the number of utilizers (SoonerCare members utilizing the pharmacy benefit) and total claims decreased by approximately 6.9% and 1.1%, respectively, from FY 2024 to FY 2025. Despite the decreases in enrollment, utilizers, and claims, the total pharmacy reimbursement and the annual pharmacy cost per utilizer increased approximately 6.7% and 14.6%, respectively, from FY 2024 to FY 2025.

Several factors likely contributed to the increase in pharmacy expenditures despite declining enrollment and utilization trends including stabilization following the PHE unwinding period, continued effects of Medicaid expansion, and ongoing growth in the utilization and cost of specialty pharmaceutical products. Specialty medications, orphan drugs for rare diseases, oncology therapies, and cellular and gene therapies have continued to contribute disproportionately to pharmacy expenditures in recent years. As the temporary utilization fluctuations associated with the PHE continue to diminish, pharmacy reimbursement and cost per utilizer trends are expected to more

closely reflect historical annual growth patterns observed prior to the pandemic.

Indian Health Service (IHS) reimbursement was updated in 2017 to the Federal Office of Management and Budget encounter rate; therefore, to more accurately compare FY 2025 with previous years, IHS data was excluded from this analysis. Additionally, costs in this report do not reflect the federal and state supplemental rebates that are provided by medication manufacturers. The coverage and prior authorization (PA) criteria of many medications, particularly the antiviral, attention-deficit/hyperactivity disorder (ADHD), antipsychotic, anti-diabetic, endocrine, anticoagulant, and analgesic/anti-inflammatory therapeutic categories, are significantly influenced by supplemental rebates, and SoonerCare net costs are lower than the total reimbursement to pharmacies included in this analysis.

Table 1: Total Pharmacy FY Comparison

FY	Claims	Members⁺	Utilizers*	Reimbursement	Cost/Claim	Cost/Utilizer
2023	8,428,906	1,335,290	756,018	$1,145,375,633.42	$135.89	$1,515.01
2024	7,830,396	1,120,884	713,396	$1,178,947,034.30	$150.56	$1,652.58
2025	7,747,391	1,039,069	664,177	$1,257,660,292.87	$162.33	$1,893.56

Reimbursement does not reflect rebated costs or net costs.
⁺Average monthly enrollment as obtained from OHCA Fast Facts reports.
*Total number of unduplicated utilizers.
FY = Fiscal Year
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

The per member per year (PMPY) value reflects the total pharmacy reimbursement divided by the unduplicated number of members (total enrollees) for each FY. To reflect an accurate PMPY value, average monthly enrollment was used in place of annual enrollment, and dual eligible (members eligible for Medicare and Medicaid) and IHS members were excluded. The PMPY value is used across benefit plans with similar populations to accurately assess health care spending. The following table contains the overall PMPY values for the past few FY years.

Table 2: Overall PMPY FY Comparison

Fiscal Year (FY)	FY 2023	FY 2024	FY 2025
Overall PMPY Value⁺	$1,073.72	$1,329.72	$1,536.38

⁺PMPY value calculated using average monthly enrollment, excluding dual eligible and IHS members, and does not reflect rebated costs or net costs.
Please note: Oklahoma Medicaid expansion became effective in July 2021. The federal public health emergency (PHE) declared in March 2020 due to the COVID-19 pandemic ended in May 2023. Oklahoma Medicaid transitioned from a fee-for-service (FFS) pharmacy benefit to a managed care pharmacy benefit for most members starting in April 2024.
FY = fiscal year; PMPY = per member per year
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

During FY 2023 and for the majority of FY 2024, Oklahoma used a fee-for-service (FFS) pharmacy benefit for the SoonerCare program. Pharmacy benefit managers (PBMs) are used by some states for their FFS pharmacy programs, contracting out services such as claims processing and payment, PA processing, drug utilization review (DUR), and formulary management. Similarly, Medicaid managed care organizations (MCOs) frequently subcontract the management of the pharmacy benefit to a separate PBM. The Oklahoma Health Care Authority (OHCA) currently contracts with Pharmacy Management Consultants (PMC), a department within the University of Oklahoma College of Pharmacy, for many of these services.

Oklahoma Medicaid transitioned from a FFS pharmacy benefit to a managed care pharmacy benefit for most members on April 1, 2024. At that time, the majority of SoonerCare members were transitioned to one of the three managed care SoonerSelect plans: Aetna Better Health of Oklahoma, Humana Healthy Horizons of Oklahoma, or Oklahoma Complete Health (operated by the Centene Corporation). The SoonerSelect health plans provide prescription benefits, health services, and behavioral health services with oversight from OHCA. Previously, the prescription drug benefit was carried out exclusively by PMC, including managing the formulary and reviewing PA requests. SoonerSelect plans have the responsibility of reviewing the PA requests for their active members but do not have a role in managing the formulary, which remains a responsibility of PMC. PMC also continues to review PA requests for members who were not transitioned to a managed care plan.

The data included in this FY 2025 review of the SoonerCare pharmacy benefit combines FFS and managed care utilization and enrollment data. SoonerCare PA policies, quantity limits, and monthly prescription limits, incorporated with supplemental rebate agreements and value-based agreements (VBAs), continue to yield better than average results while still providing a comprehensive pharmacy benefit for over 1 million SoonerCare members.

Medicaid Drug Rebate Program[2,3,4]

Medicaid coverage of a drug requires the manufacturer to have a federal drug rebate agreement with the Secretary of Health and Human Services (HHS). Participation in the federal drug rebate program requires Medicaid coverage with limited exceptions (e.g., weight loss medications, cosmetic medications, fertility medications). Rebate amounts are based on the “best price” for each drug. Best price refers to the lowest price paid to a manufacturer for a drug by any commercial payer. Best prices are reported to the Centers for Medicare and Medicaid Services (CMS) by the manufacturer but are not publicly available.

If a drug's price increases more quickly than inflation, an additional rebate penalty is included based on the change in price compared with the consumer price index (CPI). The CPI penalty of the federal rebate is designed to keep Medicaid net cost relatively flat despite increases in drug prices and has applied to both brand and generic medications since 2017. Reimbursement amounts and drug costs included in this report do not reflect Medicaid net costs.

Additionally, many states have negotiated supplemental rebate agreements with manufacturers to produce added rebates. In FY 2025, OHCA collected over $750.7 million in federal and state supplemental rebates, resulting in a total increase from FY 2024 of approximately $21.7 million ($729 million in federal and state supplemental rebates). The rebates are collected after reimbursement for the medication and are not reflected in this report.

Alternative Payment Models[5,6,7,8,9]

The introduction of a greater number of costly specialty medications, finite Medicaid budgets, Medicaid policy, and access requirements has resulted in alternative payment arrangements as particularly compelling opportunities. Medicaid programs must provide comprehensive care to vulnerable individuals while operating under limited budgets and regulatory requirements. An alternative payment model (APM) is an agreement between a payer and manufacturer that is intended to provide improved patient care or increased access to evidence-based therapies while lowering costs or improving health outcomes.

In general, there are 2 types of APMs:

- **Financial APM:** Caps or discounts are used to provide predictability or limit spending; these types of contracts are intended to lower costs and expand access. Data collection for financial APMs is minimal, making them easier to administer.
    - Examples: Price volume agreements, market share, patient level utilization caps, manufacturer funded treatment initiation
- **Health Outcome-Based APM:** Payments for medications are tied to clinical outcomes or measurements; these types of contracts are often referred to as VBAs. Health outcome based APMs require additional planning and data collection but do have the potential to increase the quality and value of treatments.
    - Examples: Outcomes guarantee, conditional coverage, PMPY guarantees, event avoidance (e.g., hospitalizations)

Oklahoma was the first Medicaid state to receive approval from CMS to participate in APMs in June 2018, and since that time, PMC and OHCA have initiated discussions with numerous pharmaceutical manufacturers regarding

APMs and have established multiple contracts, with 3 APM contracts being active in FY 2025. Future considerations include the expectation that initial SoonerCare value-based contracts will set the precedent for further collaboration among manufacturers and state Medicaid agencies.

Table 3: Overview of FY 2025 Established APM Contracts	
Manufacturer	**Details**
AbbVie	▪ Treatment patterns in hepatitis C – utilization, treatment duration, and non-responder/re-treatment/ treatment failures (2022-2026)
Novartis	▪ Spinal muscular atrophy (SMA) medication – utilization (2021-2026)
Supernus	▪ Adherence and persistence in ADHD – medication possession ratios (2022-2025)

ADHD = attention-deficit/hyperactivity disorder; FY = fiscal year
FY 2025 = 07/01/2024 to 06/30/2025

Drug Approval Trends[10,11,12,13,14,15,16,17,18,19,20]

During FY 2025, the U.S. Food and Drug Administration (FDA) approved the first generic product of several key medications that may have a significant impact on SoonerCare reimbursement.

Key first-time generics approved by the FDA in FY 2025 included perampanel (generic Fycompa®), rivaroxaban (generic Xarelto®), sitagliptin/metformin extended-release (ER; generic Janumet® XR), baricitinib (generic Olumiant®), and aripiprazole for ER injection (Abilify Maintena®). However, it's important to note that not all first-time generics that were FDA approved in FY 2025 are currently available on the market, either due to patent litigation with the branded product or due to the generic product not being launched yet. A total of 56 novel drugs, including cellular and gene therapies, were approved by the FDA during FY 2025. Select novel drugs approved during FY 2025 that are expected to be highly utilized or have a particular impact in the SoonerCare population are included in the following table.

Table 4: Select Novel Drugs FDA Approved During Fiscal Year 2025			
Drug Name	**Date Approved**	**FDA-Approved Indication**	**Estimated Annual Cost Per Member***
donanemab-azbt (Kisunla™)	07/02/2024	Alzheimer's disease	$33,018.80¥
palopegteriparatide (Yorvipath®)	08/09/2024	hypoparathyroidism in adults	$307,827.16±
xanomeline/trospium chloride (Cobenfy™)	09/26/2024	schizophrenia	$21,780.00Ω
vanzacaftor/tezacaftor/ deutivacaftor (Alyftrek®)	12/20/2024	cystic fibrosis	$369,256.16∞

suzetrigine (Journavx®)	01/30/2025	moderate to severe acute pain in adults	$415.56†
gepotidacin (Blujepa)	03/25/2025	uncomplicated UTI in female adults and pediatrics	$1,900.00Δ
atrasentan (Vanrafia™)	04/02/2025	to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression	$171,493.20£
nipocalimab-aahu (Imaavy™)	04/29/2025	generalized myasthenia gravis (gMG) in adults and pediatric patients 12 years of age and older	$324,480.00α

UTI = urinary tract infection
*Costs do not include rebated or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
¥Based on the FDA approved every 4 week dosing schedule starting with 350mg, 700mg, and 1,050mg for the initial doses, and 1,400mg for subsequent doses for 1 year.
‡Based on an FDA approved dose of 30mcg subcutaneously once daily for 1 year.
ΩBased on an FDA approved dose of (1) 125mg/30mg capsule orally twice daily for 1 year.
℅Based on and FDA approved dose of (2) 10mg/50mg/125mg tablets once daily for 1 year.
†Based on an FDA approved dose of 50mg orally twice daily for 14 days for a member requiring 1 episode of acute treatment.
ΔBased on an FDA approved dose of (2) 750mg tablets twice daily for 5 days for uncomplicated urinary tract infection for a member requiring 1 episode of infection treatment.
£Based on an FDA approved dose of 0.75mg once daily for 1 year.
αBased on an FDA approved maintenance dose of 15mg/kg every 2 weeks for 1 year for an 80kg member.

Traditional Versus Specialty Pharmacy Products

Traditional pharmaceuticals include products that are typically non-injectable, do not require special transportation, storage, or administration, and are not typically indicated for rare diseases requiring unique management. These products treat many common chronic diseases such as diabetes, hypertension, and chronic obstructive pulmonary disease (COPD). Traditional pharmaceuticals carried the bulk of the reimbursement costs, accounting for approximately 59% of the total pharmacy reimbursement and 99% of the total claims in FY 2025.

Specialty products, in contrast, are typically injectable, require special handling such as refrigerated transport and special administration techniques, or are indicated for rare diseases requiring unique management. These products include treatments for cystic fibrosis (CF), hemophilia, rheumatoid arthritis, and genetic deficiencies. Specialty pharmaceuticals have become a larger part of reimbursement over the last several years. Specifically, specialty pharmaceuticals accounted for approximately 41% of the total pharmacy

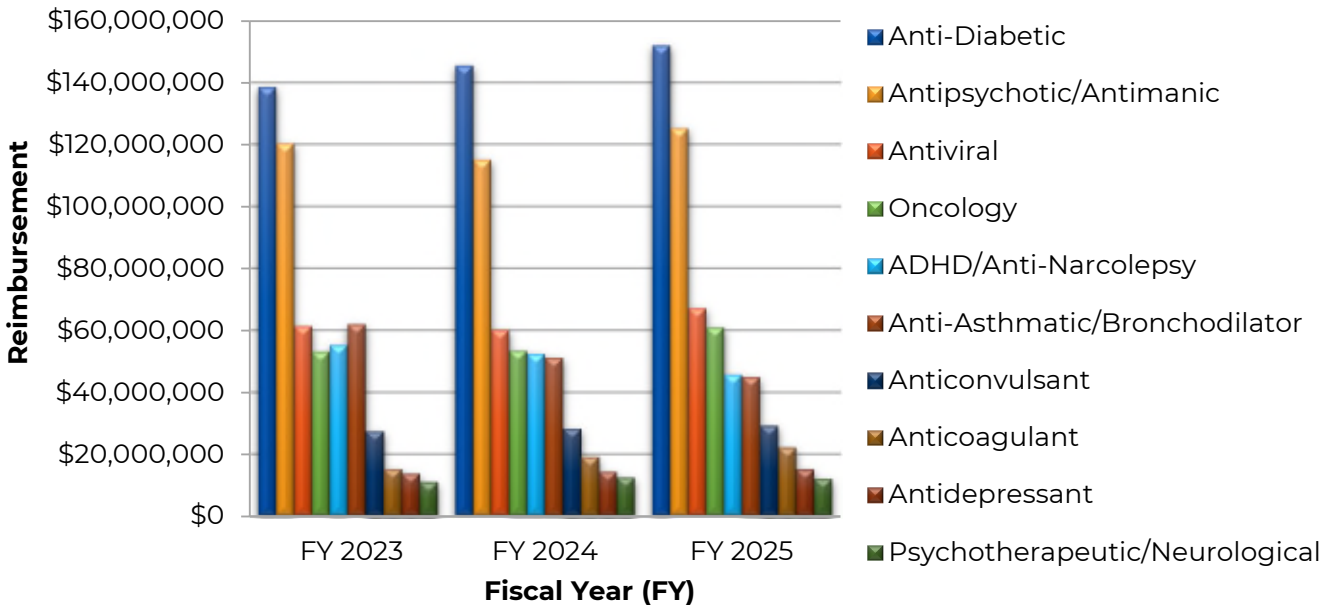
reimbursement and 1% of the total claims in FY 2025. OHCA maintains the current SoonerCare specialty drug list.

Top 10 Traditional Therapeutic Categories by Reimbursement: FY 2025[21,22,23]

Costs in this report do not reflect the federal and state supplemental rebates that are provided by pharmaceutical manufacturers. Many branded agents, particularly antiviral, ADHD, antipsychotic, anti-diabetic, and anticoagulant medications, are significantly influenced by supplemental rebates, and net costs are substantially lower than the total reimbursement paid to pharmacies included in this analysis.

Table 5: FY 2025 Top 10 Traditional Therapeutic Categories			
FY 2023	**FY 2024**	**FY 2025**	**Therapeutic Category**
$138,407,603.70	$145,304,316.25	**$151,793,596.43**	**Anti-Diabetic**
$120,135,828.41	$114,889,280.09	**$125,036,214.69**	**Antipsychotic/Antimanic**
$61,178,386.05	$59,980,271.66	**$67,003,939.31**	**Antiviral**
$52,883,199.03	$53,192,551.02	**$60,725,418.85**	**Oncology**
$55,077,141.24	$52,202,719.52	**$45,526,921.06**	**ADHD/Anti-Narcolepsy**
$61,794,906.42	$50,997,726.90	**$44,740,088.32**	**Anti-Asthmatic/Bronchodilator**
$27,315,149.15	$28,133,110.25	**$29,071,258.97**	**Anticonvulsant**
$15,127,014.98	$19,047,761.50	**$22,065,683.82**	**Anticoagulant**
$13,617,935.39	$14,314,303.57	**$15,030,548.88**	**Antidepressant**
$10,822,472.60	$12,421,446.04	**$11,959,749.30**	**Psychotherapeutic/Neurological**

Reimbursement does not reflect rebated prices or net costs.
Therapeutic Category based on Medi-Span® Generic Product Identifier (GPI) classification.
FY = fiscal year; ADHD = attention-deficit/hyperactivity disorder
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025



The top 10 traditional therapeutic categories that showed the most significant change from FY 2024 to FY 2025 were the anticoagulant and oncology categories. Other traditional classes saw minor fluctuations.

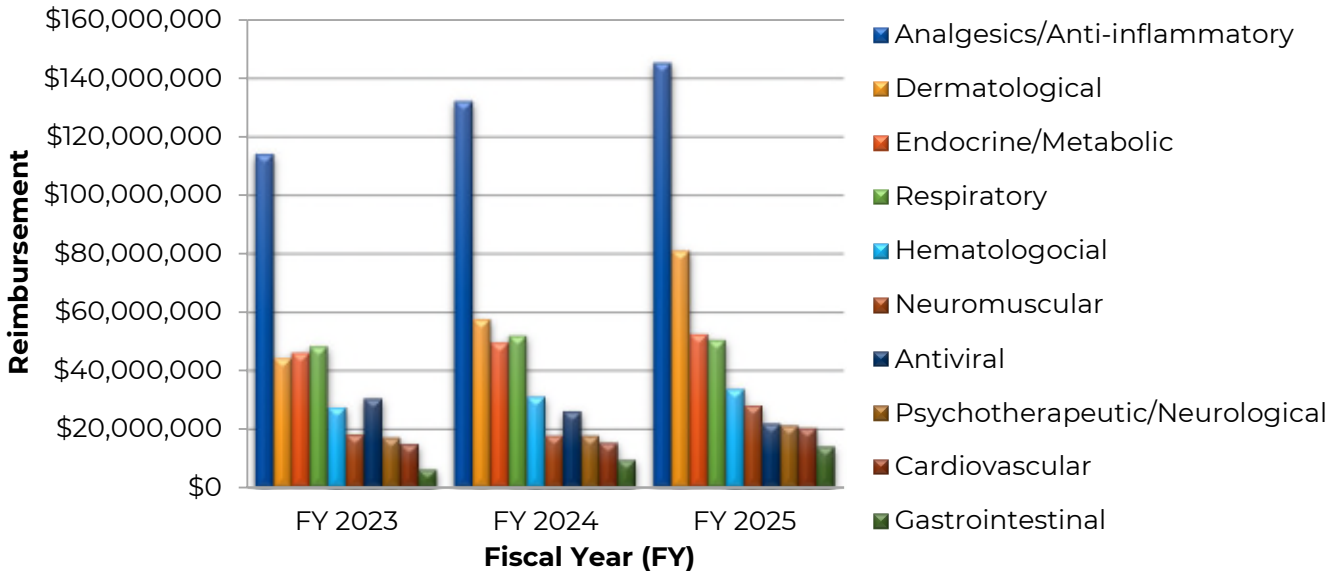
- Anticoagulant medications' reimbursement increased by almost 16% ($3 million) in FY 2025. This increase in pharmacy reimbursement can be attributed to the removal of the PA requirement in May 2023 for select direct oral anticoagulants (DOACs), including Xarelto® (rivaroxaban) and Eliquis® (apixaban). Xarelto® and Eliquis® represent about 97.5% ($21.5 million) of the total anticoagulant medications reimbursement. The PA removal was intended to improve access for immediate outpatient treatment of acute venous thromboembolism (VTE) and to reduce the related medical costs of members needing to utilize the emergency department (ED) or other hospital resources for immediate anticoagulation. Although there was an increase in pharmacy reimbursement, there was a decrease in inpatient and ED costs related to VTE after the PA removal. Additionally, both Xarelto® and Eliquis® had supplemental rebate agreements with SoonerCare in FY 2025; however, net costs are not reflected in this analysis.
- Oncology medications' reimbursement increased by roughly 14% ($7.5 million) in FY 2025. This increase was largely driven by the continued availability of high-cost, oral, targeted therapies and precision oncology medications used to treat rare and complex cancers, including several agents associated with recent FDA approvals and expanded indications. Examples of high-cost, oral, traditional oncology agents included Verzenio® (abemaciclib), Kisqali® (ribociclib), Ibrance® (palbociclib), and Jakafi® (ruxolitinib), each associated with more than $2 million in total reimbursement during FY 2025 despite relatively low utilization. In contrast, utilization of generic oncology agents such as dasatinib (Sprycel®) may help offset the trend toward increasing cost through lower reimbursement costs compared with branded products when available.

Top 10 Specialty Therapeutic Categories by Reimbursement: FY 2025[24,25]

Table 6: FY 2025 Top 10 Specialty Therapeutic Categories			
FY 2023	**FY 2024**	**FY 2025**	**Therapeutic Categories**
$113,980,864.63	$132,119,510.09	**$145,239,930.86**	**Analgesics/Anti-inflammatory**
$44,245,516.62	$57,467,552.04	**$80,988,295.44**	**Dermatological**
$46,023,501.61	$49,510,887.38	**$52,390,365.23**	**Endocrine/Metabolic**
$48,167,938.93	$51,827,475.52	**$50,419,020.92**	**Respiratory**
$27,382,292.11	$31,045,387.98	**$33,672,895.42**	**Hematological**
$18,042,438.99	$17,700,677.29	**$28,076,871.30**	**Neuromuscular**
$30,365,950.28	$25,972,835.28	**$21,751,837.48**	**Antiviral**

$16,919,754.46	$17,674,020.48	**$21,131,460.63**	**Psychotherapeutic/Neurological**
$14,732,435.84	$15,267,262.67	**$20,250,771.97**	**Cardiovascular**
$6,138,642.47	$9,404,919.95	**$13,875,072.63**	**Gastrointestinal**

Reimbursement does not reflect rebated prices or net costs.
Therapeutic Category based on Medi-Span® Generic Product Identifier (GPI) classification.
FY = fiscal year
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025



The cost of specialty therapeutic products is high, largely in part due to the targeted immunomodulator agents and therapies focused on rare diseases, including CF, hemophilia, and spinal muscular atrophy (SMA). The increasing number of new FDA approvals and subsequent increase in utilizers make the management of specialty therapeutic products challenging; however, continuous review and management of these products has promoted minimal reimbursement increases, other than expected yearly price increases by product manufacturers and the rising cost of newly approved products. Net cost increases are not reflected in this analysis.

- Neuromuscular medications' reimbursement increased by 59% ($10.4 million) in FY 2025, a substantial increase primarily driven by utilization of ultra-high-cost gene and rare disease therapies for SMA and Duchenne muscular dystrophy (DMD), including Zolgensma® (onasemnogene abeparvovec-xioi), Elevidys® (delandistrogene moxeparvovec-rokl), Spinraza® (nusinersen), and Evrysdi® (risdiplam). Several of these therapies were associated with total reimbursement ranging from approximately $1.5 million to over $9 million during FY 2025 despite utilization among only a small number of members. In addition, FY 2025 included major FDA activity involving these therapies, including

expanded approval of Elevidys® for additional DMD populations and approval of a tablet formulation for Evrysdi®.

- Dermatological medications' reimbursement increased by approximately 41% ($23.5 million) in FY 2025, a considerable increase largely driven by continued utilization of high-cost biologic and targeted immunologic therapies for inflammatory skin conditions. Dupixent® (dupilumab) alone accounted for approximately 49% of total dermatological reimbursement during FY 2025. Additional contributors included specialty psoriasis biologics such as Stelara® (ustekinumab), Skyrizi® (risankizumab-rzaa), Cosentyx® (secukinumab), and Taltz® (ixekizumab). Continued expansion of biologic therapies and evolving dermatologic indications, including additional FDA labeling updates for Dupixent® in atopic dermatitis, likely contributed to increased utilization and reimbursement during FY 2025.

Top 10 Medications by Reimbursement: FY 2025

Many of the top 10 medications by reimbursement are branded at this time and may not have an available generic formulation. The top products are typically high-cost branded or specialty products, particularly within immunologic, anti-diabetic, and rare disease therapeutic categories. Top drug reimbursement rankings only slightly change from year to year for several reasons: high use, broad use between age demographics, and high costs of therapies for rare diseases such as those indicated for CF, inflammatory skin conditions, and human immunodeficiency virus (HIV). Dupilumab continues to increase within the top 10 due to a continued increase in FDA approved indications and resultant increased utilization. In contrast, reimbursement within the ADHD/anti-narcolepsy category decreased during FY 2025, potentially reflecting increased generic competition following FDA approval of multiple generic lisdexamfetamine products in 2023. Additionally, semaglutide-containing products continued to experience substantial growth in utilization and reimbursement, emerging among the top 10 medications by reimbursement in FY 2025.

Table 7: Top 10 Medications by Reimbursement

Rank	FY 2023	FY 2024	FY 2025
1	adalimumab	adalimumab	adalimumab
2	paliperidone palmitate	paliperidone palmitate	paliperidone palmitate
3	dulaglutide	dulaglutide	dulaglutide
4	elexacaftor/tezacaftor/ ivacaftor	elexacaftor/tezacaftor/ ivacaftor	dupilumab
5	lisdexamfetamine	lisdexamfetamine	elexacaftor/tezacaftor/ ivacaftor
6	bictegravir/emtricitabine/ tenofovir	bictegravir/emtricitabine/ tenofovir	etanercept

7	glecaprevir/pibrentasvir	etanercept	bictegravir/emtricitabine/ tenofovir
8	etanercept	dupilumab	lisdexamfetamine
9	insulin glargine	glecaprevir/pibrentasvir	empagliflozin
10	lurasidone	empagliflozin	semaglutide

Rank does not reflect rebated prices or net costs.
Medications are listed by generic name but may include both generic and brand formulations where applicable.
FY = fiscal year
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

Cost Per Claim

The SoonerCare cost per claim of traditional medications increased by 2.1% in FY 2025 in comparison to FY 2024, and the cost per specialty medication claim decreased by 3%. This decrease is largely due to the decrease in total enrollment related to the end of the PHE as previously referenced and the associated decrease in utilizers and claims. Drug costs in general continue to increase as evidenced by continued increases in the percentage of utilizing members, cost per member per year, and use of specialty products.

As mentioned previously, specialty costs are largely driven by the significant cost associated with targeted immunomodulator agents and other medications for rare diseases.

Table 8: Cost Per Claim

Drug Class	FY 2023	FY 2024	FY 2025
Specialty	$7,163.70	$7,012.65	$6,802.00
Traditional	$89.06	$94.31	$96.28

Reimbursement does not reflected rebated prices or net costs.
FY = fiscal year
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

Market Projections[26,27,28]

As previously noted, specialty medications made up about 1% of the claims for FY 2025 but generated approximately 41% of the total cost. In 2025, the FDA approved 56 novel drugs, with oncology medications accounting for approximately 43% of the novel approvals. Continued growth in specialty biologics, oncology therapies, cellular and gene therapies, and rare disease treatments is expected to significantly impact future reimbursement trends. Multiple specialty therapies approved during FY 2025 targeted oncology, hematologic disorders, neurologic diseases, and rare genetic conditions, as shown in the following table (Table 9). Novel approvals included therapies for CF, hereditary angioedema, hemophilia, neurofibromatosis type 1, and multiple oncologic indications including non-small cell lung cancer, breast cancer,

ovarian cancer, acute leukemia, biliary tract cancer, and pancreatic adenocarcinoma. Several cellular and gene therapies were also approved during FY 2025, including Aucatzyl™ (obecabtagene autoleucel), Kebilidi™ (eladocagene exuparvovec-tneq), and Zevaskyn™ (prademagene zamikeracel). As specialty biologics, targeted oncology therapies, cellular and gene therapies, and rare disease treatments continue entering the market, ongoing evaluation of utilization and reimbursement trends will remain necessary due to the substantial costs associated with these therapies.

Table 9: Cellular Therapy, Gene Therapy, and Oncology Medications FDA Approved in FY 2025

Brand	Generic	Initial Indication(s)	Initial FDA Approval Date
*Tecelra®	afamitresgene autoleucel	Synovial sarcoma	8/2/2024
Voranigo®	vorasidenib	Astrocytoma or oligodendroglioma with susceptible mutations	8/6/2024
Niktimvo™	axatilimab-csfr	Chronic graft-versus-host disease	8/14/2024
Lazcluze®	lazertinib	NSCLC	8/19/2024
Tecentriq Hybreza®	atezolizumab/ hyaluronidase-tqjs	NSCLC, SCLC, HCC, melanoma, ASPS, MIBC	9/12/2024
Itovebi™	inavolisib	Locally advanced or metastatic breast cancer	10/10/2024
Vyloy®	zolbetuximab-clzb	Gastric or GEJ adenocarcinoma	10/18/2024
*Aucatzyl®	obecabtagene autoleucel	Relapsed or refractory B-cell precursor ALL	11/8/2024
^Kebilidi™	eladocagene exuparvovec-tneq	Aromatic L-amino acid decarboxylase deficiency	11/13/2024
Revuforj®	revumenib	Relapsed or refractory acute leukemia	11/15/2024
*Regenecyte®	hematopoietic progenitor cell, cord blood	Hematopoietic and immunologic reconstitution	11/20/2024
Ziihera®	zanidatamab-hrii	HER2-positive biliary tract cancer	11/20/2024
Bizengri®	zenocutuzumab-zbco	NSCLC and pancreatic adenocarcinoma	12/4/2024
Unloxcyt™	cosibelimab-ipdl	Cutaneous squamous cell carcinoma	12/13/2024
Ensacove™	ensartinib	ALK-positive NSCLC	12/18/2024
*Ryoncil®	remestemcel-L-rknd	Steroid-refractory acute graft-versus-host disease	12/18/2024
*Symvess™	acellular tissue engineered vessel-tyod	Extremity vascular trauma requiring vascular reconstruction	12/19/2024
Opdivo Qvantig™	nivolumab/ hyaluronidase-nvhy	RCC, melanoma, NSCLC, SCCHN, urothelial carcinoma, CRC, HCC, esophageal cancer, gastric cancer, GEJ cancer, and esophageal adenocarcinoma	12/27/2024

Datroway®	datopotamab deruxtecan-dlnk	HR-positive, HER2-negative breast cancer	1/17/2025
Grafapex™	treosulfan	Preparative regimen for allogeneic HSCT in AML or MDS	2/6/2025
Gomekli™	mirdametinib	NF1 with symptomatic plexiform neurofibromas	2/11/2025
Romvimza™	vimseltinib	Symptomatic tenosynovial giant cell tumor	2/14/2025
^Encelto™	revakinagene taroretcel-lwey	Macular telangiectasia type 2	3/5/2025
Penpulimab	penpulimab-kcqx	Non-keratinizing nasopharyngeal carcinoma	4/23/2025
^Zevaskyn®	prademagene zamikeracel	Recessive dystrophic epidermolysis bullosa	4/29/2025
Avmapki Fakzynja Co-Pack™	avutometinib and defactinib	KRAS-mutated recurrent low-grade serous ovarian cancer	5/8/2025
Emrelis™	telisotuzumab vedotin-tllv	NSCLC	5/14/2025
Ibtrozi™	taletrectinib	ROS1-positive NSCLC	6/11/2025
Zusduri™	mitomycin	Low-grade intermediate-risk non-muscle invasive bladder cancer	6/12/2025

*Cellular therapy
^Gene therapy
Please note: SoonerCare coverage of the medications and therapies listed in the above table is contingent upon the manufacturer entering into a Federal Drug Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS).
ALK = anaplastic lymphoma kinase; ALL = acute lymphoblastic leukemia; AML = acute myeloid leukemia; ASPS = alveolar soft part sarcoma; CRC = colorectal cancer; DMD = Duchenne muscular dystrophy; FDA = U.S. Food and Drug Administration; FY = fiscal year; GEJ = gastroesophageal junction; HCC = hepatocellular carcinoma; HER2 = human epidermal growth factor receptor 2; HR = hormone receptor; KRAS = Kirsten rat sarcoma viral oncogene homolog; HSCT = hematopoietic stem cell transplantation; MDS = myelodysplastic syndrome; MIBC = muscle invasive bladder cancer; NF1 = neurofibromatosis type 1; NSCLC = non-small cell lung cancer; ROS1 = ROS proto-oncogene 1; SCCHN = squamous cell carcinoma of the head and neck; SCLC = small cell lung cancer
FY 2025 = 07/01/2024 to 06/30/2025

Conclusion

New PA categories and continuous evaluation of categories such as oncology, hemophilia medications, cellular and gene therapies, and high-cost specialty biologics, along with new respiratory and anti-diabetic medications that continue to be FDA approved, help ensure clinically appropriate and cost-effective care. Modifications to tier structures and other generic categories reduced elevated spending on high-priced generic products, while biosimilar market expansion may provide future opportunities to improve access and reduce costs. When new drugs are FDA approved and become available on the market, a cost-effectiveness analysis, which also incorporates SoonerCare's rebated prices and net costs, is performed to minimize spending while ensuring appropriate clinical care. The goal of the SoonerCare program is to provide members with the most appropriate health care in a fiscally

responsible manner. For the pharmacy benefit, this is accomplished through DUR services, PA criteria, quantity limits, monthly total prescription limits and brand name prescription limits for non-institutionalized adult members, continuous product pricing maintenance, provider outreach and education, and evaluation of alternative payment arrangements and value-based strategies. Constant market review and response to changes, including evolving cellular and gene therapies, targeted oncology therapies, growth of the specialty market, and continued introduction of biosimilars, remains necessary. As the pharmaceutical market continues to evolve, SoonerCare will continue striving to provide value-based pharmacy services while maintaining clinically appropriate and fiscally responsible care for its members.

Top 50 Reimbursed Drugs: Fiscal Year 2025

Table 10: FY 2025 Top 50 Reimbursed Drugs

Generic	Brand	FY 2024		FY 2025	
		Rank	Amount Paid	Rank	Amount Paid
adalimumab	various	1	$84,207,834.22	**1**	**$84,736,228.36**
paliperidone palmitate	various	2	$57,465,136.98	**2**	**$59,056,859.64**
dulaglutide	Trulicity®	3	$45,796,070.87	**3**	**$44,221,955.00**
dupilumab	Dupixent®	8	$25,511,447.79	**4**	**$39,805,668.55**
elexacaftor/tezacaftor/ivacaftor	Trikafta®	4	$41,629,173.65	**5**	**$39,518,606.89**
etanercept	Enbrel®	7	$27,509,117.66	**6**	**$34,049,894.68**
bictegravir/emtricitabine/tenofovir	Biktarvy®	6	$27,807,423.65	**7**	**$33,186,798.32**
lisdexamfetamine	Vyvanse®	5	$30,337,868.63	**8**	**$29,521,046.23**
empagliflozin	Jardiance®	10	$19,739,199.71	**9**	**$27,103,023.05**
semaglutide	various	18	$11,605,351.75	**10**	**$20,733,161.84**
aripiprazole	various	11	$17,553,440.92	**11**	**$19,609,837.21**
somatropin	various	12	$16,017,087.04	**12**	**$19,251,431.47**
glecaprevir/pibrentasvir	Mavyret®	9	$22,987,074.72	**13**	**$18,849,770.10**
cariprazine	Vraylar®	14	$15,057,834.33	**14**	**$18,238,350.02**
apixaban	Eliquis®	15	$13,786,530.70	**15**	**$16,484,553.92**
emicizumab-kxwh	Hemlibra®	13	$15,706,786.27	**16**	**$14,573,195.07**
dapagliflozin	Farxiga®	22	$8,906,837.28	**17**	**$13,045,311.93**
tirzepatide	Mounjaro®	38	$5,844,962.59	**18**	**$12,714,176.03**
ustekinumab	Stelara®	16	$11,970,666.04	**19**	**$10,405,304.41**
secukinumab	Cosentyx®	35	$6,287,111.81	**20**	**$10,370,038.16**
tiotropium	various	19	$9,958,064.16	**21**	**$9,752,383.53**
onasemnogene abeparvovec-xioi	Zolgensma®	205	$946,968.00	**22**	**$8,999,414.58**
upadacitinib	Rinvoq®	34	$6,436,640.43	**23**	**$8,846,746.54**
pancrelipase	various	25	$7,733,736.88	**24**	**$8,845,460.60**

Table 10: FY 2025 Top 50 Reimbursed Drugs					
Generic	Brand	FY 2024		FY 2025	
		Rank	Amount Paid	Rank	Amount Paid
deutetrabenazine	Austedo®	36	$6,000,899.46	**25**	**$8,180,538.77**
valbenazine	Ingrezza®	28	$7,164,258.56	**26**	**$7,592,980.52**
sacubitril/valsartan	Entresto®	30	$6,727,907.50	**27**	**$7,374,755.66**
fluticasone/salmeterol	various	23	$8,801,344.95	**28**	**$7,266,923.88**
buprenorphine	various	29	$6,801,294.04	**29**	**$7,216,561.43**
risankizumab-rzaa	Skyrizi®	40	$5,757,661.47	**30**	**$7,141,023.36**
risperidone	various	55	$4,173,572.06	**31**	**$7,047,977.20**
albuterol	various	21	$9,149,358.80	**32**	**$7,017,655.47**
aripiprazole lauroxil	Aristada®	26	$7,628,831.75	**33**	**$6,947,981.99**
budesonide/formoterol	Symbicort®	24	$7,934,295.61	**34**	**$6,850,110.14**
cannabidiol	Epidiolex®	37	$5,893,786.72	**35**	**$6,707,433.91**
esketamine	Spravato®	62	$3,509,011.90	**36**	**$6,417,294.67**
apremilast	Otezla®	43	$4,905,834.83	**37**	**$6,125,894.89**
rifaximin	Xifaxan®	33	$6,474,383.90	**38**	**$6,081,336.31**
risankizumab-rzaa	Skyrizi Pen®	40	$4,033,561.59	**39**	**$5,847,535.03**
insulin glargine	various	17	$11,785,730.17	**40**	**$5,499,448.03**
ixekizumab	Taltz®	41	$5,702,374.85	**41**	**$5,421,034.82**
ofatumumab	Kesimpta®	51	$4,330,539.06	**42**	**$5,236,211.66**
dornase alfa	Pulmozyme®	39	$5,797,215.44	**43**	**$5,200,670.29**
belimumab	Benlysta®	71	$3,174,545.35	**44**	**$5,102,166.65**
rivaroxaban	Xarelto®	48	$4,609,783.43	**45**	**$5,028,535.88**
setmelanotide	Imcivree®	44	$4,807,296.90	**46**	**$5,015,071.62**
risdiplam	Evrysdi®	64	$3,457,793.57	**47**	**$4,965,041.37**
nirmatrelvir/ritonavir	Paxlovid™	129	$1,658,855.18	**48**	**$4,732,407.42**
selexipag	Uptravi®	86	$2,530,801.97	**49**	**$4,526,880.42**
asfotase alfa	Strensiq®	42	$4,966,656.14	**50**	**$4,449,909.67**

Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.
FY = fiscal year
FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

Top 50 Medications by Total Number of Claims: Fiscal Year 2025

Table 11: FY 2024 Top 50 Medications by Total Number of Claims							
Rank	Generic Name	Claims	Members	Cost	Claims/ Member	Cost/ Claim	% Cost
1	albuterol	272,382	117,139	$8,801,325.55	2.33	$32.31	0.67%
2	amoxicillin	216,205	163,116	$2,885,012.46	1.33	$13.34	0.22%
3	cetirizine	166,754	75,555	$1,992,336.85	2.21	$11.95	0.15%
4	gabapentin	138,858	36,966	$2,501,925.30	3.76	$18.02	0.19%
5	hydrocodone/APAP	130,461	53,639	$2,422,167.71	2.43	$18.57	0.19%

Table 11: FY 2024 Top 50 Medications by Total Number of Claims							
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Claims/ Member**	**Cost/ Claim**	**% Cost**
6	ondansetron	128,957	90,590	$1,853,456.78	1.42	$14.37	0.14%
7	azithromycin	108,665	87,395	$1,617,473.17	1.24	$14.88	0.12%
8	trazodone	106,708	27,725	$1,290,918.07	3.85	$12.10	0.10%
9	sertraline	106,078	30,412	$1,476,485.63	3.49	$13.92	0.11%
10	ibuprofen	99,297	67,675	$1,309,735.29	1.47	$13.19	0.10%
11	fluticasone propionate NS	99,048	54,848	$1,728,265.83	1.81	$17.45	0.13%
12	prednisone	96,912	69,550	$929,092.31	1.39	$9.59	0.07%
13	montelukast	89,428	26,770	$1,228,731.31	3.34	$13.74	0.09%
14	fluoxetine	88,664	23,755	$1,201,141.63	3.73	$13.55	0.09%
15	atorvastatin	87,105	30,038	$1,217,122.42	2.90	$13.97	0.09%
16	clonidine	84,435	17,745	$932,906.90	4.76	$11.05	0.07%
17	lisdexamfetamine	82,370	15,212	$30,151,346.51	5.41	$366.05	2.31%
18	amoxicillin & K clavulanate	81,831	69,229	$1,585,788.68	1.18	$19.38	0.12%
19	hydroxyzine HCl	80,841	29,629	$1,177,598.77	2.73	$14.57	0.09%
20	omeprazole	79,913	30,632	$1,091,167.08	2.61	$13.65	0.08%
21	escitalopram	79,145	24,119	$1,138,400.32	3.28	$14.38	0.09%
22	lisinopril	75,444	25,876	$980,204.88	2.92	$12.99	0.08%
23	levothyroxine	73,783	19,928	$1,348,494.85	3.70	$18.28	0.10%
24	metformin	72,105	25,442	$883,062.74	2.83	$12.25	0.07%
25	bupropion	70,669	20,724	$1,309,307.37	3.41	$18.53	0.10%
26	aripiprazole	70,620	17,323	$20,060,983.01	4.08	$284.07	1.54%
27	amphetamine/ dextroamphetamine	69,625	12,408	$1,888,075.17	5.61	$27.12	0.14%
28	methylphenidate	67,333	11,320	$4,009,175.51	5.95	$59.54	0.31%
29	cefdinir	66,060	53,021	$1,355,909.75	1.25	$20.53	0.10%
30	buspirone	65,886	20,951	$965,588.22	3.14	$14.66	0.07%
31	cephalexin	65,366	56,268	$997,207.09	1.16	$15.26	0.08%
32	pantoprazole	64,919	25,108	$894,559.34	2.59	$13.78	0.07%
33	cyclobenzaprine	64,152	28,680	$753,057.69	2.24	$11.74	0.06%
34	quetiapine	62,373	14,631	$941,058.06	4.26	$15.09	0.07%
35	amlodipine	59,817	20,787	$756,286.52	2.88	$12.64	0.06%
36	meloxicam	55,778	24,226	$639,401.44	2.30	$11.46	0.05%
37	duloxetine	55,371	15,308	$936,950.00	3.62	$16.92	0.07%
38	guanfacine ER	54,799	10,122	$1,014,828.86	5.41	$18.52	0.08%
39	triamcinolone TOP	51,000	37,246	$758,765.86	1.37	$14.88	0.06%
40	lamotrigine	49,599	10,816	$942,631.51	4.59	$19.01	0.07%
41	oxycodone/APAP	49,168	17,327	$1,168,254.91	2.84	$23.76	0.09%
42	methylprednisolone	47,059	40,391	$600,153.82	1.17	$12.75	0.05%

Table 11: FY 2024 Top 50 Medications by Total Number of Claims							
Rank	Generic Name	Claims	Members	Cost	Claims/ Member	Cost/ Claim	% Cost
43	mupirocin TOP	46,952	39,794	$720,279.78	1.18	$15.34	0.06%
44	famotidine	45,592	20,406	$858,892.51	2.23	$18.84	0.07%
45	risperidone	45,573	9,148	$7,239,934.59	4.98	$158.86	0.55%
46	alprazolam	45,539	8,276	$557,459.36	5.50	$12.24	0.04%
47	tizanidine	45,031	14,755	$594,010.81	3.05	$13.19	0.05%
48	prednisolone	43,575	32,072	$600,156.24	1.36	$13.77	0.05%
49	losartan	41,602	14,635	$554,215.76	2.84	$13.32	0.04%
50	atomoxetine	41,599	9,672	$1,154,373.88	4.30	$27.75	0.09%

APAP = acetaminophen; ER = extended-release; FY = fiscal year; HCl = hydrochloride; K = potassium; NS = nasal spray; TOP = topical
Reimbursement does not reflect rebated costs or net costs.
Medications are listed by generic name but may include both generic and brand formulations where applicable.
FY 2025 = 07/01/2024 to 06/30/2025

Top 10 Traditional and Specialty Therapeutic Categories by Fiscal Year

Table 12: FY 2025 Top 10 Traditional and Specialty Therapeutic Categories by Reimbursement					
FY 2024			FY 2025		
Claims	Members	Reimbursement	Claims	Members	Reimbursement
TRADITIONAL THERAPEUTIC CATEGORIES					
Anti-Diabetic					
288,993	46,726	$145,304,316.25	309,281	46,337	$151,793,596.43
Antipsychotic/Antimanic					
316,037	53,803	$114,889,280.09	315,166	52,329	$125,036,214.69
Antiviral					
90,524	57,922	$59,980,271.66	93,661	59,728	$67,003,939.31
Oncology					
19,207	5,015	$53,192,551.02	21,574	5,110	$60,725,418.85
ADHD/Anti-Narcolepsy					
356,281	50,890	$52,202,719.52	366,773	50,910	$45,526,921.06
Anti-Asthmatic/Bronchodilator					
507,951	140,323	$50,997,726.90	515,403	137,067	$44,740,088.32
Anticonvulsant					
449,346	81,790	$28,133,110.25	448,558	78,801	$29,071,258.97
Anticoagulant					
43,575	8,949	$19,047,761.50	46,997	9,337	$22,065,683.82
Antidepressant					
693,101	142,462	$14,314,303.57	683,843	133,981	$15,030,548.88
Psychotherapeutic/Neurological					
23,791	9,027	$12,421,446.04	24,508	8,766	$11,959,749.30
SPECIALTY THERAPEUTIC CATEGORIES					
Analgesics/Anti-inflammatory					
17,423	2,938	$132,119,510.09	18,804	3,038	$145,239,930.86

Table 12: FY 2025 Top 10 Traditional and Specialty Therapeutic Categories by Reimbursement					
FY 2024			FY 2025		
Claims	Members	Reimbursement	Claims	Members	Reimbursement
Dermatological					
9,393	1,778	$57,467,552.04	13,633	2,353	$80,988,295.44
Endocrine/Metabolic					
4,756	712	$49,510,887.38	5,472	695	$52,390,365.23
Respiratory					
3,367	265	$51,827,475.52	3,107	249	$50,419,020.92
Hematological					
1,121	151	$31,045,387.98	1,002	142	$33,672,895.42
Neuromuscular					
308	45	$17,700,677.29	336	47	$28,076,871.30
Antiviral					
2,036	1,059	$25,972,835.28	1,725	908	$21,751,837.48
Psychotherapeutic/Neurological					
2,540	365	$17,674,020.48	2,803	409	$21,131,460.63
Cardiovascular					
3,775	506	$15,267,262.67	4,523	517	$20,250,771.97
Gastrointestinal					
674	161	$9,404,919.95	1,057	247	$13,875,072.63

Reimbursement does not reflect rebated costs or net costs.
Therapeutic Category based on Medi-Span® Generic Product Identifier (GPI) classification.
ADHD = attention-deficit/hyperactivity disorder; FY = fiscal year
FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

Fiscal Year Age Group Comparison

Table 13: Traditional Pharmacy Reimbursement by Age Group			
Age Group (Years)	FY 2023	FY 2024	FY 2025
Age 0 to 2	$10,232,267.96	$7,919,934.60	$6,063,208.08
Age 3 to 5	$15,948,475.62	$13,603,749.92	$10,228,614.92
Age 6 to 9	$41,578,476.63	$36,384,345.64	$32,678,897.93
Age 10 to 14	$60,171,580.98	$53,510,892.82	$44,824,986.44
Age 15 to 18	$50,093,627.30	$42,129,100.50	$38,380,512.15
Age 19 to 25	$59,755,984.11	$54,085,996.14	$50,753,173.91
Age 26 to 34	$93,660,858.20	$89,362,452.54	$92,234,742.91
Age 35 to 54	$242,056,832.29	$253,910,109.39	$269,783,583.61
Age 55 to 64	$152,383,697.49	$158,878,614.06	$168,144,955.28
Age 65+	$19,787,482.04	$22,726,962.38	$25,455,247.07
Total (All Ages)	**$745,669,282.62**	**$732,512,157.99**	**$738,547,922.30**

Reimbursement does not reflect rebated costs or net costs.
FY = fiscal year
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

Table 14: Specialty Pharmacy Reimbursement by Age Group			
Age Group (Years)	**FY 2023**	**FY 2024**	**FY 2025**
Age 0 to 2	$10,312,883.33	$7,072,346.05	$14,721,697.16
Age 3 to 5	$12,524,351.37	$15,182,441.24	$19,669,142.37
Age 6 to 9	$29,190,762.01	$30,846,659.06	$32,193,266.54
Age 10 to 14	$51,441,159.80	$54,037,835.36	$68,976,695.88
Age 15 to 18	$40,893,872.38	$46,240,005.65	$50,889,978.71
Age 19 to 25	$43,339,301.65	$46,585,048.93	$52,189,188.82
Age 26 to 34	$49,670,838.52	$57,908,906.27	$60,646,001.77
Age 35 to 54	$109,928,251.86	$129,028,621.52	$151,641,629.21
Age 55 to 64	$48,042,799.58	$54,246,242.30	$61,482,368.28
Age 65+	$4,361,706.59	$5,284,352.87	$6,697,892.03
Total (All Ages)	**$399,705,927.09**	**$446,432,459.25**	**$519,107,860.77**

Reimbursement does not reflect rebated costs or net costs.
FY = fiscal year
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

Table 15: Total Enrollment by Age Group				
Age Group (Years)	**FY 2023**	**FY 2024**	**FY 2025**	**% Change (FY 2024 vs. 2025)**
Age 0 to 2	101,306	90,831	85,872	-5.46%
Age 3 to 5	106,192	90,265	143,508	58.99%
Age 6 to 9	141,099	122,377	113,938	-6.90%
Age 10 to 14	169,070	142,134	135,601	-4.60%
Age 15 to 18	128,267	105,874	102,748	-2.95%
Age 19 to 25	143,844	103,900	88,556	-14.77%
Age 26 to 34	145,032	116,721	102,853	-11.88%
Age 35 to 54	226,413	216,316	170,918	-20.99%
Age 55 to 64	92,514	82,590	77,293	-6.41%
Age 65+	93,515	79,380	78,458	-1.16%
Total (All Ages)	**1,347,252**	**1,150,388**	**1,099,745**	**-4.40%**

Age group totals included reflect the average monthly enrollment per age group as obtained from OHCA Fast Facts reports; therefore, the sum of each age group does not add up to the average monthly total enrollment for each fiscal year.
FY = fiscal year
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024; FY 2025 = 07/01/2024 to 06/30/2025

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Appendix N

Fiscal Year 2025 Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection)

Oklahoma Health Care Authority
June 2026

Current Prior Authorization Criteria

Akynzeo® (Netupitant/Palonosetron) and Akynzeo® IV (Fosnetupitant/ Palonosetron) Approval Criteria:

1. An FDA approved indication for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy; and
2. For Akynzeo® oral capsules, a previously failed trial of oral aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why oral aprepitant cannot be used must be provided; and
3. For Akynzeo® IV, a previously failed trial of intravenous (IV) fosaprepitant (Emend® IV) that resulted in an inadequate response, or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
4. Akynzeo® IV will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. Approval length will be based on duration of need; and
6. A quantity limit of 1 capsule or vial per chemotherapy cycle will apply; and
7. Akynzeo® oral capsules will not require prior authorization for members with cancer and claims will pay at the point of sale if the member has a reported oncology diagnosis within the past 6 months of claims history.
    a. Based on the current low net cost, Akynzeo® oral capsules will not require prior authorization for members with cancer; however, Akynzeo® oral capsules will follow the original criteria and require a previously failed trial of oral aprepitant if the net cost increases compared to other available products.

Anzemet® (Dolasetron), Cinvanti® and Emend® (Aprepitant), Emend® IV (Fosaprepitant), Focinvez™ (Fosaprepitant), and Kytril® and Sancuso® (Granisetron) Approval Criteria:

1. An FDA approved diagnosis; and

2. A recent trial of ondansetron (within the past 6 months) used for at least 3 days or 1 cycle that resulted in an inadequate response is required for authorization in members receiving moderately emetogenic chemotherapy; and
3. No ondansetron trial is required for authorization in members receiving highly emetogenic chemotherapy; and
4. For Emend® (aprepitant) oral suspension, an age restriction of 6 years and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. For Cinvanti® [aprepitant intravenous (IV) emulsion] and Focinvez™ (fosaprepitant), a previously failed trial of IV fosaprepitant (Emend® IV) that resulted in an inadequate response or a patient-specific, clinically significant reason why IV fosaprepitant (Emend® IV) cannot be used must be provided; and
6. Approval length will be based on duration of need.

Aponvie® (Aprepitant 32mg/4.4mL Vial) Approval Criteria:

1. An FDA approved diagnosis for the prevention of postoperative nausea and vomiting (PONV); and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention of PONV (e.g., ondansetron) must be provided.

Barhemsys® (Amisulpride) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an anti-emetic of a different class; or
    b. Treatment of PONV in members who have received anti-emetic prophylaxis with an agent of a different class or who have not received prophylaxis; and
2. Member must be 18 years of age or older; and
3. Member must not have received a preoperative dopamine-2 (D2) antagonist (e.g., metoclopramide); and
4. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention or treatment of PONV (e.g., ondansetron, dexamethasone) must be provided.

Bonjesta® (Doxylamine/Pyridoxine) and Doxylamine/Pyridoxine (Generic Diclegis®) Approval Criteria:

1. Authorization of Bonjesta® (doxylamine/pyridoxine) or the generic doxylamine/pyridoxine tablets requires a patient-specific, clinically significant reason why brand formulation Diclegis® (doxylamine/pyridoxine) tablets are not appropriate.

Marinol® and Syndros® (Dronabinol) Approval Criteria*:

1. An FDA approved diagnosis; and
2. Approval length will be based on duration of need; and
3. For Marinol® (dronabinol), a quantity limit of 60 capsules per 30 days will apply; and
4. For Syndros® (dronabinol) oral solution, the quantity approved will be patient-specific depending on patient diagnosis, maximum recommended dosage, and manufacturer packaging; and
5. For Syndros® (dronabinol) oral solution, an age restriction of 6 years and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why dronabinol oral capsules cannot be used.

Ondansetron 16mg Orally Disintegrating Tablet (ODT) Approval Criteria:

1. An FDA approved indication for the prevention of postoperative nausea and vomiting (PONV); and
2. A patient-specific, clinically significant reason why the member cannot use 2 of the 8mg ODTs to achieve the 16mg dose must be provided.

Palonosetron 0.25mg/5mL Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic Aloxi® (palonosetron 0.25mg/5mL), which is available without a prior authorization, must be provided.

Sustol® (Granisetron Subcutaneous Injection) Approval Criteria:

1. An FDA approved indication for use in the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens; and
2. Chemotherapy regimen must be listed on the prior authorization request; and
3. A recent trial of ondansetron (within the past 6 months) used for at least 3 days or 1 cycle that resulted in inadequate response is required for authorization in members receiving MEC; and
4. No ondansetron trial is required for authorization of granisetron in members receiving AC combination chemotherapy regimens; and
5. A patient-specific, clinically significant reason why the member cannot use Kytril® (granisetron hydrochloride injection) must be provided; and
6. A quantity limit of 1 injection per chemotherapy cycle will apply.

*Current prior authorization criteria is only applicable to anti-emetic medications with a current federal drug rebate agreement. All criteria, regardless of coverage, are provided in this report for informational purposes.

Utilization of Anti-Emetic Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	97,766	138,732	$2,208,009.37	$15.92	$2.04	2,615,630	1,080,412
Aetna	5,602	6,690	$104,398.21	$15.61	$2.49	123,427	41,885
Humana	6,300	7,551	$119,504.28	$15.83	$2.00	162,156	59,804
OCH	5,568	6,457	$106,234.92	$16.45	$2.30	121,880	46,253
2024 Total	**109,314**	**159,430**	**$2,538,146.78**	**$15.92**	**$2.07**	**3,023,093**	**1,228,354**
Fiscal Year 2025							
FFS	36,016	53,244	$810,669.57	$15.23	$1.88	1,072,280	430,995
Aetna	23,569	33,803	$530,252.13	$15.69	$2.35	638,183	225,512
Humana	24,415	35,762	$558,955.88	$15.63	$1.88	746,329	297,858
OCH	26,424	37,353	$566,046.34	$15.15	$2.28	694,000	247,985
2025 Total	**107,412**	**160,162**	**$2,465,923.92**	**$15.40**	**$2.05**	**3,150,791**	**1,202,350**
% Change	**-1.70%**	**0.50%**	**-2.80%**	**-3.30%**	**-1.00%**	**4.20%**	**-2.10%**
Change	**-1,902**	**732**	**-$72,222.86**	**-$0.52**	**-$0.02**	**127,698**	**-26,004**

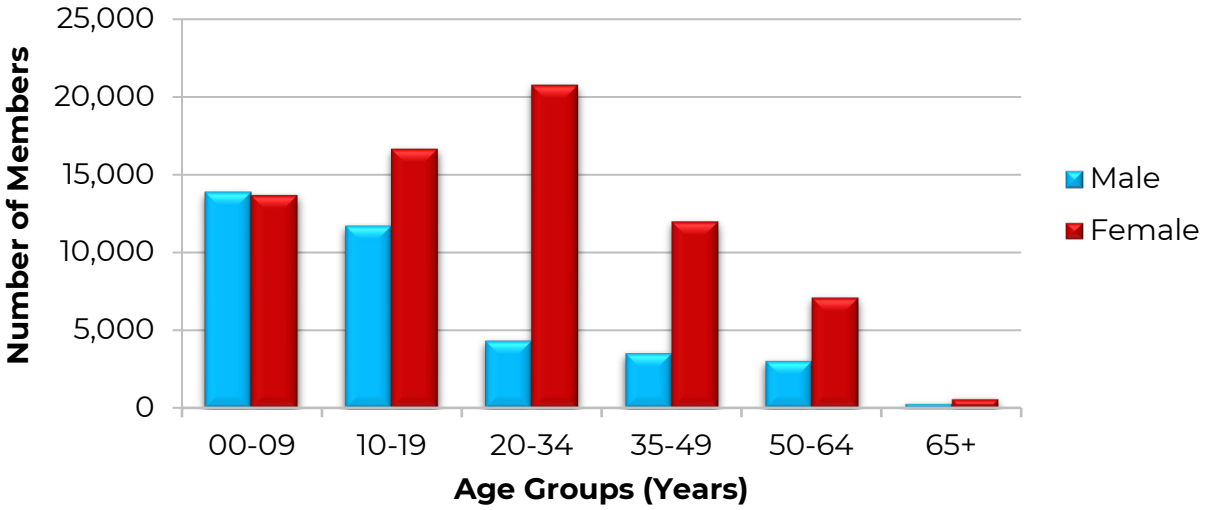
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025= 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Comparison of Fiscal Years: Medical Claims (All Plans)

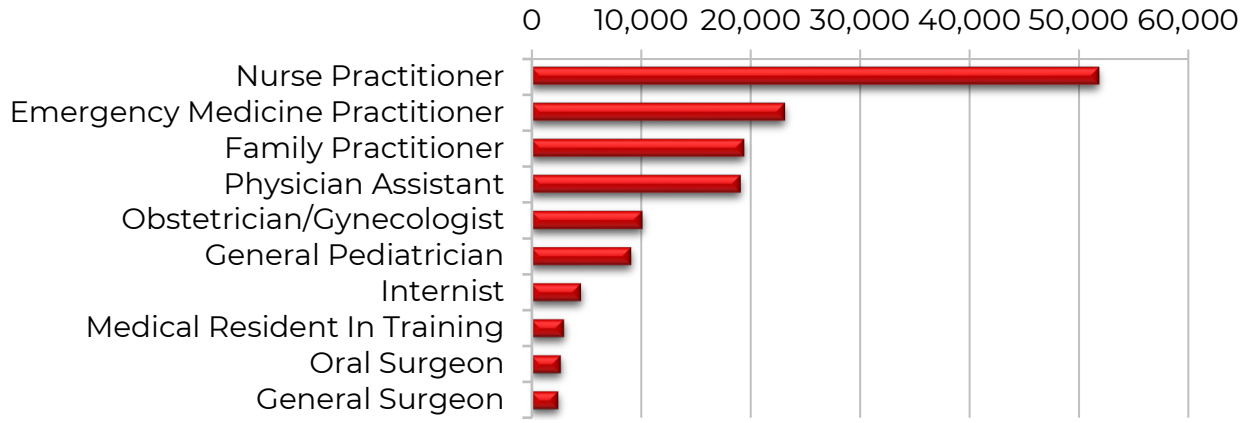
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	755	3,396	$386,702.23	$113.87	4.5
Aetna	7	13	$2,742.90	$210.99	1.86
Humana	6	8	$492.76	$61.60	1.33
OCH	25	53	$5,355.12	$101.04	2.12
2024 Total	**772**	**3,470**	**$395,293.01**	**$113.92**	**4.49**
Fiscal Year 2025					
FFS	392	1,541	$162,562.18	$105.49	3.93
Aetna	123	389	$33,854.36	$87.03	3.16
Humana	87	244	$20,695.05	$84.82	2.8
OCH	135	466	$52,257.84	$112.14	3.45
2025 Total	**672**	**2,640**	**$269,369.43**	**$102.03**	**3.93**
% Change	**-12.95%**	**-23.92%**	**-31.86%**	**-10.43%**	**-12.47%**
Change	**-100**	**-830**	**-$125,923.58**	**-$11.89**	**-0.56**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025= 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Anti-Emetic Medications: Pharmacy Claims (All Plans)



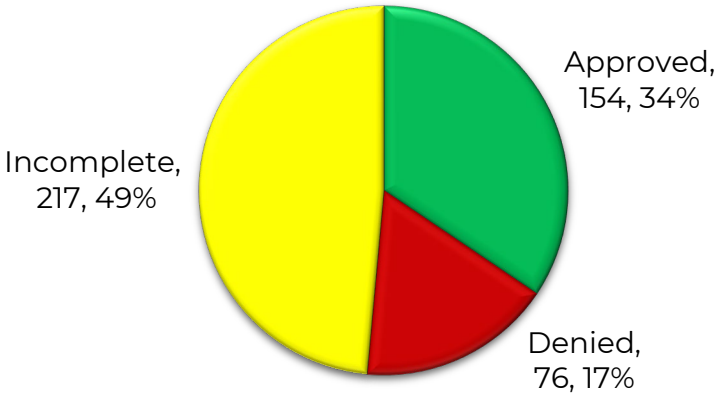
Top Prescriber Specialties of Anti-Emetic Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anti-Emetic Medications

There were 447 prior authorization requests submitted for anti-emetic medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	45	17%	195	72%	31	11%	**271**
Aetna	82	72%	12	11%	20	18%	**114**
Humana	2	14%	0	0%	12	86%	**14**
OCH	25	52%	10	21%	13	27%	**48**
Total	**154**	**34%**	**217**	**49%**	**76**	**17%**	**447**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4]

Anticipated Patent Expiration(s):

- Emend® (aprepitant oral suspension): September 2027
- Syndros® (dronabinol oral solution): August 2028
- Bonjesta® [doxylamine/pyridoxine extended-release (ER) tablet]: February 2033
- Akynzeo® (netupitant/palonosetron capsule): September 2035
- Aponvie® (aprepitant injectable emulsion): September 2035
- Cinvanti® [aprepitant intravenous (IV) emulsion]: September 2035
- Nereus® (tradipitant capsule): March 2036
- Akynzeo® IV (fosnetupitant/palonosetron powder and solution): June 2037
- Barhemsys® (amisulpride injection): February 2038
- Focinvez™ (fosaprepitant injection): January 2039

New U.S. Food and Drug Administration (FDA) Approval(s):

- **April 2025:** The FDA approved Posfrea™ (palonosetron injection) through the 505(b)(2) approval pathway based primarily on the existing safety and efficacy data from another intravenous (IV) formulation of palonosetron in chemotherapy induced nausea and vomiting (CINV) and postoperative nausea and vomiting (PONV). Additionally, the

supplemental new drug application (sNDA) provided data for the addition of the indication for pediatric patients 1 month of age to younger than 17 years of age for CINV.
- **December 2025:** The FDA approved Nereus™ (tradipitant) for the prevention of vomiting induced by motion in adults.

Nereus™ (Tradipitant) Product Summary[5,6,7,8]

Therapeutic Class: Substance P/neurokinin-1 (NK-1) receptor antagonist

Indication(s): For the prevention of vomiting induced by motion in adults

How Supplied: 85mg capsule

Dosing and Administration:
- The recommended dosage of Nereus™ is 85mg or 170mg as a single oral dose approximately 60 minutes before an event expected to cause vomiting induced by motion.
- The maximum dosage in a 24-hour period is a single dose of 85mg or 170mg.
- Administer on an empty stomach, at least 1 hour prior to or 2 hours after a full meal.

Efficacy: The efficacy of Nereus™ for the prevention of vomiting induced by motion was evaluated in 2 randomized, double-blind, placebo-controlled trials called Motion Syros (Study 1) and Motion Serifos (Study 2).
- Key Inclusion Criteria:
  - 18 years of age or older
  - History of motion sickness
- Key Exclusion Criteria:
  - Nausea-inducing disorders other than motion sickness
- Intervention: Participants were randomized 1:1:1 to receive a single dose of Nereus™ 85mg, 170mg, or placebo approximately 60 minutes prior to a boat trip scheduled to last approximately 2 to 5 hours.
- Primary Outcome: The primary endpoint in both studies was the percentage of subjects with vomiting during the boat trip.
- Results:
  - Study 1: The percentage of subjects with vomiting during a boat trip were 20% in the Nereus™ 85mg group, 18% in the Nereus™ 170mg group, and 44% in the placebo group with a treatment difference of -25% in the Nereus™ 85mg group compared to placebo [95% confidence interval (CI): -36%, -14%] and -26% in the Nereus™ 170mg group compared to placebo (95% CI: -37%, -15%).
  - Study 2: The percentage of subjects with vomiting during a boat trip were 18% in the Nereus™ 85mg group, 10% in the Nereus™ 170mg group, and 38% in the placebo group with a treatment

difference of -19% in the Nereus™ 85mg group compared to placebo (95% CI: -31%, -8%) and -27% in the Nereus™ 170mg group compared to placebo (95% CI: -38%, -16%).

Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment
Nereus® (tradipitant) 85mg capsule	**$255.00**	**$510.00¥**
scopolamine 1mg/3-day patch (generic)	$4.45	$4.45*
Dramamine® (dimenhydrinate) 50mg tablet	$0.27	$2.16α
meclizine 25mg tablet (generic)	$0.08	$0.16β

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Please note: Dramamine® is an over-the-counter product; therefore, it is not covered by SoonerCare.
Unit = each capsule, patch, or tablet
¥Cost is based on the FDA approved maximum dose of 170mg per day.
*Cost is based on the FDA approved maximum dosing of 1 patch every 3 days.
αCost is based on the FDA approved maximum dose of 8 tablets per day.
βCost is based on the FDA approved maximum dosing of 50mg per day.

Cost Comparison: Palonosetron Products

Product	Cost Per mL	Cost Per Vial
Posfrea™ (palonosetron 0.25mg/5mL injection)	**$123.66**	**$618.30**
palonosetron 0.25mg/5mL injection (generic)	$8.03	$40.15

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Recommendations

The College of Pharmacy recommends the prior authorization of Nereus™ (tradipitant) with the following criteria (shown in red):

Nereus™ (Tradipitant) Approval Criteria:

1. An FDA approved indication for the prevention of vomiting induced by motion; and
2. Member must be 18 years of age or older; and
3. Member must have a history of vomiting induced by motion; and
4. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention of vomiting induced by motion (i.e., Dramamine®, meclizine, scopolamine) must be provided; and
5. Approval length will be based on the duration of need which must be documented on the request; and
6. Approval of the 170mg dose will require documentation of failure at the lower dose; and
7. A quantity limit of 16 capsules per 30 days will apply.

The College of Pharmacy recommends the prior authorization of Posfrea™ (palonosetron injection) with criteria similar to the criteria for palonosetron 0.25mg/5mL single-dose prefilled syringes (changes shown in red):

Palonosetron 0.25mg/5mL Single-Dose Prefilled Syringe and Posfrea™ (Palonosetron 0.25mg/5mL Injection) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic Aloxi® (palonosetron 0.25mg/5mL), which is available without a prior authorization, must be provided.

Utilization Details of Anti-Emetic Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ONDANSETRON PRODUCTS						
ONDANSETRON 4MG ODT	109,636	81,199	$1,556,492.99	$14.20	1.35	63.12%
ONDANSETRON 8MG ODT	19,320	11,992	$296,949.52	$15.37	1.61	12.04%
ONDANSETRON TAB 4MG	18,716	13,347	$240,758.28	$12.86	1.4	9.76%
ONDANSETRON SOL 4MG/5ML	6,046	5,414	$129,906.36	$21.49	1.12	5.27%
ONDANSETRON TAB 8MG	5,596	3,399	$74,342.30	$13.28	1.65	3.01%
ONDANSETRON INJ 40MG/20ML	38	2	$1,157.58	$30.46	19	0.05%
ONDANSETRON INJ 4MG/2ML	29	11	$393.79	$13.58	2.64	0.02%
SUBTOTAL	**159,381**	**115,364**	**$2,300,000.82**	**$14.43**	**1.38**	**93.27%**
DOXYLAMINE/PYRIDOXINE PRODUCTS						
DICLEGIS TAB 10-10MG	612	422	$106,806.33	$174.52	1.45	4.33%
DOXYL/PYRID TAB 10-10MG	46	38	$3,516.36	$76.44	1.21	0.14%
BONJESTA TAB 20-20MG	23	18	$11,396.64	$495.51	1.28	0.46%
SUBTOTAL	**681**	**478**	**$121,719.33**	**$178.74**	**1.42**	**4.94%**
DRONABINOL PRODUCTS						
DRONABINOL CAP 2.5MG	19	14	$1,681.76	$88.51	1.36	0.07%
DRONABINOL CAP 10MG	12	2	$2,538.98	$211.58	6	0.10%
DRONABINOL CAP 5MG	10	8	$1,639.87	$163.99	1.25	0.07%
SYNDROS SOL 5MG/ML	2	2	$14,608.82	$7,304.41	1	0.59%
SUBTOTAL	**43**	**26**	**$20,469.43**	**$476.03**	**1.65**	**0.83%**
GRANISETRON PRODUCTS						
GRANISETRON TAB 1MG	30	10	$1,231.38	$41.05	3	0.05%
SANCUSO DIS 3.1MG	13	7	$17,694.44	$1,361.11	1.86	0.72%
SUBTOTAL	**43**	**17**	**$18,925.82**	**$440.14**	**2.53**	**0.77%**
APREPITANT PRODUCTS						
APREPITANT PAK 125MG & 80MG	8	4	$1,447.22	$180.90	2	0.06%
APREPITANT CAP 40MG	4	2	$1,130.21	$282.55	2	0.05%
APREPITANT CAP 125MG	1	1	$1,974.11	$1,974.11	1	0.08%
APREPITANT CAP 80MG	1	1	$256.98	$256.98	1	0.01%
SUBTOTAL	**14**	**8**	**$4,808.52**	**$343.47**	**1.75**	**0.19%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TOTAL	**160,162**	**107,412***	**$2,465,923.92**	**$15.40**	**1.49**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DIS = patches; DOXYL = doxylamine; INJ = injection; ODT = orally disintegrating tablet; PAK = pack; PYRID = pyridoxine; SOL = solution, TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FOSAPREPITANT INJ (J1453)	1,400	374	$26,783.83	$19.13	3.74
APREPITANT INJ (J0185)	1,063	302	$234,302.97	$220.42	3.52
GRANISETRON INJ (J1626)	147	24	$540.36	$3.68	6.13
FOSAPREPITANT INJ (J1456)	23	14	$6,132.12	$266.61	1.64
AMISULPRIDE INJ (J0184)	5	5	$360.00	$72.00	1
FOSNETUPITANT/PALONOSETRON INJ (J1454)	1	1	$687.15	$687.15	1
GRANISETRON ER INJ (J1627)	1	1	$563.00	$563.00	1
TOTAL	**2,640**	**672**	**$269,369.43**	**$102.03**	**3.93**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
ER = extended release; INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 05/2026. Last accessed 05/07/2026.
[2] U.S. FDA. Posfrea™ (Palonosetron Injection) Supplemental Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/203050Orig1s003ltr.pdf. Issued 04/16/2025. Last accessed 05/20/2026.
[3] Posfrea™ (Palonosetron Injection) Prescribing Information. Avyxa Pharma LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/203050s003lbl.pdf. Last revised 04/2025. Last accessed 05/20/2026.
[4] Vanda Pharmaceuticals, Inc. Vanda Pharmaceuticals Announces FDA Approval of Nereus™ (Tradipitant) for the Prevention of Vomiting Induced by Motion: A Historic Scientific Milestone in the Prevention of Motion Sickness. Available online at: https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-announces-fda-approval-of-nereus-tradipitant-for-the-prevention-of-vomiting-induced-by-motion-a-historic-scientific-milestone-in-the-prevention-of-motion-sickness-302650965.html. Issued 12/30/2025. Last accessed 05/07/2026.
[5] Nereus™ (Tradipitant) Prescribing Information. Vanda Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/220152Orig1s000lbl.pdf. Last revised 12/2025. Last accessed 05/07/2026.
[6] Motion Syros: A Study to Investigate the Efficacy of Tradipitant in Subjects Affected by Motion Sickness. *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT04327661. Last revised 12/11/2024. Last accessed 05/07/2026.
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[8] Dramamine® Original Dual-Action Motion Sickness Relief Tablets, 36 Count. CVS Pharmacy. Available online at: https://www.cvs.com/shop/dramamine-original-dual-action-motion-sickness-relief-tablets-36-ct-prodid-464430. Last accessed 05/2026.

Appendix O

Fiscal Year 2025 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Bysanti™ (Milsaperidone)

Oklahoma Health Care Authority
June 2026

Current Prior Authorization Criteria

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole ODT, sol, & tab (Abilify®)¥	asenapine sublingual tab (Saphris®)	aripiprazole oral film (Opipza™)+
clozapine tab (Clozaril®)	iloperidone tab (Fanapt®)	asenapine transdermal system (Secuado®)+
olanzapine IM inj, ODT, & tab (Zyprexa®, Zyprexa® Zydis®)	lurasidone tab (Latuda®)	brexpiprazole tab (Rexulti®)
quetiapine tab (Seroquel®)	paliperidone ER tab (Invega®)	cariprazine cap (Vraylar®)
quetiapine ER tab (Seroquel XR®)		clozapine ODT (Fazaclo®)+
risperidone ODT, sol, & tab (Risperdal®)		clozapine oral susp (Versacloz®)+
ziprasidone cap & IM inj (Geodon®)		lumateperone cap (Caplyta®)
		olanzapine/fluoxetine cap (Symbyax®)+
		olanzapine/samidorphan tab (Lybalvi®)β
		quetiapine 150mg tab+
Unique Mechanisms of Action		
		xanomeline/trospium cap (Cobenfy™)
Long-Acting Injectables (LAIs)^		
aripiprazole IM inj (Abilify Asimtufii®)^		risperidone IM inj (Risperdal Consta®)^∞
aripiprazole IM inj (Abilify Maintena®)^		risperidone IM inj (Rykindo®)^∞
aripiprazole lauroxil IM inj (Aristada®)^		
aripiprazole lauroxil IM inj (Aristada Initio®)^		

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
olanzapine pamoate IM inj (Zyprexa® Relprevv™)		
paliperidone palmitate IM inj (Erzofri®)^		
paliperidone palmitate IM inj (Invega Hafyera®)^		
paliperidone palmitate IM inj (Invega Sustenna®)^		
paliperidone palmitate IM inj (Invega Trinza®)^		
risperidone ER sub-Q inj (Perseris®)^		
risperidone sub-Q inj (Uzedy®)^		

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
cap = capsule; ER = extended-release; IM = intramuscular; inj = injection; ODT = orally disintegrating tablet; sol = solution; sub-Q = subcutaneous; susp = suspension
¥Aripiprazole (Abilify®) ODT is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
^Use of a long-acting injectable product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
+Unique criteria applies in addition to tier trial requirements.
βUnique criteria applies to Lybalvi® (olanzapine/samidorphan).
∞Unique criteria applies to Tier-3 long-acting injectable (LAI) products.

Tier-1 products are available without prior authorization for members 5 years of age and older. Prior authorization requests for members younger than 5 years of age are reviewed by an Oklahoma Health Care Authority (OHCA)- or SoonerSelect health plan-contracted child psychiatrist.

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
2. Members currently stable on a Tier-2 medication may be approved for continuation of therapy.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
2. Trials of 2 oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or

3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Members currently stable on a Tier-3 medication may be approved for continuation of therapy; and
5. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Use of Opipza™ (aripiprazole oral film) will require a patient-specific, clinically significant reason why the member cannot use the oral tablet or oral disintegrating tablet formulation; and
7. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered quetiapine products, which are available without a prior authorization; and
8. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
9. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD):

1. Authorization of Symbyax® (olanzapine/fluoxetine), Rexulti® (brexpiprazole), or Vraylar® (cariprazine) for a diagnosis of MDD requires current use of an antidepressant and previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting medication) and aripiprazole tablets that did not yield adequate response; and
2. Members currently stable on the requested medication may be approved for continuation of therapy; and
3. Tier structure rules still apply.

Long-Acting Injectable (LAI) Products Tier-3 Approval Criteria:

1. Use of LAI products will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the lower tiered LAI products available for the medication being requested, which are available without a prior authorization; and
2. Members currently stable on the requested medication may be approved for continuation of therapy.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must meet 1 of the following:
    a. Member has a positive clinical response to olanzapine and experienced weight gain ≥7% from baseline body weight or other metabolic complications [e.g., increased waist circumference, increased metabolic parameters, worsening diabetes (i.e., increased A1c or glucose despite optimal adherent therapy for diabetes)] after starting olanzapine (baseline and current weight must be provided or documentation of metabolic complications); or
    b. Member has a trial of 1 Tier-1 and 1 Tier-2 medication with a lower weight gain or metabolic profile (e.g., aripiprazole, ziprasidone, lurasidone), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and
4. Member must not be taking opioids or undergoing acute opioid withdrawal; and
5. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and any increase in body weight is ≤10% of baseline body weight (current weight must be provided) or has had no increase or worsening in metabolic complications (documentation must be provided) while on therapy must be provided.

Rexulti® (Brexpiprazole) Approval Criteria [Agitation Associated with Dementia Due to Alzheimer's Disease Diagnosis]:

1. An FDA approved indication of the treatment of agitation associated with dementia due to Alzheimer's disease; and
2. Diagnosis must be confirmed by the following:
    a. Mini-Mental State Exam (MMSE) score between 5 and 22; and
    b. Documentation of the member’s dementia due to Alzheimer's disease diagnosis [i.e., chart notes consistent with findings of a diagnosis of dementia due to Alzheimer's disease as per the National Institute on Aging and the Alzheimer’s Association (NIA-AA)]; and
    c. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson’s disease dementia); and
    d. Neuropsychiatric Inventory (NPI)/NPI-Nursing Home (NH) agitation/aggression score ≥4; and
    e. Exhibiting sufficient agitation behaviors warranting the use of pharmacotherapy; and

3. Prescriber must document a baseline evaluation using the Cohen-Mansfield Agitation Inventory (CMAI) total score; and
4. Prescriber must verify member will be closely monitored due to the risk of dementia-related psychosis; and
5. Initial approvals will be for 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the CMAI total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Utilization of Atypical Antipsychotics: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

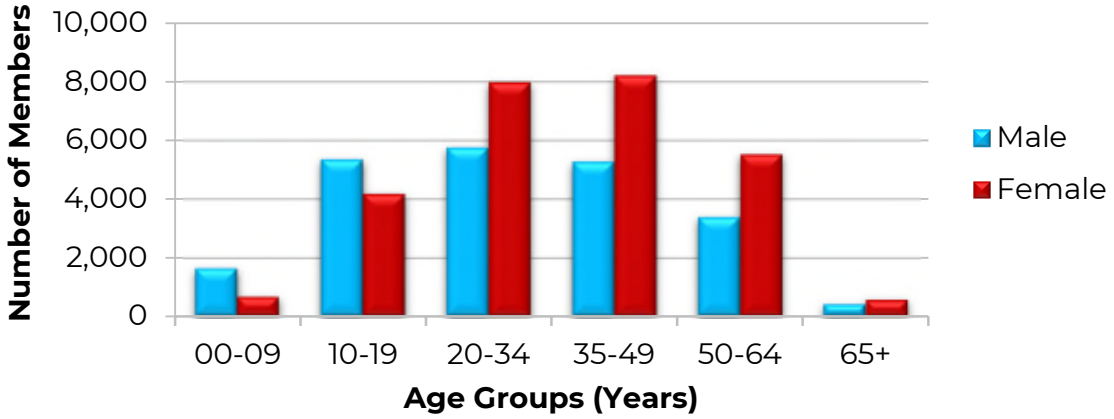
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	46,771	254,780	$103,047,362.60	$404.46	$11.21	10,561,852	9,190,357
Aetna	4,451	8,727	$3,539,209.22	$405.55	$10.84	355,574	326,619
Humana	5,385	11,183	$4,809,883.95	$430.11	$11.75	444,330	409,356
OCH	5,678	11,826	$3,579,011.67	$302.64	$8.61	465,238	415,898
2024 Total	**49,844**	**286,516**	**$114,975,467.44**	**$401.29**	**$11.12**	**11,826,995**	**10,342,230**
Fiscal Year 2025							
FFS	26,839	153,411	$75,519,922.61	$492.27	$13.69	6,459,295	5,517,104
Aetna	8,315	36,347	$14,894,806.80	$409.79	$10.85	1,495,041	1,373,220
Humana	9,804	46,763	$20,604,044.07	$440.61	$11.68	1,912,430	1,763,488
OCH	10,546	50,176	$15,582,718.83	$310.56	$8.25	2,136,198	1,888,775
2025 Total	**48,796**	**286,697**	**$126,601,492.31**	**$441.59**	**$12.01**	**12,002,965**	**10,542,587**
% Change	**-2.10%**	**0.10%**	**10.10%**	**10.00%**	**8.00%**	**1.50%**	**1.90%**
Change	**-1,048**	**181**	**$11,626,024.87**	**$40.30**	**$0.89**	**175,970**	**200,357**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

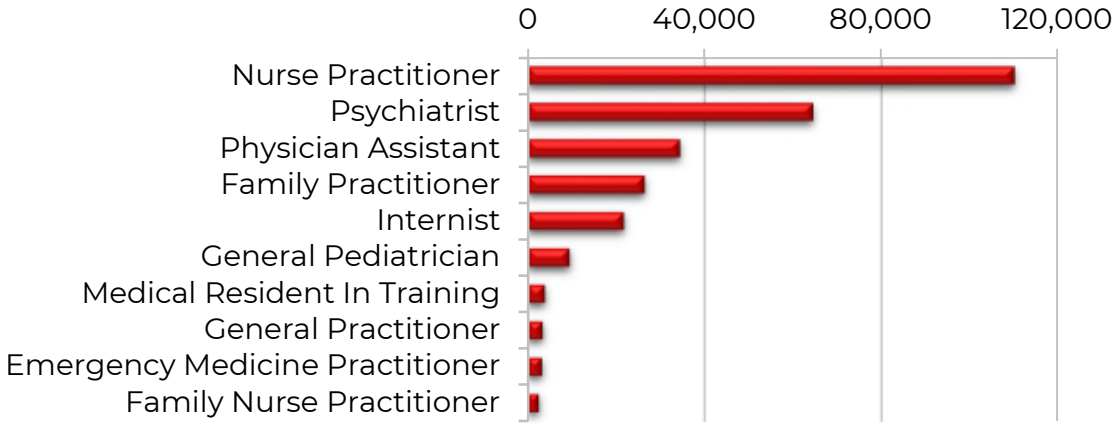
- Aggregate drug rebates collected during fiscal year 2025 for atypical antipsychotics totaled $80,234,287.52.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Demographics of Members Utilizing Atypical Antipsychotics: Pharmacy Claims (All Plans)



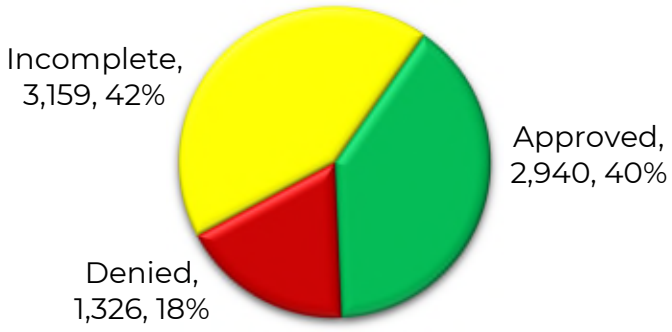
Top Prescriber Specialties of Atypical Antipsychotics by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Atypical Antipsychotics

There were 7,425 prior authorization requests submitted for atypical antipsychotics during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	1,984	39%	2,573	50%	540	11%	**5,097**
Aetna	330	30%	394	36%	359	33%	**1,083**
Humana	7	37%	0	0%	12	63%	**19**
OCH	619	50%	192	16%	415	34%	**1,226**
Total	**2,940**	**40%**	**3,159**	**42%**	**1,326**	**18%**	**7,425**

FFS = fee-for-service; OCH = OK Complete Health

Oklahoma Resources

The following list includes local resources available to prescribers, specifically regarding psychotropic medications:

- **Consultation with a Child Psychiatrist:** For children with especially challenging symptoms, a consultation with a child psychiatrist is available for the SoonerCare fee-for-service (FFS) population and can be scheduled by calling 1-405-522-7597.
- **Care Management (Including Behavioral Health):** Additional services are available for SoonerCare members, including Behavioral Health Care Management, through the member's SoonerCare (FFS) or SoonerSelect (managed care) health plan.
- **Project ECHO:** Project ECHO (Extension for Community Health Care Outcomes) is available online for medical education and care management for chronic and complex medical conditions at: https://medicine.okstate.edu/echo/.
- **Oklahoma Pediatric Psychotropic Medication Resource Guide:** The Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences has provided a psychotropic medication resource guide that can assist in the management of pediatric patients in the state of Oklahoma and can be found at: https://medicine.okstate.edu/academics/psychiatry/.
- **Statewide Psychiatry Access, Resources, and Knowledge (SPARK):** SPARK provides services directly to primary care providers (PCPs) who deliver pediatric mental health care in the primary care setting and can be found online at: https://okspark.org. Provider-to-provider services include telephone consultation, enhanced mental health education, referral assistance, medication management assistance, diagnostic decision making, in-office interventions, and family engagement. Many of the learning opportunities also provide Category 1-A Continuing Medical Education (CME).

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16]

Anticipated Patent Expiration(s):

- Saphris® [asenapine sublingual (SL) tablet]: October 2026
- Perseris® [risperidone extended-release (ER) subcutaneous (sub-Q) injection]: February 2028
- Versacloz® (clozapine oral suspension): May 2028
- Vraylar® (cariprazine capsule): March 2030
- Invega Sustenna® [paliperidone intramuscular (IM) injection]: January 2031
- Latuda® (lurasidone tablet): November 2031
- Fanapt® (iloperidone tablet): December 2031
- Rykindo® (risperidone ER IM injection): April 2032
- Abilify Asimtufii® (aripiprazole IM injection): April 2033
- Rexulti® (brexpiprazole tablet): April 2033
- Secuado® (asenapine transdermal system): September 2033
- Abilify Maintena® (aripiprazole IM injection): April 2034
- Invega Trinza® (paliperidone IM injection): April 2036
- Aristada® (aripiprazole lauroxil IM injection): April 2039
- Erzofri® (paliperidone palmitate ER injection): September 2039
- Cobenfy™ (xanomeline/trospium capsule): October 2039
- Uzedy® (risperidone ER sub-Q injection): September 2040
- Caplyta® (lumateperone capsule): December 2040
- Invega Hafyera® (paliperidone palmitate IM injection): November 2041
- Lybalvi® (olanzapine/samidorphan tablet): November 2041
- Opipza™ (aripiprazole film): December 2041
- Bysanti™ (milsaperidone tablet): May 2044

New U.S. Food and Drug Administration (FDA) Approval(s):

- **October 2025:** The FDA approved a new indication for Uzedy® (risperidone ER sub-Q injection) for monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. The approval is based on existing clinical data for Uzedy® and on previous safety and efficacy data of risperidone formulations approved for bipolar I disorder. Uzedy® was previously approved for the treatment of schizophrenia in adults in 2023.
- **November 2025:** The FDA approved Caplyta® (lumateperone) for a new indication as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults. Caplyta® was previously approved for the treatment of schizophrenia or as monotherapy or adjunctive therapy for bipolar I and II depression in adults.
- **December 2025:** The FDA approved Vraylar® (cariprazine) for an age expansion for the treatment of schizophrenia in pediatric patients 13 years of age and older and for the acute treatment of manic or mixed

episodes associated with bipolar I disorder in pediatric patients 10 years of age or older. Previously, Vraylar® was approved only for adults for both indications. The approval was based on evidence from previous studies in adults, pharmacokinetic data in adults and pediatric patients, and safety data in pediatric patients for both indications. Additionally, 2 new strengths of Vraylar® were approved: 0.5mg and 0.75mg.

- **February 2026:** The FDA approved Bysanti™ (milsaperidone) for the treatment of schizophrenia and for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.
- **April 2026:** The FDA approved a supplemental New Drug Application (sNDA) to include long-term data evaluating the safety and efficacy of Caplyta® for the prevention of relapse in schizophrenia to the package labeling. The Phase 3 trial showed a 63% lower risk of relapse for patients who received Caplyta® versus placebo (hazard ratio: 0.37; P=0.0002) and 84% of patients on Caplyta® being relapse-free over 6 months.

Pipeline:

- **Igalmi® (Dexmedetomidine):** Igalmi® is a selective alpha-2 adrenergic receptor agonist that is currently FDA approved for the acute treatment of agitation associated with schizophrenia and bipolar disorder I or II in adults under the supervision of a health care provider. Igalmi® is currently being studied for the acute treatment of agitation associated with Alzheimer's dementia and for the acute treatment of agitation associated with bipolar I or II disorder or schizophrenia in the at-home setting. BioXcel announced that the FDA accepted an sNDA and set a Prescription Drug User Fee Act (PDUFA) target date of November 14, 2026 for Igalmi® in the at-home setting.
- **NBI-117568:** NBI-1117568 is an investigational oral muscarinic M4 selective orthosteric agonist being studied for the treatment of schizophrenia. Based on positive data from a Phase 2 trial that showed a clinically meaningful and statistically significant reduction from baseline in the Positive and Negative Syndrome Scale (PANSS) total score, a Phase 3 trial has been initiated. The Phase 3 trial will evaluate NBI-1117568 in adults with a diagnosis of schizophrenia who are experiencing an acute exacerbation or relapse of symptoms.
- **NRX-101:** NRX-101 is an investigational oral combination of d-cycloserine, an N-methyl-D-aspartate (NMDA) receptor modulator, and lurasidone being studied for severe bipolar depression with acute and sub-acute suicidal ideation or behavior. NRX-101 demonstrated a statistically significant reduction of suicidality and akathisia in a randomized, well-controlled trial compared to lurasidone alone. A New Drug Application (NDA) has been submitted to the FDA and has since been amended to include the use of NRX-101 with transcranial

magnetic stimulation (TMS) for the treatment of depression, including suicidal depression. NRX-101 was previously granted Breakthrough Therapy designation by the FDA.

- **Roluperidone:** Roluperidone is an investigational compound that blocks serotonin, sigma, and alpha-adrenergic receptors that is being studied for the treatment of negative symptoms in schizophrenia. In February 2024, the FDA issued a Complete Response Letter (CRL) for the NDA citing that an additional confirmatory trial would be required for resubmission. The CRL included deficiencies in substantial evidence of effectiveness, data on concomitant antipsychotic administration, additional data to establish the change in negative symptoms, and inadequate number of subjects exposed to the proposed dosage for at least 12 months. A confirmatory Phase 3 trial has been initiated to address the CRL with data expected in the second half of 2027. If approved, roluperidone would be the first FDA approved medication for the specific indication of treating negative symptoms in schizophrenia.
- **TEV-'749:** TEV-'749 is an investigational once monthly sub-Q injectable formulation of olanzapine. The Phase 3 SOLARIS trial evaluated the efficacy, safety, and tolerability of TEV-'749 in patients with schizophrenia and demonstrated an efficacy and safety profile consistent with currently available olanzapine formulations. An NDA has been accepted by the FDA based on these results, but no official PDUFA target date has been announced.

Bysanti™ (Milsaperidone) Product Summary[17,18]

Therapeutic Class: Atypical antipsychotic

Indication(s):

- Treatment of schizophrenia in adults; and
- Acute treatment of manic or mixed episodes associated with bipolar I disorder

How Supplied: 1mg, 2mg, 4mg, 6mg, 8mg, 10mg, and 12mg oral tablets

Dosing and Administration:

- Bysanti™ should be titrated to reduce the risk of orthostatic hypotension.
- After titration the recommended maintenance dose of Bysanti™ is:
  - Schizophrenia: 6mg to 12mg twice daily
  - Bipolar mania: 12mg twice daily
- See the full *Prescribing Information* for titration schedules and recommended dosing based on CYP2D6 poor metabolizers and hepatic impairment.

Efficacy: The safety and efficacy of Bysanti™ were based primarily on the existing data from studies utilizing iloperidone tablets. Milsaperidone is an active metabolite that rapidly and non-enzymatically interconverts in vivo to iloperidone and was determined to have comparable bioavailability to iloperidone tablets.

Cost Comparison:

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year
Bysanti™ (milsaperidone) 12mg tablet	**$62.93**	**$3,775.80**	**$45,309.60**
Fanapt® (iloperidone) 12mg tablet	$60.11	$3,606.60	$43,279.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month based on the maximum FDA recommend dosing of 12mg twice daily.

Cost Comparison: Atypical Antipsychotics for Adjunct Treatment of MDD

Product	Cost Per Unit	Cost Per Month*	Cost Per Year
Caplyta® (lumateperone) 42mg capsule	**$57.33**	**$1,719.90**	**$20,638.80**
Vraylar® (cariprazine) 3mg capsule	$50.96	$1,528.80	$18,345.60
Rexulti® (brexpiprazole) 3mg tablet	$49.60	$1,488.00	$17,856.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule or tablet
*Cost per month based on the maximum FDA approved dosing for each product: 42mg once daily for Caplyta®, 3mg once daily for Vraylar®, and 3mg once daily for Rexulti®.

Recommendations

The College of Pharmacy recommends the following changes to the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category (changes noted in red in the following PBPA Tier charts and approval criteria):

1. Creation of a new Special Prior Authorization (PA) Tier based on net costs; and
2. Prior Authorization of Bysanti™ (milsaperidone) and placement into the Special PA Tier with additional approval criteria; and
3. Moving Latuda® (lurasidone) from Tier-2 to Tier-1 based on net costs; and
4. Moving Lybalvi® (olanzapine/samidorphan) from Tier-3 to the Special PA Tier based on net costs and updating the Lybalvi® approval criteria based on the recommended Tier changes; and
5. Moving Caplyta® (lumateperone), Cobenfy™ (xanomeline/trospium), Fazaclo® (clozapine orally disintegrating tablet), Opipza™ (aripiprazole oral film), quetiapine 150mg tablet, Secuado® (asenapine transdermal system), Symbyax® (olanzapine/fluoxetine), and Versacloz® (clozapine

oral suspension) from Tier-3 to the Special PA Tier based on net costs; and

6. Moving Risperdal Consta® (risperidone IM injection) and Rykindo® (risperidone IM injection) to the Special PA Tier, designating Risperdal Consta® as brand preferred, and updating the Long-Acting Injectable (LAI) Products Approval Criteria based on net costs; and
7. Updating the Atypical Antipsychotic Medications as Adjunctive Treatment of MDD Approval Criteria based on the FDA approval of Caplyta® for this indication and net costs.

Atypical Antipsychotic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
aripiprazole ODT, sol, & tab (Abilify®)¥	asenapine sublingual tab (Saphris®)	~~**aripiprazole oral film (Opipza™)⁺**~~	**aripiprazole oral film (Opipza™)⁺**
clozapine tab (Clozaril®)◊	iloperidone tab (Fanapt®)	~~**asenapine transdermal system (Secuado®)⁺**~~	**asenapine transdermal system (Secuado®)⁺**
lurasidone tab (Latuda®)	~~**lurasidone tab (Latuda®)**~~	brexpiprazole tab (Rexulti®)**~**	**clozapine ODT (Fazaclo®)⁺**
olanzapine IM inj, ODT, & tab (Zyprexa®)	paliperidone ER tab (Invega®)	cariprazine cap (Vraylar®)**~**	**clozapine oral susp (Versacloz®)⁺**
quetiapine tab (Seroquel®)		~~**clozapine ODT (Fazaclo®)⁺**~~	**lumateperone cap (Caplyta®)~**
quetiapine ER tab (Seroquel XR®)		~~**clozapine oral susp (Versacloz®)⁺**~~	**milsaperidone tab (Bysanti™)⁺**
risperidone ODT, sol, & tab (Risperdal®)		~~**lumateperone cap (Caplyta®)**~~	**olanzapine/fluoxetine cap (Symbyax®)⁺**
ziprasidone cap & IM inj (Geodon®)		~~**olanzapine/fluoxetine cap (Symbyax®)⁺~**~~	**olanzapine/samidorphan tab (Lybalvi®)ᵝ**
		~~**olanzapine/samidorphan tab (Lybalvi®)ᵝ**~~	**quetiapine 150mg tab⁺**
		~~**quetiapine 150mg tablets⁺**~~	
Unique Mechanisms of Action			
		~~**xanomeline/trospium (Cobenfy™)**~~	**xanomeline/trospium (Cobenfy™)**
Long-Acting Injectables (LAIs)^			
aripiprazole IM inj (Abilify Asimtufii®)^		~~**risperidone IM inj (Risperdal Consta®)^∞**~~	**risperidone IM inj (Risperdal Consta®)^∞**
aripiprazole IM inj (Abilify Maintena®)^		~~**risperidone IM inj (Rykindo®)^∞**~~	**risperidone IM inj (Rykindo®)^∞**
aripiprazole lauroxil IM inj (Aristada®)^			
aripiprazole lauroxil IM inj (Aristada Initio®)^			

Atypical Antipsychotic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
olanzapine pamoate IM inj (Zyprexa® Relprevv™)			
paliperidone palmitate IM inj (Erzofri®)^			
paliperidone palmitate IM inj (Invega Hafyera®)^			
paliperidone palmitate IM inj (Invega Sustenna®)^			
paliperidone palmitate IM inj (Invega Trinza®)^			
risperidone ER sub-Q inj (Perseris®)^			
risperidone sub-Q inj (Uzedy®)^			

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.

cap = capsule; ER = extended-release; IM = intramuscular; inj = injection; ODT = orally disintegrating tablet; sol = solution; sub-Q = subcutaneous; susp = suspension; tab = tablet

¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.

^Use of a long-acting injectable product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.

⁺Unique criteria applies in addition to tier trial requirements.

ᵝUnique criteria applies to Lybalvi® (olanzapine/samidorphan).

ᵒᵒUnique criteria applies to ~~Tier 3~~ Special PA long-acting injectable (LAI) products.

~Unique criteria applies for a diagnosis of adjunctive treatment of major depressive disorder (MDD).

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
2. Trial~~s~~ of ~~2~~ 1 oral Tier-2 medication~~s~~, at least 14 days in duration ~~each~~, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Members currently stable on a Tier-3 medication may be approved for continuation of therapy; and

~~5. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and~~
~~6. Use of Opipza™ (aripiprazole oral film) will require a patient-specific, clinically significant reason why the member cannot use the oral tablet or oral disintegrating tablet formulation; and~~
~~7. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered quetiapine products, which are available without a prior authorization; and~~
~~8. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and~~
~~9. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.~~

Atypical Antipsychotic Medications Special PA Approval Criteria:

1. Trials of 1 Tier-1 medication, 1 Tier-2 medication, and 2 Tier-3 medications at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; or
2. A manual prior authorization may be submitted for consideration of a Special PA medication when the member has had at least 5 trials of Tier-1, Tier-2, and Tier-3 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
3. Members currently stable on a Special PA medication may be approved for continuation of therapy; and
4. Use of Bysanti™ (milsaperidone) will require a patient-specific, clinically significant reason why the member cannot use Fanapt® (iloperidone). Tier structure rules continue to apply; and
5. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Use of Opipza™ (aripiprazole oral film) will require a patient-specific, clinically significant reason why the member cannot use the oral tablet or oral disintegrating tablet formulation; and
7. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered

quetiapine products, which are available without a prior authorization; and
8. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
9. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD):

1. Authorization of Caplyta® (lumateperone), ~~Symbyax® (olanzapine/fluoxetine),~~ Rexulti® (brexpiprazole), or Vraylar® (cariprazine) for a diagnosis of MDD requires current use of an antidepressant and previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting medication) and aripiprazole tablets that did not yield adequate response; and
2. For Caplyta®, a patient-specific, clinically significant reason why the member cannot use Rexulti® and Vraylar® must be provided; and
3. Members currently stable on the requested medication may be approved for continuation of therapy; and
4. Tier structure rules still apply.

Long-Acting Injectable (LAI) Products ~~Tier 3~~ Special PA Approval Criteria:

1. Use of LAI products will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the lower tiered LAI products available for the medication being requested, which are available without a prior authorization; and
2. Risperdal Consta® [risperidone intramuscular (IM) injection] is brand preferred. Requests for generic risperidone IM injection will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
3. Requests for Rykindo® (risperidone IM injection) will require a patient-specific, clinically significant reason why the member cannot use brand name Risperdal Consta®; and
4. Members currently stable on the requested medication may be approved for continuation of therapy.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must meet 1 of the following:
    a. Member has a positive clinical response to olanzapine and experienced weight gain ≥7% from baseline body weight or other

metabolic complications [e.g., increased waist circumference, increased metabolic parameters, worsening diabetes (i.e., increased A1c or glucose despite optimal adherent therapy for diabetes)] after starting olanzapine (baseline and current weight must be provided or documentation of metabolic complications); or

b. Member has a trial of ~~one Tier-1 and one Tier-2~~ 2 lower tiered medications with a lower weight gain or metabolic profile (e.g., aripiprazole, ziprasidone, lurasidone, brexpiprazole), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and

4. Member must not be taking opioids or undergoing acute opioid withdrawal; and
5. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and any increase in body weight is ≤10% of baseline body weight (current weight must be provided) or has had no increase or worsening in metabolic complications (documentation must be provided) while on therapy must be provided.

Utilization Details of Atypical Antipsychotics: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ARIPIPRAZOLE ORAL PRODUCTS						
ARIPIPRAZOLE TAB 5MG	20,892	7,595	$318,119.45	$15.23	2.75	0.25%
ARIPIPRAZOLE TAB 10MG	16,704	5,908	$260,499.18	$15.60	2.83	0.21%
ARIPIPRAZOLE TAB 2MG	9,347	3,533	$144,658.76	$15.48	2.65	0.11%
ARIPIPRAZOLE TAB 15MG	8,846	2,785	$139,737.01	$15.80	3.18	0.11%
ARIPIPRAZOLE TAB 20MG	5,059	1,342	$92,017.39	$18.19	3.77	0.07%
ARIPIPRAZOLE TAB 30MG	2,560	601	$44,371.25	$17.33	4.26	0.04%
ARIPIPRAZOLE SOL 1MG/ML	644	121	$63,892.24	$99.21	5.32	0.05%
ARIPIPRAZOLE ODT 10MG	17	4	$1,814.87	$106.76	4.25	0.00%
ABILIFY TAB 2MG	5	2	$2,577.87	$515.57	2.5	0.00%
ARIPIPRAZOLE ODT 15MG	4	3	$398.87	$99.72	1.33	0.00%
ABILIFY TAB 20MG	3	1	$2,406.32	$802.11	3	0.00%
ABILIFY TAB 5MG	2	2	$2,267.64	$1,133.82	1	0.00%
SUBTOTAL	**64,083**	**21,897**	**$1,072,760.85**	**$16.74**	**2.93**	**0.85%**
QUETIAPINE ORAL PRODUCTS						
QUETIAPINE TAB 100MG	15,166	4,976	$203,230.20	$13.40	3.05	0.16%
QUETIAPINE TAB 50MG	13,812	4,899	$176,193.82	$12.76	2.82	0.14%
QUETIAPINE TAB 25MG	9,403	3,514	$121,465.74	$12.92	2.68	0.10%
QUETIAPINE TAB 200MG	8,078	2,368	$120,979.48	$14.98	3.41	0.10%
QUETIAPINE TAB 300MG	6,463	1,761	$110,316.43	$17.07	3.67	0.09%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
QUETIAPINE TAB 400MG	5,227	1,246	$102,762.04	$19.66	4.2	0.08%
QUETIAPINE TAB 50MG ER	1,145	403	$18,493.70	$16.15	2.84	0.01%
QUETIAPINE TAB 150MG ER	872	303	$14,921.03	$17.11	2.88	0.01%
QUETIAPINE TAB 300MG ER	825	208	$17,311.97	$20.98	3.97	0.01%
QUETIAPINE TAB 400MG ER	722	156	$17,324.18	$23.99	4.63	0.01%
QUETIAPINE TAB 200MG ER	513	156	$9,367.55	$18.26	3.29	0.01%
SEROQUEL TAB 400MG	13	1	$14,589.81	$1,122.29	13	0.01%
SEROQUEL TAB 50MG	5	1	$1,688.21	$337.64	5	0.00%
SEROQUEL TAB 300MG	4	1	$4,779.57	$1,194.89	4	0.00%
SEROQUEL TAB 100MG	1	1	$203.66	$203.66	1	0.00%
SEROQUEL TAB 200MG	1	1	$370.85	$370.85	1	0.00%
SUBTOTAL	**62,250**	**19,995**	**$933,998.24**	**$15.00**	**3.11**	**0.74%**
RISPERIDONE ORAL PRODUCTS						
RISPERIDONE TAB 1MG	13,101	3,656	$169,280.84	$12.92	3.58	0.13%
RISPERIDONE TAB 0.5MG	10,141	2,757	$131,728.71	$12.99	3.68	0.10%
RISPERIDONE TAB 2MG	8,404	2,257	$105,882.86	$12.60	3.72	0.08%
RISPERIDONE TAB 0.25MG	3,797	1,095	$45,365.72	$11.95	3.47	0.04%
RISPERIDONE TAB 3MG	3,466	860	$46,922.66	$13.54	4.03	0.04%
RISPERIDONE TAB 4MG	2,025	433	$27,497.47	$13.58	4.68	0.02%
RISPERIDONE SOL 1MG/ML	1,476	294	$50,116.84	$33.95	5.02	0.04%
RISPERIDONE ODT 0.5MG	377	100	$16,665.13	$44.20	3.77	0.01%
RISPERIDONE ODT 1MG	275	78	$13,701.45	$49.82	3.53	0.01%
RISPERIDONE ODT 0.25	160	52	$13,050.58	$81.57	3.08	0.01%
RISPERIDONE ODT 2MG	120	46	$5,278.45	$43.99	2.61	0.00%
RISPERIDONE ODT 3MG	53	13	$3,095.77	$58.41	4.08	0.00%
RISPERDAL TAB 3MG	12	1	$4,565.54	$380.46	12	0.00%
RISPERIDONE ODT 4MG	10	5	$1,337.64	$133.76	2	0.00%
RISPERDAL TAB 1MG	7	3	$1,637.39	$233.91	2.33	0.00%
RISPERDAL SOL 1MG/ML	4	1	$9,965.48	$2,491.37	4	0.01%
RISPERDAL TAB 0.5MG	1	1	$144.11	$144.11	1	0.00%
SUBTOTAL	**43,429**	**11,652**	**$646,236.64**	**$14.88**	**3.73**	**0.51%**
OLANZAPINE ORAL PRODUCTS						
OLANZAPINE TAB 10MG	10,965	3,456	$177,171.96	$16.16	3.17	0.14%
OLANZAPINE TAB 20MG	7,783	1,712	$126,644.27	$16.27	4.55	0.10%
OLANZAPINE TAB 5MG	7,660	2,812	$114,294.03	$14.92	2.72	0.09%
OLANZAPINE TAB 15MG	4,124	1,169	$65,693.76	$15.93	3.53	0.05%
OLANZAPINE TAB 2.5MG	2,219	864	$30,587.79	$13.78	2.57	0.02%
OLANZAPINE TAB 7.5MG	1,466	441	$20,957.83	$14.30	3.32	0.02%
OLANZAPINE ODT 10MG	945	374	$24,426.68	$25.85	2.53	0.02%
OLANZAPINE ODT 5MG	892	381	$17,625.85	$19.76	2.34	0.01%
OLANZAPINE ODT 20MG	410	117	$15,746.05	$38.41	3.5	0.01%
OLANZAPINE ODT 15MG	251	82	$8,993.23	$35.83	3.06	0.01%
ZYPREXA TAB 10MG	8	1	$5,539.60	$692.45	8	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ZYPREXA TAB 20MG	4	1	$6,012.74	$1,503.19	4	0.00%
ZYPREXA TAB 15MG	2	1	$2,068.35	$1,034.18	2	0.00%
SUBTOTAL	**36,729**	**11,411**	**$615,762.14**	**$16.77**	**3.22**	**0.49%**
PALIPERIDONE INJECTABLE PRODUCTS						
INVEGA SUST INJ 234MG/1.5ML	8,887	1,727	$29,985,495.98	$3,374.09	5.15	23.68%
INVEGA SUST INJ 156MG/ML	3,468	1,151	$7,779,768.09	$2,243.30	3.01	6.15%
INVEGA TRINZ INJ 819MG/2.63ML	1,182	417	$12,125,760.51	$10,258.68	2.83	9.58%
INVEGA SUST INJ 117MG/0.75ML	699	172	$1,188,738.81	$1,700.63	4.06	0.94%
INVEGA TRINZ INJ 546MG/1.75ML	414	157	$2,883,695.00	$6,965.45	2.64	2.28%
INVEGA HAFYE INJ 1,560MG/5ML	142	91	$2,944,886.07	$20,738.63	1.56	2.33%
INVEGA TRINZ INJ 410MG/1.32ML	134	53	$686,719.28	$5,124.77	2.53	0.54%
INVEGA SUST INJ 78MG/0.5ML	104	30	$111,353.77	$1,070.71	3.47	0.09%
INVEGA HAFYE INJ 1,092MG/3.5ML	90	53	$1,267,112.25	$14,079.03	1.7	1.00%
INVEGA SUST INJ 39MG/0.25ML	37	7	$21,214.23	$573.36	5.29	0.02%
INVEGA TRINZ INJ 273MG/0.88ML	34	19	$121,767.13	$3,581.39	1.79	0.10%
SUBTOTAL	**15,191**	**3,877**	**$59,116,511.12**	**$3,891.55**	**3.92**	**46.69%**
CLOZAPINE ORAL PRODUCTS						
CLOZAPINE TAB 100MG	5,338	568	$259,192.23	$48.56	9.4	0.20%
CLOZAPINE TAB 200MG	2,623	281	$140,550.65	$53.58	9.33	0.11%
CLOZAPINE TAB 50MG	2,230	302	$78,695.62	$35.29	7.38	0.06%
CLOZAPINE TAB 25MG	998	161	$25,569.38	$25.62	6.2	0.02%
CLOZARIL TAB 100MG	24	2	$42,868.44	$1,786.19	12	0.03%
SUBTOTAL	**11,213**	**1,314**	**$546,876.32**	**$48.77**	**8.53**	**0.43%**
ARIPIPRAZOLE INJECTABLE PRODUCTS						
ABILIFY MAIN INJ 400MG PFS	4,543	849	$12,442,529.12	$2,738.84	5.35	9.83%
ABILIFY MAIN INJ 300MG PFS	792	206	$1,623,475.26	$2,049.84	3.84	1.28%
ABILIFY ASIM INJ 960MG/3.2ML	579	187	$3,127,758.96	$5,402.00	3.1	2.47%
ABILIFY MAIN INJ 400MG VIAL	425	99	$1,170,430.19	$2,753.95	4.29	0.92%
ABILIFY ASIM INJ 720MG/2.4ML	105	37	$432,732.74	$4,121.26	2.84	0.34%
ABILIFY MAIN INJ 300MG VIAL	93	26	$191,295.89	$2,056.95	3.58	0.15%
SUBTOTAL	**6,537**	**1,404**	**$18,988,222.16**	**$2,904.73**	**4.66**	**15.00%**
ZIPRASIDONE ORAL PRODUCTS						
ZIPRASIDONE CAP 20MG	1,953	693	$49,116.61	$25.15	2.82	0.04%
ZIPRASIDONE CAP 40MG	1,812	566	$44,453.32	$24.53	3.2	0.04%
ZIPRASIDONE CAP 80MG	1,483	298	$42,668.69	$28.77	4.98	0.03%
ZIPRASIDONE CAP 60MG	1,148	287	$35,493.78	$30.92	4	0.03%
SUBTOTAL	**6,396**	**1,844**	**$171,732.40**	**$26.85**	**3.47**	**0.14%**
ARIPIPRAZOLE LAUROXIL INJECTABLE PRODUCTS						
ARISTADA INJ 882MG/3.2ML	1,363	237	$4,040,445.52	$2,964.38	5.75	3.19%
ARISTADA INJ 1,064MG/3.9ML	493	160	$1,764,875.34	$3,579.87	3.08	1.39%
ARISTADA INJ 662MG/2.4ML	286	59	$637,879.08	$2,230.35	4.85	0.50%
ARISTADA INJ 441MG/1.6ML	226	43	$338,491.63	$1,497.75	5.26	0.27%
ARISTADA INJ INITIO 675MG/2.4ML	81	76	$177,609.14	$2,192.71	1.07	0.14%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**2,449**	**575**	**$6,959,300.71**	**$2,841.69**	**4.26**	**5.50%**
RISPERIDONE INJECTABLE PRODUCTS						
UZEDY INJ 100MG/0.28ML	466	161	$1,173,112.89	$2,517.41	2.89	0.93%
PERSERIS INJ 120MG	418	90	$1,147,535.09	$2,745.30	4.64	0.91%
UZEDY INJ 125MG/0.35ML	375	118	$1,174,706.52	$3,132.55	3.18	0.93%
PERSERIS INJ 90MG	198	51	$391,128.85	$1,975.40	3.88	0.31%
UZEDY INJ 200MG/0.56ML	187	79	$974,301.87	$5,210.17	2.37	0.77%
UZEDY INJ 75MG/0.21ML	185	58	$352,502.88	$1,905.42	3.19	0.28%
UZEDY INJ 250MG/0.7ML	155	74	$1,010,496.55	$6,519.33	2.09	0.80%
UZEDY INJ 50MG/0.14ML	96	36	$126,091.16	$1,313.45	2.67	0.10%
UZEDY INJ 150MG/0.42ML	64	26	$243,822.14	$3,809.72	2.46	0.19%
SUBTOTAL	**2,144**	**693**	**$6,593,697.95**	**$3,075.42**	**3.09**	**5.21%**
OLANZAPINE INJECTABLE PRODUCTS						
OLANZAPINE INJ 10MG	22	1	$1,609.48	$73.16	22	0.00%
ZYPREXA RELP INJ 300MG	2	1	$2,550.02	$1,275.01	2	0.00%
SUBTOTAL	**24**	**2**	**$4,159.50**	**$173.31**	**12**	**0.00%**
ZIPRASIDONE INJECTABLE PRODUCTS						
GEODON INJ 20MG	1	1	$75.84	$75.84	1	0.00%
SUBTOTAL	**1**	**1**	**$75.84**	**$75.84**	**1**	**0.00%**
TIER-1 SUBTOTAL	**250,446**	**74,665**	**$95,649,333.87**	**$381.92**	**3.35**	**75.55%**
TIER-2 PRODUCTS						
LURASIDONE ORAL PRODUCTS						
LURASIDONE TAB 40MG	4,437	1,513	$97,735.87	$22.03	2.93	0.08%
LURASIDONE TAB 20MG	3,638	1,491	$67,575.08	$18.57	2.44	0.05%
LURASIDONE TAB 80MG	2,591	645	$75,840.19	$29.27	4.02	0.06%
LURASIDONE TAB 60MG	2,403	727	$62,350.86	$25.95	3.31	0.05%
LURASIDONE TAB 120MG	924	225	$34,927.77	$37.80	4.11	0.03%
LATUDA TAB 80MG	106	29	$189,003.59	$1,783.05	3.66	0.15%
LATUDA TAB 40MG	97	31	$133,931.54	$1,380.74	3.13	0.11%
LATUDA TAB 20MG	77	34	$113,859.23	$1,478.69	2.26	0.09%
LATUDA TAB 60MG	73	20	$97,437.92	$1,334.77	3.65	0.08%
LATUDA TAB 120MG	41	10	$111,738.16	$2,725.32	4.1	0.09%
SUBTOTAL	**14,387**	**4,725**	**$984,400.21**	**$68.42**	**3.04**	**0.78%**
PALIPERIDONE ORAL PRODUCTS						
PALIPERIDONE TAB ER 6MG	1,132	289	$76,931.11	$67.96	3.92	0.06%
PALIPERIDONE TAB ER 3MG	719	266	$43,758.67	$60.86	2.7	0.03%
PALIPERIDONE TAB ER 9MG	495	124	$37,148.88	$75.05	3.99	0.03%
PALIPERIDONE TAB ER 1.5MG	124	54	$5,760.15	$46.45	2.3	0.00%
INVEGA TAB 3MG	3	1	$3,224.52	$1,074.84	3	0.00%
INVEGA TAB 6MG	1	1	$366.27	$366.27	1	0.00%
SUBTOTAL	**2,474**	**735**	**$167,189.60**	**$67.58**	**3.37**	**0.13%**
ASENAPINE ORAL PRODUCTS						
ASENAPINE SUB 10MG	416	87	$62,634.14	$150.56	4.78	0.05%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ASENAPINE SUB 5MG	305	103	$34,477.41	$113.04	2.96	0.03%
ASENAPINE SUB 2.5MG	127	45	$20,484.12	$161.29	2.82	0.02%
SAPHRIS SUB 5MG	12	6	$13,197.04	$1,099.75	2	0.01%
SAPHRIS SUB 10MG	9	5	$9,442.69	$1,049.19	1.8	0.01%
SUBTOTAL	**869**	**246**	**$140,235.40**	**$161.38**	**3.53**	**0.11%**
ILOPERIDONE ORAL PRODUCTS						
FANAPT TAB 8MG	168	55	$266,656.64	$1,587.24	3.05	0.21%
FANAPT TAB 12MG	158	39	$420,891.59	$2,663.87	4.05	0.33%
FANAPT TAB 6MG	141	49	$287,552.43	$2,039.38	2.88	0.23%
FANAPT TAB 4MG	119	52	$142,672.01	$1,198.92	2.29	0.11%
FANAPT TAB 10MG	66	13	$202,941.47	$3,074.87	5.08	0.16%
FANAPT TAB 2MG	20	9	$20,338.68	$1,016.93	2.22	0.02%
FANAPT 1/2/4/6MG PACK	14	14	$3,563.32	$254.52	1	0.00%
FANAPT TAB 1MG	8	8	$10,566.19	$1,320.77	1	0.01%
SUBTOTAL	**694**	**239**	**$1,355,182.33**	**$1,952.71**	**2.9**	**1.07%**
TIER-2 SUBTOTAL	**18,424**	**5,945**	**$2,647,007.54**	**$143.67**	**3.1**	**2.09%**
TIER-3 PRODUCTS						
CARIPRAZINE ORAL PRODUCTS						
VRAYLAR CAP 3MG	4,228	1,085	$6,904,209.13	$1,632.97	3.9	5.45%
VRAYLAR CAP 1.5MG	3,837	1,292	$6,225,751.40	$1,622.56	2.97	4.92%
VRAYLAR CAP 6MG	1,636	289	$2,559,566.76	$1,564.53	5.66	2.02%
VRAYLAR CAP 4.5MG	1,629	401	$2,619,847.29	$1,608.25	4.06	2.07%
SUBTOTAL	**11,330**	**3,067**	**$18,309,374.58**	**$1,616.01**	**3.69**	**14.46%**
BREXPIPRAZOLE ORAL PRODUCTS						
REXULTI TAB 1MG	840	306	$1,321,840.67	$1,573.62	2.75	1.04%
REXULTI TAB 2MG	825	229	$1,419,723.70	$1,720.88	3.6	1.12%
REXULTI TAB 3MG	492	121	$817,357.86	$1,661.30	4.07	0.65%
REXULTI TAB 0.5MG	267	105	$414,067.07	$1,550.81	2.54	0.33%
REXULTI TAB 4MG	233	51	$397,783.92	$1,707.23	4.57	0.31%
REXULTI TAB 0.25MG	16	10	$23,145.22	$1,446.58	1.6	0.02%
SUBTOTAL	**2,673**	**822**	**$4,393,918.44**	**$1,643.82**	**3.25**	**3.47%**
LUMATEPERONE ORAL PRODUCTS						
CAPLYTA CAP 42MG	1,709	329	$2,731,701.86	$1,598.42	5.19	2.16%
CAPLYTA CAP 21MG	231	67	$360,702.02	$1,561.48	3.45	0.28%
CAPLYTA CAP 10.5MG	82	24	$130,186.53	$1,587.64	3.42	0.10%
SUBTOTAL	**2,022**	**420**	**$3,222,590.41**	**$1,593.76**	**4.81**	**2.55%**
OLANZAPINE/SAMIDORPHAN COMBINATION ORAL PRODUCTS						
LYBALVI TAB 10-10MG	207	53	$304,790.07	$1,472.42	3.91	0.24%
LYBALVI TAB 5-10MG	183	44	$284,541.74	$1,554.87	4.16	0.22%
LYBALVI TAB 15-10MG	178	36	$276,335.77	$1,552.45	4.94	0.22%
LYBALVI TAB 20-10MG	172	36	$251,280.12	$1,460.93	4.78	0.20%
SUBTOTAL	**740**	**169**	**$1,116,947.70**	**$1,509.39**	**4.38**	**0.88%**
XANOMELINE/TROSPIUM COMBINATION ORAL PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
COBENFY CAP 125-30MG	258	72	$440,958.28	$1,709.14	3.58	0.35%
COBENFY CAP 100-20MG	232	102	$387,508.02	$1,670.29	2.27	0.31%
COBENFY CAP 50-20MG	136	89	$195,942.94	$1,440.76	1.53	0.15%
COBENFY CAP STR PACK	8	7	$13,841.19	$1,730.15	1.14	0.01%
SUBTOTAL	**634**	**270**	**$1,038,250.43**	**$1,637.62**	**2.35**	**0.82%**
CLOZAPINE ORALLY DISINTEGRATING PRODUCTS						
CLOZAPINE ODT 100MG	108	9	$25,582.56	$236.88	12	0.02%
CLOZAPINE ODT 25MG	10	2	$1,033.05	$103.31	5	0.00%
CLOZAPINE ODT 150MG	9	2	$17,139.17	$1,904.35	4.5	0.01%
CLOZAPINE ODT 200MG	8	2	$12,374.10	$1,546.76	4	0.01%
SUBTOTAL	**135**	**15**	**$56,128.88**	**$415.77**	**9**	**0.04%**
QUETIAPINE ORAL PRODUCTS						
QUETIAPINE TAB 150MG	120	43	$7,038.93	$58.66	2.79	0.01%
SUBTOTAL	**120**	**43**	**$7,038.93**	**$58.66**	**2.79**	**0.01%**
RISPERIDONE INJECTABLE PRODUCTS						
RISPERDAL CONSTA INJ 50MG	52	6	$75,781.57	$1,457.34	8.67	0.06%
RISPERIDONE INJ 50MG ER	33	5	$48,694.13	$1,475.58	6.6	0.04%
RISPERDAL CONSTA INJ 12.5MG	8	1	$4,644.72	$580.59	8	0.00%
RISPERIDONE INJ 37.5MG	5	1	$7,104.90	$1,420.98	5	0.01%
RISPERDAL CONSTA INJ 37.5MG	3	1	$4,280.28	$1,426.76	3	0.00%
SUBTOTAL	**101**	**14**	**$140,505.60**	**$1,391.14**	**7.21**	**0.11%**
OLANZAPINE/FLUOXETINE COMBINATION ORAL PRODUCTS						
OLANZ/FLUOX CAP 12-50MG	35	3	$11,448.27	$327.09	11.67	0.01%
OLANZ/FLUOX CAP 12-25MG	11	1	$2,854.47	$259.50	11	0.00%
OLANZ/FLUOX CAP 6-50MG	11	2	$1,868.10	$169.83	5.5	0.00%
OLANZ/FLUOX CAP 3-25MG	11	3	$1,074.44	$97.68	3.67	0.00%
OLANZ/FLUOX CAP 6-25MG	2	2	$340.92	$170.46	1	0.00%
SUBTOTAL	**70**	**11**	**$17,586.20**	**$251.23**	**6.36**	**0.01%**
ASENAPINE TRANSDERMAL SYSTEM PRODUCTS						
SECUADO PATCH 7.6MG/24HR	1	1	$1,417.43	$1,417.43	1	0.00%
SECUADO PATCH 5.7MG/24HR	1	1	$1,392.30	$1,392.30	1	0.00%
SUBTOTAL	**2**	**2**	**$2,809.73**	**$1,404.87**	**1**	**0.00%**
TIER-3 SUBTOTAL	**17,827**	**4,833**	**$28,305,150.90**	**$1,587.77**	**3.69**	**22.36%**
TOTAL	**286,697**	**48,796***	**$126,601,492.31**	**$441.59**	**5.88**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ASIM = Asimtufii; CAP = capsule; ER/XR = extended release; HAFYE = Hafyera; HR = hour; INJ = injection; MAIN = Maintena; ODT = orally disintegrating tablet; OLANZ/FLUOX = olanzapine/fluoxetine; PFS = prefilled syringe; RELP = Relprevv; SOL = solution; STR = starter; SUB = sublingual; SUST = Sustenna; TAB = tablet; TRINZ = Trinza
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix P

Fiscal Year 2025 Annual Review of Antiviral Medications and 30-Day Notice to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder), and Xofluza® (Baloxavir)

Oklahoma Health Care Authority
June 2026

Current Prior Authorization Criteria

Acyclovir 5% Cream (Generic Zovirax®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand formulation must be provided.

Denavir® (Penciclovir Cream) Approval Criteria:

1. An FDA approved diagnosis of recurrent herpes labialis (cold sores); and
2. A patient-specific, clinically significant reason why the member cannot use oral acyclovir, famciclovir, or valacyclovir tablets must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use acyclovir cream must be provided; and
4. For penciclovir cream, a patient-specific, clinically significant reason why the member cannot use the brand formulation must be provided.

Epclusa® (Sofosbuvir/Velpatasvir) Tablets and Pellets Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype-1, genotype-2, genotype-3, genotype-4, genotype-5, or genotype-6; and
3. Epclusa must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
5. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA

(>15 IU/mL) test 6 months after date of positive HCV antibody test; or
    ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and
6. The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:
    a. Genotype-1, -2, -3, -4, -5, -6:
        i. Treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A):
            1. Epclusa® for 12 weeks
        ii. Treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Pugh B and C):
            1. Epclusa® + weight-based ribavirin for 12 weeks
    b. New regimens will apply as approved by the FDA
7. Member must sign and submit the Hepatitis C Intent to Treat contract; and
8. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
11. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for ribavirin users); and
14. Member must not be taking the following medications: H2-receptor antagonists at doses >40mg famotidine equivalent, amiodarone, omeprazole or other proton pump inhibitors, topotecan, rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, efavirenz, tenofovir disoproxil fumarate, tipranavir/ritonavir, St. John's wort, and rosuvastatin doses >10mg; and
15. If member is using antacids, they must agree to separate antacid and Epclusa® administration by 4 hours; and
16. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy,

obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and

17. Member must not have a limited life expectancy (<12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another direct therapy; and
18. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
19. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
20. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Harvoni® (Ledipasvir/Sofosbuvir Tablets and Oral Pellets) Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype-1, genotype-4, genotype-5, or genotype-6; and
3. Request for the generic formulation will require a patient-specific, clinically significant reason the member cannot use the brand formulation; and
4. Harvoni® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
6. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required (must be within last 3 months if requesting 8-week regimen); or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and
7. The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:

a. Genotype-1:
    i. Treatment-naïve without cirrhosis who have a pre-treatment HCV-RNA less than 6 million IU/mL:
        1. Harvoni® for 8 weeks
    ii. Treatment-naïve with or without compensated cirrhosis:
        1. Treatment-naïve patients who are cirrhotic or have a pre-treatment HCV-RNA greater than 6 million IU/mL
        2. Harvoni® for 12 weeks
    iii. Treatment-experienced without cirrhosis:
        1. Harvoni® for 12 weeks
    iv. Treatment-experienced with compensated cirrhosis:
        1. Harvoni® with weight-based ribavirin for 12 weeks
        2. Harvoni® for 24 weeks
    v. Treatment-naïve or treatment-experienced with decompensated cirrhosis:
        1. Harvoni® with weight-based ribavirin for 12 weeks
b. Genotype-1 or Genotype-4:
    i. Treatment-naïve or treatment-experienced liver transplant recipients with or without compensated cirrhosis:
        1. Harvoni® with weight-based ribavirin for 12 weeks
c. Genotype-4, Genotype-5, or Genotype-6:
    i. Treatment-naïve or treatment-experienced with or without compensated cirrhosis:
        1. Harvoni® for 12 weeks
d. New regimens will apply as approved by the FDA

8. Members who are older than 6 years of age and request the oral pellet formulation of Harvoni® must provide a patient-specific, clinically significant reason for use of the oral pellet formulation in place of the tablet formulation; and
9. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
10. Member must sign and submit the Hepatitis C Intent to Treat contract; and
11. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
12. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
13. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
14. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and

15. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for six months after therapy completion for those on ribavirin); and
16. Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, tipranavir/ritonavir, simeprevir, rosuvastatin, St. John's wort, or elvitegravir/cobicistat/emtricitabine in combination with tenofovir disoproxil fumarate; and
17. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and
18. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
21. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Livtencity® (Maribavir) Approval Criteria:

1. An FDA approved diagnosis of post-transplant cytomegalovirus (CMV) infection and disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric members (12 years of age and older weighing ≥35kg); and
2. A previously failed trial at least 14 days in duration with ganciclovir, valganciclovir, cidofovir, or foscarnet; and
3. Prescriber must verify the member does not have CMV disease involving the central nervous system including the retina (CMV retinitis); and
4. Prescriber must verify member will not receive concurrent treatment with ganciclovir and/or valganciclovir while taking Livtencity®; and
5. Prescriber must verify the member will be monitored for virologic failure during and after treatment with Livtencity®; and

6. Livtencity® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
7. Prescriber must verify Livtencity® will not be used concomitantly with strong inducers of CYP3A4 (e.g., rifampin, rifabutin, St. John's wort) except carbamazepine, phenobarbital, or phenytoin. Use of carbamazepine, phenobarbital, or phenytoin concomitantly with Livtencity® will require dose adjustment according to package labeling; and
8. Prescriber must agree to monitor drug concentrations of immunosuppressant drugs that are CYP3A4 and/or P-glycoprotein (P-gp) substrates (e.g., tacrolimus, cyclosporine, sirolimus, everolimus) throughout treatment with Livtencity® and adjust the dose of immunosuppressant drug(s) as needed; and
9. Approvals will be for a maximum duration of 8 weeks, and a quantity limit of 112 tablets per 28 days will apply.

Prevymis® (Letermovir Tablets, Oral Pellets, and Injection) Approval Criteria [Hematopoietic Stem Cell Transplant (HSCT) Diagnosis]:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) infection and disease in CMV-seropositive recipients [R+] of an allogenic HSCT; and
2. Member must be 6 months of age or older and weigh at least 6kg; and
3. Member must be CMV R+; and
4. Member must have received a HSCT within the last 28 days; and
    a. If the member was previously started on Prevymis®, the date of the first dose must be provided; and
5. Members taking concomitant cyclosporine will only be approved for the 240mg dose; and
6. Members must not be taking the following medications:
    a. Pimozide; or
    b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
    c. Rifampin; or
    d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
7. For Prevymis® oral pellets, an age restriction will apply. The oral pellet formulation may be approvable for members 6 years of age and younger. Members 7 years and older must have a patient-specific, clinically significant reason why the member cannot use the Prevymis® tablet formulation; and
8. Prevymis® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or advanced care practitioner with a

supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
9. Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and
10. Approvals will be for the duration of 100 days post-transplant.
    a. For Prevymis® vials, authorization will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
    b. Approval length for vial formulation will be based on duration of need; and
11. Approvals may be extended to 200 days post-transplant if the member is at risk for developing a late CMV infection (the member's risk factors must be provided); and
12. The following quantity limits will apply:
    a. Tablets and vials for IV injection: 1 tablet or vial per day; or
    b. Oral pellets:
        i. 20mg: 4 packets per day; or
        ii. 120mg: 2 packets per day; and
        iii. For requests exceeding the quantity limit, additional information about why the member cannot use the oral tablet formulation must be provided.

Prevymis® (Letermovir Tablets, Oral Pellets, and Injection) Approval Criteria [Kidney Transplant Diagnosis]:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) disease in kidney transplant recipients; and
2. Member must be 12 years of age or older and weigh at least 40kg; and
3. Member must be at high risk [i.e., donor CMV-seropositive/recipient CMV-seronegative (D+/R-)]; and
4. Member must have received a kidney transplant within the last 7 days; and
    a. If the member was previously started on Prevymis®, the date of the first dose must be provided; and
5. Members taking concomitant cyclosporine will only be approved for the 240mg dose; and
6. Members must not be taking the following medications:
    a. Pimozide; or
    b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
    c. Rifampin; or
    d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
7. For Prevymis® oral pellets, member must have a patient-specific, clinically significant reason why the member cannot use the Prevymis® tablet formulation; and

8. Prevymis® must be prescribed by an oncology, hematology, infectious disease, or transplant specialist (or an advanced care practitioner with a supervising physician who is an oncology, hematology, infectious disease, or transplant specialist); and
9. Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and
10. Approvals will be for the duration of 200 days post-transplant; and
    a. For Prevymis® vials, authorization will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
    b. Approval length for vial formulation will be based on duration of need; and
11. The following quantity limits will apply:
    a. Tablets and vials for IV injection: 1 tablet or vial per day; or
    b. Oral pellets:
        i. 20mg: 4 packets per day; or
        ii. 120mg: 2 packets per day; and
        iii. For requests exceeding the quantity limit, additional information about why the member cannot use the oral tablet formulation must be provided.

Sovaldi® (Sofosbuvir Tablets and Oral Pellets) Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) genotype-1, genotype-2, genotype-3, or genotype-4; and
3. Requests for the generic formulation will require a patient-specific, clinically significant reason the member cannot use the brand formulation; and
4. Sovaldi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
5. Sovaldi® must be used as a component of a combination regimen; and
6. Member must be eligible for ribavirin (RBV) or daclatasvir therapy. Approvals will not be granted for regimens without RBV or daclatasvir; and
7. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
8. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:

i. Positive (i.e., reactive) HCV antibody test and has a recent (within the last 3 months) detectable and quantifiable HCV RNA (>15 IU/mL); or
ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

9. The following regimens and requirements based on genotype, prior treatment experience, and cirrhosis status will apply:
    a. Genotype 1:
        i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:
            1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
    b. Genotype 2:
        i. Treatment-naïve, non-cirrhotic:
            1. Sovaldi® with weight-based ribavirin for 12 weeks
        ii. Treatment-naïve, cirrhotic:
            1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks
        iii. Treatment-experienced, non-cirrhotic or cirrhotic:
            1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks
            2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
    c. Genotype 3:
        i. Treatment-naïve, non-cirrhotic
            1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
            2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)
        ii. Treatment-naïve, cirrhotic
            1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
            2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)
        iii. Treatment-experienced, non-cirrhotic
            1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
            2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)
        iv. Treatment-experienced, cirrhotic
            1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
            2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)
    d. Genotype 4:
        i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:

        1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
    e. New regimens will apply as approved by the FDA.
10. Members who are older than 6 years of age and request the oral pellet formulation of Sovaldi® must provide a patient-specific, clinically significant reason for use of the oral pellet formulation in place of the tablet formulation; and
11. Member must sign and submit the Hepatitis C Intent to Treat contract; and
12. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
13. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
14. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
15. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
16. Member must not have decompensated cirrhosis; and
17. Female members must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin members); and
18. Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, phenytoin, oxcarbazepine, tipranavir/ritonavir, didanosine, or St. John's wort; and
19. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and
20. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
21. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
22. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
23. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype 1, genotype 2, genotype 3, genotype 4, genotype 5, or genotype 6; and
3. Vosevi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on the prior authorization request; and
5. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and
6. The following regimens and requirements based on treatment history will apply:
    a. Adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A):
        i. Genotype 1, 2, 3, 4, 5, or 6 patients who were previously treated with an HCV regimen containing an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir): Vosevi® for 12 weeks; or
        ii. Genotype 1a or 3 patients who were previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor: Vosevi® for 12 weeks; or
    b. New regimens will apply as approved by the FDA; and
7. Member must sign and submit the Hepatitis C Intent to Treat contract; and
8. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
9. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
10. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and

11. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
12. Member must not have decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C); and
13. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
14. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy; and
15. Member must not be taking the following medications: H2-receptor antagonists at doses greater than 40mg famotidine twice daily equivalent, omeprazole doses greater than 20mg daily or other proton pump inhibitors, amiodarone, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, St. John's wort, pravastatin doses greater than 40mg daily, rosuvastatin, pitavastatin, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan; and
16. If member is using antacids they must agree to separate antacid and Vosevi® administration by four hours; and
17. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
18. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
19. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and
20. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Zepatier® (Elbasvir/Grazoprevir) Approval Criteria:

1. Member must be 12 years of age or older or weigh at least 30kg; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype-1 or genotype-4; and
3. Zepatier® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or

transplant specialist for hepatitis C therapy within the last three months; and

4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
5. If the member has genotype-1a, testing results for the presence of virus with NS5A resistance-associated polymorphisms must be indicated on the prior authorization request; and
6. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test and has a recent (within the last 3 months) detectable and quantifiable HCV RNA (>15 IU/mL); or
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and
7. The following regimens and requirements based on genotype, polymorphisms, and prior treatment status will apply (all regimens apply to patients with and without cirrhosis, HIV/HCV co-infected patients, and patients with or without renal impairment):
    a. Genotype-1a, treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms:
        i. Zepatier® for 12 weeks
    b. Genotype-1a, treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms:
        i. Zepatier® with weight-based ribavirin for 16 weeks
    c. Genotype-1b, treatment-naïve or peginterferon alfa + ribavirin experienced:
        i. Zepatier® for 12 weeks
    d. Genotype-1a or -1b, peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, teleprevir) experienced:
        i. Zepatier® with weight-based ribavirin for 12 weeks
    e. Genotype-4, treatment-naïve:
        i. Zepatier® for 12 weeks
    f. Genotype-4, treatment-experienced:
        i. Zepatier® with weight-based ribavirin for 16 weeks
    g. New regimens will apply as approved by the FDA
8. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and

9. Member must sign and submit the Hepatitis C Intent to Treat contract; and
10. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
11. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
12. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
13. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
14. Member must not have decompensated cirrhosis or moderate-to-severe hepatic impairment (Child-Pugh B and C); and
15. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for ribavirin users); and
16. The prescriber must verify that the member's ALT levels will be monitored prior to treatment initiation, at treatment week eight, and as clinically indicated thereafter (patients receiving 16 weeks of therapy should receive additional ALT levels at treatment week 12); and
17. Member must not be taking the following medications: phenytoin, carbamazepine, rifampin, St. John's wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, bosentan, etravirine, elvitegravir/cobicstat/ emtricitabine/tenofovir, or modafinil; and
18. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
19. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
20. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
21. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
22. Approvals for treatment regimen initiation for 12 or 16 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Zovirax® (Acyclovir 5% Cream) Approval Criteria:

1. A patient-specific clinically signification reason why the member cannot use the following products, which are available without prior authorization, must be provided:
   a. Zovirax® (acyclovir ointment); and
   b. Oral acyclovir, famciclovir, or valacyclovir tablets.

Utilization of Antiviral Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

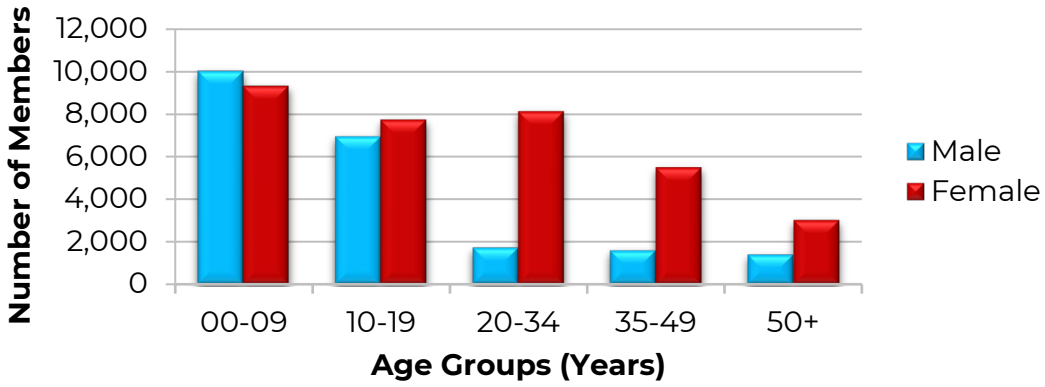
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	50,329	63,304	$24,516,968.45	$387.29	$31.84	3,184,205	769,958
Aetna	1,432	1,819	$1,506,473.81	$828.19	$51.78	77,561	29,095
Humana	1,584	2,076	$1,323,554.44	$637.55	$39.07	81,994	33,877
OCH	1,458	1,834	$1,415,427.56	$771.77	$51.57	77,221	27,449
2024 Total	**52,979**	**69,033**	**$28,762,424.26**	**$416.65**	**$33.43**	**3,420,981**	**860,379**
Fiscal Year 2025							
FFS	17,233	21,498	$8,727,064.95	$405.95	$32.50	1,038,104	268,561
Aetna	12,159	15,882	$4,674,527.01	$294.33	$26.62	762,510	175,631
Humana	12,638	16,967	$6,215,090.87	$366.30	$27.99	809,495	222,059
OCH	14,227	18,183	$5,042,682.77	$277.33	$27.62	862,846	182,589
2025 Total	**55,248**	**72,530**	**$24,659,365.60**	**$339.99**	**$29.05**	**3,472,955**	**848,840**
% Change	**4.30%**	**5.10%**	**-14.30%**	**-18.40%**	**-13.10%**	**1.50%**	**-1.30%**
Change	**2,269**	**3,497**	**-$4,103,058.66**	**-$76.66**	**-$4.38**	**51,974**	**-11,539**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for antiviral medications totaled $13,232,672.09.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Demographics of Members Utilizing Antiviral Medications: Pharmacy Claims (All Plans)

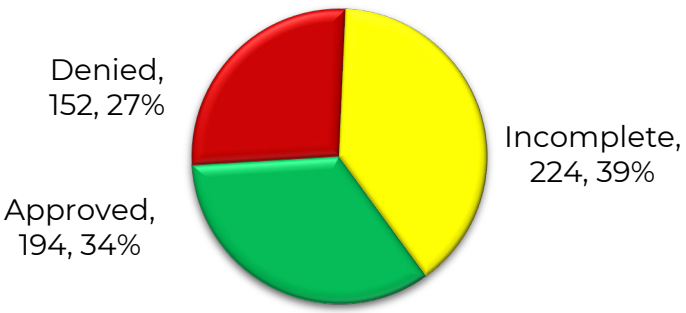


Top Prescriber Specialties of Antiviral Medications by Number of Claims: Pharmacy Claims (All Plans)

Prior Authorization of Antiviral Medications

There were 570 prior authorization requests submitted for antiviral medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	133	36%	185	51%	47	13%	**365**
Aetna	6	12%	19	38%	25	50%	**50**
Humana	16	32%	0	0%	34	68%	**50**
OCH	39	37%	20	19%	46	44%	**105**
Total	**194**	**34%**	**224**	**39%**	**152**	**27%**	**570**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7]

Anticipated Patent Expiration(s):

- Rapivab® (peramivir injection): May 2027
- Prevymis® (letermovir oral pellets): January 2029
- Prevymis® (letermovir oral tablets): January 2029
- Sovaldi® (sofosbuvir pellets and tablets): June 2031
- Livtencity® (maribavir tablets): January 2032
- Prevymis® (letermovir injection): February 2033
- Harvoni® (ledipasvir/sofosbuvir pellets): March 2033
- Epclusa® (sofosbuvir/velpatasvir pellets and tablets): July 2034
- Harvoni® (ledipasvir/sofosbuvir tablets): July 2034
- Mavyret® (glecaprevir/pibrentasvir pellets): December 2035
- Mavyret® (glecaprevir/pibrentasvir tablets): December 2036
- Vosevi® (sofosbuvir/velpatasvir/voxilaprevir tablets): December 2037
- Xofluza® (baloxavir tablet): October 2039

New U.S. Food and Drug Administration (FDA) Approval(s) and Label Update(s):

- **June 2025:** The FDA approved an expanded indication for Mavyret® (glecaprevir/pibrentasvir) for the treatment of acute hepatitis C virus (HCV) in adults and pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis.
- **May 2026:** The FDA approved Hepcludex® (bulevirtide-gmod) for the treatment of chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.

News:

- In October 2025, Merck announced that Zepatier® (elbasvir/grazoprevir) would be discontinued effective December 31, 2025, based on a business decision and not due to safety or efficacy reasons.

Pipeline:

- **Bepirovirsen:** GSK announced that the FDA accepted the New Drug Application (NDA) and granted priority review and breakthrough designation for bepirovirsen, an antisense oligonucleotide (ASO) for the

treatment of adults with chronic hepatitis B virus (HBV) infection. The NDA was supported by data from the Phase 3 B-Well 1 and B-Well 2 trials, in which bepirovirsen plus standard-of-care led to statistically significant and clinically meaningful functional cure rates [i.e., undetectable HBV deoxyribonucleic acid (DNA) and surface antigen in blood for at least 24 weeks post-treatment] compared to standard-of-care alone. The Prescription Drug User Fee Act (PDUFA) date is October 26, 2026.

- **Pritelivir:** Aicuris announced that pritelivir, an investigational and novel helicase-primase inhibitor, met the primary endpoint of the Phase 3 PRIOH-1 trial. In the trial, pritelivir demonstrated superiority in the healing of refractory herpes simplex virus (HSV) lesions, with or without resistance, in immunocompromised patients compared with standard-of-care regimens (i.e., foscarnet, cidofovir, or compounded topical cidofovir or imiquimod) after 28 days (P=0.0047) and 42 days (P<0.0001) of treatment. By targeting the helicase-primase complex of HSV, pritelivir does not require activation by viral enzymes for activity against both HSV-1 and HSV-2, thereby bypassing viral resistance mechanisms to nucleoside analogs. Aicuris has submitted an NDA with the FDA and received priority review with a target PDUFA date in the fourth quarter of 2026.

Hepcludex® (Bulevirtide-gmod) Product Summary[8,9]

Therapeutic Class: HDV attachment inhibitor

Indication(s): Treatment of chronic HDV infection in adults without cirrhosis or with compensated cirrhosis

- This indication is approved under accelerated approval based on a decrease in HDV ribonucleic acid (RNA) and alanine aminotransferase (ALT) normalization. An improvement in disease-related clinical outcomes has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied: 8.5mg as a lyophilized powder or cake in a single dose vial (SDV)

Dosing and Administration:

- The recommended dose is 8.5mg once daily administered by subcutaneous (sub-Q) injection into the upper thigh, lower abdomen, or back of the upper arm (if administered by a caregiver).
- Each Hepcludex® SDV should be reconstituted with 1mL of sterile water for injection and used immediately.
- The underlying HBV infection should be managed as clinically appropriate.

- Hepcludex® should be continued as long as it is associated with a response to treatment.
    - The optimal treatment duration is unknown.
    - Hepcludex® has a *Boxed Warning* for the potential of severe acute exacerbations of hepatitis D and B after treatment discontinuation.

Efficacy: The safety and efficacy of Hepcludex® were evaluated in a Phase 3 multicenter, randomized, open-label, parallel arm trial.

- Key Inclusion Criteria:
    - Positive serum anti-HDV antibody or HDV RNA for at least 6 months before screening
    - Positive HDV RNA at screening
    - ALT level >1 times the upper limit of normal (ULN) but <10 times the ULN
    - Serum albumin >2.8 g/dL
- Key Exclusion Criteria:
    - Child-Pugh hepatic insufficiency score >7
    - Current or previous (within the last 2 years) decompensated liver disease, including coagulopathy, hepatic encephalopathy, and esophageal varices hemorrhage)
- Intervention(s): Participants were randomized and stratified by presence of compensated cirrhosis to immediate treatment with Hepcludex® 8.5mg sub-Q once daily for 144 weeks or to delayed treatment with an observational period of 48 weeks followed by Hepcludex® 8.5mg sub-Q once daily for 96 weeks. Both groups were followed for 96 weeks after treatment discontinuation.
    - Of note, the original trial protocol specified the Hepcludex® dose as 10mg; however, a dose recovery study indicated the delivered dose was 8.5mg.
- Primary Endpoint(s): Combined response, defined as undetectable HDV RNA or ≥2 $\log_{10}$ IU/mL decline from baseline and ALT normalization, at week 48
- Results:
    - At week 48, the combined response rate was 48% in the immediate treatment group (N=50) and 2% in the delayed treatment group (N=51), which was a treatment difference of 46% [96% confidence interval (CI): 31%, 61%; P<0.0001].
        - Additionally, the rate of undetectable HDV RNA was 20% in the immediate treatment group compared with 0% in the delayed treatment group.
    - At week 96, the combined response rate in the immediate treatment group was 56%.

- At week 144, the combined response rate for the immediate treatment group was 54% compared to 56% of the delayed treatment group (96 weeks after beginning treatment in week 48).
- At week 96 post-treatment, 24% of participants in both groups had combined response, and 22% of participants in the immediate treatment group compared to 20% in the delayed treatment group had undetectable HDV RNA.

Cost: The Wholesale Acquisition Cost (WAC) of Hepcludex® is $776.20 per SDV, resulting in an estimated cost of $23,286 per 30 days and $283,313 per year based on the FDA-approved dosing of 8.5mg (1 reconstituted SDV) sub-Q once daily.

Cost Comparison: Oral Influenza Antiviral Medications

Product	Cost Per Unit	Cost Per Treatment
Xofluza® (baloxavir) 40mg tablet	**$162.03**	**$162.03***
Xofluza® (baloxavir) 80mg tablet	**$161.96**	**$161.96***
Relenza® (zanamivir inh pow) 5mg diskhaler	**$2.95**	**$59.00†**
oseltamivir (generic Tamiflu®) 75mg capsule	$0.89	$8.90α

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule, diskhaler, tablet
inh = inhalation; pow = powder
*Cost per treatment is based on the FDA recommended dosing of 40mg as a single dose for a patient weighing <80kg or 80mg as a single dose for a patient weighing ≥80kg.
†Cost per treatment is based on the FDA recommended dosing of 10mg (2 inhalations) twice daily for 5 days.
αCost per treatment is based on the FDA recommended dosing of 75mg twice daily for 5 days.

Recommendations

The College of Pharmacy recommends the prior authorization of Hepcludex® (bulevirtide-gmod) with the following criteria (shown in red):

Hepcludex® (Bulevirtide-gmod) Approval Criteria:

1. An FDA approved diagnosis of chronic hepatitis D virus (HDV) infection; and
2. Diagnosis must be confirmed by all of the following test results conducted within the last 6 months (results must be submitted with the request):
   a. Detectable serum HDV RNA level; and
   b. Elevated alanine aminotransferase (ALT) levels between 1 and 10 times the upper limit of normal; and
3. Member must not have decompensated cirrhosis or hepatocellular carcinoma (HCC); and

4. Member must be 18 years of age or older; and
5. Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist; and
6. Prescriber must verify that underlying hepatitis B virus (HBV) infection will be managed as clinically appropriate; and
7. Prescriber must verify that the member or caregiver will be trained on the proper storage, reconstitution, and administration of Hepcludex®; and
8. A quantity limit of 30 vials per 30 days will apply; and
9. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by all of the following (results of testing must be submitted with the request):
    a. Undetectable HDV RNA or a ≥2 $\log_{10}$ IU/mL reduction in HDV RNA from baseline; and
    b. A reduction or normalization of ALT; and
    c. Member has not developed decompensated cirrhosis or HCC; and
    d. Member has not undergone a liver transplant.

The College of Pharmacy also recommends the prior authorization of Relenza® (zanamivir inhalation powder) and Xofluza® (baloxavir) based on net costs with the following criteria (shown in red):

Relenza® (Zanamivir Inhalation Powder) and Xofluza® (Baloxavir) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of acute uncomplicated influenza in members who have been symptomatic for no more than 48 hours; or
    b. Post-exposure prophylaxis of influenza following contact with an individual who has influenza; and
2. Member must be 5 years of age or older; and
3. A patient specific, clinically significant reason (beyond convenience) why the member cannot use oseltamivir (generic Tamiflu®), which is available without prior authorization, must be provided.

The College of Pharmacy also recommends updating the Epclusa® (sofosbuvir/velpatasvir), Sovaldi® (sofosbuvir tablets and oral pellets), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), and Zepatier® (elbasvir/grazoprevir) prior authorization criteria based on clinical practice, for consistency with criteria for other Hepatitis C medications, and for clarity (changes shown in red):

Epclusa® (Sofosbuvir/Velpatasvir) Tablets and Pellets Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype-1, genotype-2, genotype-3, genotype-4, genotype-5, or genotype-6;

3. Epclusa® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
5. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

~~6. The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:~~
~~a. Genotype 1, 2, 3, 4, 5, 6:~~
~~i. Treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A):~~
~~1. Epclusa® for 12 weeks~~
~~ii. Treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Pugh B and C):~~
~~1. Epclusa® + weight-based ribavirin for 12 weeks~~
~~b. New regimens will apply as approved by the FDA~~

7. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
8. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
9. Member must sign and submit the Hepatitis C Intent to Treat contract; and
10. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
11. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
12. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and

13. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
14. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for ribavirin users); and
15. ~~Member must not be taking the following medications: H2-receptor antagonists at doses >40mg famotidine equivalent, amiodarone, omeprazole or other proton pump inhibitors, topotecan, rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, efavirenz, tenofovir disoproxil fumarate, tipranavir/ritonavir, St. John's wort, and rosuvastatin doses >10mg; and~~
16. ~~If member is using antacids, they must agree to separate antacid and Epclusa® administration by 4 hours; and~~
17. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Epclusa® and agree to address interactions with concomitant medications according to package labeling; and
18. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
19. Member must not have a limited life expectancy (<12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another direct therapy; and
20. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
21. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
22. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Sovaldi® (Sofosbuvir Tablets and Oral Pellets) Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) genotype-1, genotype-2, genotype-3, or genotype-4; and
3. Sovaldi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been

evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and

4. Sovaldi must be used as a component of a combination regimen; and
5. ~~Member must be eligible for ribavirin (RBV) or daclatasvir therapy. Approvals will not be granted for regimens without RBV or daclatasvir; and~~
6. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
7. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
        i. ~~Positive (i.e., reactive) HCV antibody test and has a recent (within the last 3 months) detectable and quantifiable HCV RNA (>15 IU/mL); or~~
        ii. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
        iii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and
8. ~~The following regimens and requirements based on genotype, prior treatment experience, and cirrhosis status will apply:~~
    ~~a. Genotype 1:~~
        ~~i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:~~
            ~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
    ~~b. Genotype 2:~~
        ~~i. Treatment-naïve, non-cirrhotic:~~
            ~~1. Sovaldi® with weight-based ribavirin for 12 weeks~~
        ~~ii. Treatment-naïve, cirrhotic:~~
            ~~1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks~~
        ~~iii. Treatment-experienced, non-cirrhotic or cirrhotic:~~
            ~~1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks~~
            ~~2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
    ~~c. Genotype 3:~~
        ~~i. Treatment-naïve, non-cirrhotic~~
            ~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
            ~~2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)~~

~~ii. Treatment-naïve, cirrhotic~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)~~
~~iii. Treatment-experienced, non-cirrhotic~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)~~
~~iv. Treatment-experienced, cirrhotic~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)~~
~~d. Genotype 4:~~
~~i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~e. New regimens will apply as approved by the FDA.~~

10. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
11. Members who are older than 6 years of age and request the oral pellet formulation of Sovaldi® must provide a patient-specific, clinically significant reason for use of the oral pellet formulation in place of the tablet formulation; and
12. Member must sign and submit the Hepatitis C Intent to Treat contract; and
13. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
14. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
15. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
16. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
17. Member must not have decompensated cirrhosis; and
18. Female members must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin members); and

19. ~~Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, phenytoin, oxcarbazepine, tipranavir/ritonavir, didanosine or St. John's wort; and~~
20. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Sovaldi® and agree to address interactions with concomitant medications according to package labeling; and
21. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and
22. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
23. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
24. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
25. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype 1, genotype 2, genotype 3, genotype 4, genotype 5, or genotype 6; and
3. Vosevi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last three months; and
4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on the prior authorization request; and
5. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:

i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

~~6. The following regimens and requirements based on treatment history will apply:~~
~~a. Adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A):~~
~~i. Genotype 1, 2, 3, 4, 5, or 6 patients who were previously treated with an HCV regimen containing an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir): Vosevi® for 12 weeks; or~~
~~ii. Genotype 1a or 3 patients who were previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor: Vosevi® for 12 weeks; or~~
~~c. New regimens will apply as approved by the FDA; and~~

7. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
8. Member must sign and submit the Hepatitis C Intent to Treat contract; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
11. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C); and
14. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
15. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy; and

~~16. Member must not be taking the following medications: H2-receptor antagonists at doses greater than 40mg famotidine twice daily equivalent, omeprazole doses greater than 20mg daily or other proton~~

~~pump inhibitors, amiodarone, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, St. John's wort, pravastatin doses greater than 40mg daily, rosuvastatin, pitavastatin, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan; and~~

~~17. If member is using antacids they must agree to separate antacid and Vosevi® administration by four hours; and~~

18. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Vosevi® and agree to address interactions with concomitant medications according to package labeling; and
19. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
20. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
21. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and
22. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Zepatier® (Elbasvir/Grazoprevir) Approval Criteria:

1. Member must be 12 years of age or older or weigh at least 30kg; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype-1 or genotype-4; and
3. Zepatier® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last three months; and
4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
5. If the member has genotype-1a, testing results for the presence of virus with NS5A resistance-associated polymorphisms must be indicated on the prior authorization request; and
6. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or

b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
   ~~i. Positive (i.e., reactive) HCV antibody test and has a recent (within the last 3 months) detectable and quantifiable HCV RNA (>15 IU/mL); or~~
   ii. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
   iii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

~~7. The following regimens and requirements based on genotype, polymorphisms, and prior treatment status will apply (all regimens apply to patients with and without cirrhosis, HIV/HCV co-infected patients, and patients with or without renal impairment):~~
   ~~a. Genotype 1a, treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms:~~
      ~~i. Zepatier® for 12 weeks~~
   ~~b. Genotype 1a, treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms:~~
      ~~i. Zepatier® with weight-based ribavirin for 16 weeks~~
   ~~c. Genotype 1b, treatment-naïve or peginterferon alfa + ribavirin experienced:~~
      ~~i. Zepatier® for 12 weeks~~
   ~~d. Genotype 1a or 1b, peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, teleprevir) experienced:~~
      ~~i. Zepatier® with weight-based ribavirin for 12 weeks~~
   ~~e. Genotype 4, treatment-naïve:~~
      ~~i. Zepatier® for 12 weeks~~
   ~~f. Genotype 4, treatment-experienced:~~
      ~~i. Zepatier® with weight-based ribavirin for 16 weeks~~
   ~~g. New regimens will apply as approved by the FDA~~

8. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
9. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
10. Member must sign and submit the Hepatitis C Intent to Treat contract; and
11. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and

12. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
13. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
14. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
15. Member must not have decompensated cirrhosis or moderate-to-severe hepatic impairment (Child-Pugh B and C); and
16. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for ribavirin users); and
17. ~~The prescriber must verify that the member's ALT levels will be monitored prior to treatment initiation, at treatment week eight, and as clinically indicated thereafter (patients receiving 16 weeks of therapy should receive additional ALT levels at treatment week 12); and~~
18. ~~Member must not be taking the following medications: phenytoin, carbamazepine, rifampin, St. John's wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, bosentan, etravirine, elvitegravir/cobicstat/ emtricitabine/tenofovir, or modafinil; and~~
19. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Harvoni® and agree to address interactions with concomitant medications according to package labeling; and
20. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
21. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
22. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
23. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
24. Approvals for treatment regimen initiation for 12 or 16 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Lastly, the College of Pharmacy recommends updating the Harvoni® (ledipasvir/sofosbuvir tablets and oral pellets) prior authorization criteria based on net costs and clinical practice and for clarity (changes shown in red):

Harvoni® (Ledipasvir/Sofosbuvir Tablets and Oral Pellets) Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype-1, genotype-4, genotype-5, or genotype-6; and
3. ~~Request for the generic formulation will require a patient-specific, clinically significant reason the member cannot use the brand formulation; and~~
4. Harvoni must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
6. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required (must be within last 3 months if requesting 8-week regimen); or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and
7. ~~The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:~~
    ~~a. Genotype 1:~~
        ~~i. Treatment-naïve without cirrhosis who have a pre-treatment HCV-RNA less than 6 million IU/mL:~~
            ~~1. Harvoni for 8 weeks~~
        ~~ii. Treatment-naïve with or without compensated cirrhosis:~~
            ~~1. Treatment-naïve patients who are cirrhotic or have a pre-treatment HCV-RNA greater than 6 million IU/mL~~
            ~~2. Harvoni for 12 weeks~~
        ~~iii. Treatment-experienced without cirrhosis:~~
            ~~1. Harvoni for 12 weeks~~

~~iv. Treatment-experienced with compensated cirrhosis:~~
~~1. Harvoni with weight-based ribavirin for 12 weeks~~
~~2. Harvoni for 24 weeks~~
~~v. Treatment-naïve or treatment-experienced with decompensated cirrhosis:~~
~~1. Harvoni with weight-based ribavirin for 12 weeks~~
~~e. Genotype 1 or Genotype 4:~~
~~i. Treatment-naïve or treatment-experienced liver transplant recipients with or without compensated cirrhosis:~~
~~1. Harvoni with weight-based ribavirin for 12 weeks~~
~~f. Genotype 4, Genotype 5, or Genotype 6:~~
~~i. Treatment-naïve or treatment-experienced with or without compensated cirrhosis:~~
~~1. Harvoni for 12 weeks~~
~~g. New regimens will apply as approved by the FDA~~

8. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
9. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
10. Members who are older than 6 years of age and request the oral pellet formulation of Harvoni must provide a patient-specific, clinically significant reason for use of the oral pellet formulation in place of the tablet formulation; and
11. Member must sign and submit the Hepatitis C Intent to Treat contract; and
12. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
13. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and
14. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
15. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
16. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for six months after therapy completion for those on ribavirin); and
17. ~~Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, tipranavir/ritonavir, simeprevir,~~

~~rosuvastatin, St. John's wort, or elvitegravir/cobicistat/emtricitabine in combination with tenofovir disoproxil fumarate; and~~

18. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Harvoni® and agree to address interactions with concomitant medications according to package labeling; and
19. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and
20. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
21. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
22. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
23. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Utilization Details of Antiviral Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HEPATITIS C MEDICATIONS						
GLECAPREVIR/PIBRENTASVIR PRODUCTS						
MAVYRET TAB 100-40MG	1,466	809	$18,728,523.73	$12,775.25	1.81	75.95%
MAVYRET PAK 50-20MG	13	8	$132,154.33	$10,165.72	1.63	0.54%
SUBTOTAL	**1,479**	**817**	**$18,860,678.06**	**$12,752.32**	**1.81**	**76.48%**
SOFOSBUVIR/VELPATASVIR PRODUCTS						
SOF/VEL TAB 400-100MG	174	67	$1,338,399.72	$7,691.95	2.6	5.43%
EPCLUSA TAB 400-100MG	27	12	$650,290.79	$24,084.84	2.25	2.64%
SUBTOTAL	**201**	**79**	**$1,988,690.51**	**$9,893.98**	**2.54**	**8.06%**
SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR PRODUCTS						
VOSEVI TAB 400-100-100MG	29	13	$632,478.35	$21,809.60	2.23	2.56%
SUBTOTAL	**29**	**13**	**$632,478.35**	**$21,809.60**	**2.23**	**2.56%**
PEGINTERFERON ALPHA-2A PRODUCTS						
PEGASYS INJ 180MCG/ML	19	3	$78,129.73	$4,112.09	6.33	0.32%
SUBTOTAL	**19**	**3**	**$78,129.73**	**$4,112.09**	**6.33**	**0.32%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RIBAVIRIN PRODUCTS						
RIBAVIRIN TAB 200MG	8	5	$729.90	$91.24	1.6	0.00%
SUBTOTAL	**8**	**5**	**$729.90**	**$91.24**	**1.6**	**0.00%**
LEDIPASVIR/SOFOSBUVIR PRODUCTS						
HARVONI TAB 90-400MG	4	3	$126,045.64	$31,511.41	1.33	0.51%
LEDIP/SOF TAB 90-400 MG	3	2	$36,034.23	$12,011.41	1.5	0.15%
SUBTOTAL	**7**	**5**	**$162,079.87**	**$23,154.27**	**1.4**	**0.66%**
ELBASVIR-GRAZOPREVIR PRODUCTS						
ZEPATIER TAB 50-100MG	6	1	$43,748.46	$7,291.41	6	0.18%
SUBTOTAL	**6**	**1**	**$43,748.46**	**$7,291.41**	**6**	**0.18%**
HEPATITIS C TOTAL	**1,749**	**912***	**$21,766,534.88**	**$12,445.13**	**1.92**	**88.27%**
HERPESVIRUSES MEDICATIONS						
VALACYCLOVIR PRODUCTS						
VALACYCLOVIR TAB 1GM	10,074	5,860	$224,813.09	$22.32	1.72	0.91%
VALACYCLOVIR TAB 500MG	7,655	3,309	$153,208.35	$20.01	2.31	0.62%
VALTREX TAB 1GM	3	2	$1,252.61	$417.54	1.5	0.01%
VALTREX TAB 500MG	1	1	$88.82	$88.82	1	0.00%
SUBTOTAL	**17,733**	**9,172**	**$379,362.87**	**$21.39**	**1.93**	**1.54%**
ACYCLOVIR PRODUCTS						
ACYCLOVIR TAB 400MG	5,153	2,479	$74,521.65	$14.46	2.08	0.30%
ACYCLOVIR TAB 800MG	1,975	1,206	$31,197.91	$15.80	1.64	0.13%
ACYCLOVIR SUS 200MG/5ML	688	500	$18,018.78	$26.19	1.38	0.07%
ACYCLOVIR CAP 200MG	661	334	$10,035.10	$15.18	1.98	0.04%
ZOVIRAX 5% CREAM	159	109	$32,183.21	$202.41	1.46	0.13%
ACYCLOVIR 5% OINTMENT	67	63	$1,400.17	$20.90	1.06	0.01%
ACYCLOVIR 5% CREAM	16	15	$1,271.98	$79.50	1.07	0.01%
ACYCLOVIR INJ 50MG/ML	1	1	$189.07	$189.07	1	0.00%
ZOVIRAX 5% OINTMENT	1	1	$155.22	$155.22	1	0.00%
SUBTOTAL	**8,721**	**4,708**	**$168,973.09**	**$19.38**	**1.85**	**0.69%**
FAMCICLOVIR PRODUCTS						
FAMCICLOVIR TAB 500MG	297	177	$8,922.19	$30.04	1.68	0.04%
FAMCICLOVIR TAB 250MG	81	30	$2,024.69	$25.00	2.7	0.01%
FAMCICLOVIR TAB 125MG	2	2	$27.73	$13.87	1	0.00%
SUBTOTAL	**380**	**209**	**$10,974.61**	**$28.88**	**1.82**	**0.04%**
VALGANCICLOVIR PRODUCTS						
VALGANCICLOVIR TAB 450MG	265	89	$35,993.70	$135.83	2.98	0.15%
VALGANCICLOVIR SOL 50MG/ML	94	29	$37,002.76	$393.65	3.24	0.15%
SUBTOTAL	**359**	**118**	**$72,996.46**	**$203.33**	**3.04**	**0.30%**
LETERMOVIR PRODUCTS						
PREVYMIS TAB 480MG	67	19	$501,504.13	$7,485.14	3.53	2.03%
PREVYMIS TAB 2400MG	8	1	$60,456.76	$7,557.10	8	0.25%
PREVYMIS PAK 120MG	1	1	$2,069.41	$2,069.41	1	0.01%
SUBTOTAL	**76**	**21**	**$564,030.30**	**$7,421.45**	**3.62**	**2.29%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MARIBAVIR PRODUCTS						
LIVTENCITY TAB 200MG	3	1	$76,964.25	$25,654.75	3	0.31%
SUBTOTAL	**3**	**1**	**$76,964.25**	**$25,654.75**	**3**	**0.31%**
HERPESVIRUS TOTAL	**27,272**	**13,054***	**$1,273,301.58**	**$46.69**	**2.09**	**5.16%**
INFLUENZA MEDICATIONS						
OSELTAMIVIR PRODUCTS						
OSELTAMIVIR SUS 6MG/ML	20,022	19,435	$580,782.52	$29.01	1.03	2.36%
OSELTAMIVIR CAP 75MG	18,568	18,172	$391,172.27	$21.07	1.02	1.59%
OSELTAMIVIR CAP 30MG	929	901	$24,731.89	$26.62	1.03	0.10%
OSELTAMIVIR CAP 45MG	522	512	$12,896.54	$24.71	1.02	0.05%
TAMIFLU SUS 6MG/ML	241	240	$66,710.20	$276.81	1	0.27%
TAMIFLU CAP 75MG	16	16	$2,510.24	$156.89	1	0.01%
TAMIFLU CAP 30MG	4	4	$881.68	$220.42	1	0.00%
TAMIFLU CAP 45MG	2	2	$301.50	$150.75	1	0.00%
SUBTOTAL	**40,304**	**39,282**	**$1,079,986.84**	**$26.80**	**1.03**	**4.38%**
BALOXAVIR PRODUCTS						
XOFLUZA TAB 40MG	2,178	2,131	$367,883.55	$168.91	1.02	22.72%
XOFLUZA TAB 80MG	1,025	1,003	$171,522.65	$167.34	1.02	10.59%
SUBTOTAL	**3,203**	**3,134**	**$539,406.20**	**$168.41**	**1.02**	**33.30%**
ZANAMIVIR PRODUCTS						
RELENZA DISKHALER	2	2	$136.10	$68.05	1	0.01%
SUBTOTAL	**2**	**2**	**$136.10**	**$68.05**	**1**	**0.01%**
INFLUENZA SUBTOTAL	**43,509**	**42,121***	**$1,619,529.14**	**$37.22**	**1.03**	**6.57%**
TOTAL	**72,530**	**55,248***	**$24,659,365.60**	**$339.99**	**1.31**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; LEDIP = ledipasvir; PAK = pack; SOF = sofosbuvir; SOL = solution; SUS = suspension; TAB = tablet; VEL = velpatasvir
Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: Mavyret® (glecaprevir/pibrentasvir) is available without prior authorization and is SoonerCare's preferred direct acting antiviral (DAA) for the treatment of acute or chronic hepatitis C virus (HCV). Use of an alternative regimen for the treatment of HCV requires patient-specific, clinically significant reasoning why the preferred DAA is not appropriate for the member.

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[3] U.S. FDA. FDA Approves First Treatment for Chronic Hepatitis Delta Virus (HDV) Infection. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-chronic-hepatitis-delta-virus-hdv-infection. Issued 05/22/2026. Last accessed 05/29/2026.
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[9] Study to Assess Efficacy and Safety of Bulevirtide in Participants with Chronic Hepatitis Delta (CHD). *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT03852719?tab=study. Last revised 08/22/2025. Last accessed 05/29/2026.

Appendix Q

Fiscal Year 2025 Annual Review of Urea Cycle Disorder (UCD) Medications and 30-Day Notice to Prior Authorize Loargys® (Pegzilarginase-nbln)

Oklahoma Health Care Authority
June 2026

Current Prior Authorization Criteria

Carbaglu® (Carglumic Acid) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; or
    b. Maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency; or
    c. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA); and
2. Carbaglu® must be prescribed by a geneticist or in consultation with a geneticist; and
3. Carbaglu® is brand preferred; use of generic carglumic acid will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. For a diagnosis of hyperammonemia due to NAGS deficiency:
    a. Documentation of active management with a low protein diet; and
    b. Initial approvals will be for the duration of 1 year. After that time, reauthorization will require the prescriber to verify the member is responding well to therapy; or
5. For a diagnosis of acute hyperammonemia due to PA or MMA:
    a. Documentation that the member's plasma ammonia level is ≥50micromol/L; and
    b. Prescribed must confirm Carbaglu® is being used concurrently with other ammonia-lowering therapies [e.g., intravenous (IV) glucose, insulin, L-carnitine, protein restriction, dialysis]; and
    c. Number of days Carbaglu® was received while hospitalized must be provided; and
    d. Approvals will be for no longer than 7 days total (including treatment days while hospitalized) as there is currently no evidence to support the use of Carbaglu® for acute hyperammonemia due to PA or MMA beyond 7 days.

Olpruva® (Sodium Phenylbutyrate Pellets for Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
5. A maximum daily dose of 20g of sodium phenylbutyrate will apply.

Pheburane® (Sodium Phenylbutyrate Oral Pellets) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
4. A maximum daily dose of 20g sodium phenylbutyrate will apply; and
5. A quantity limit of 1,218g of pellets (equivalent to 588g of sodium phenylbutyrate) per 29 days will apply.

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Active management with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®) must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
5. Ravicti® is brand preferred; use of generic glycerol phenylbutyrate will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
6. A maximum daily dose of 17.5mL (19g) of glycerol phenylbutyrate will apply; and
7. A quantity limit of 525mL per 30 days will apply.

Utilization of UCD Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

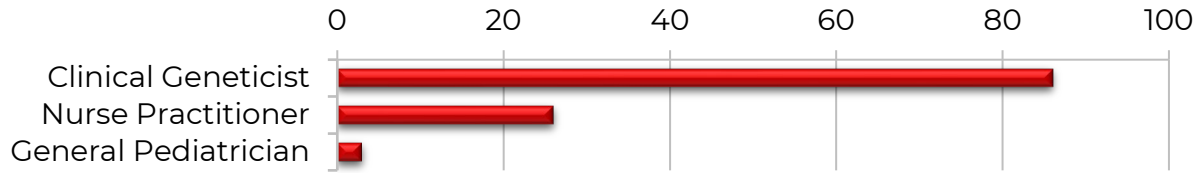
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	13	124	$6,157,183.59	$49,654.71	$1,812.54	28,190	3,397
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	2	6	$204,980.46	$34,163.41	$1,158.08	900	177
OCH	3	9	$1,095,972.09	$121,774.68	$4,104.76	4,920	267
2024 Total	**13**	**139**	**$7,458,136.14**	**$53,655.66**	**$1,941.72**	**34,010**	**3,841**
Fiscal Year 2025							
FFS	8	76	$4,049,914.16	$53,288.34	$1,992.09	17,725	2,033
Aetna	1	5	$59,197.05	$11,839.41	$514.76	250	115
Humana	2	16	$605,406.92	$37,837.93	$1,296.37	2,650	467
OCH	3	18	$2,511,937.98	$139,552.11	$4,877.55	11,205	515
2025 Total	**12**	**115**	**$7,226,456.11**	**$62,838.75**	**$2,308.77**	**31,830**	**3,130**
% Change	**-7.70%**	**-17.30%**	**-3.10%**	**17.10%**	**18.90%**	**-6.40%**	**-18.50%**
Change	**-1**	**-24**	**-$231,680.03**	**$9,183.09**	**$367.05**	**-2,180**	**-711**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing UCD Medications (All Plans)

- Due to the limited number of members utilizing UCD medications, detailed demographic information could not be provided.

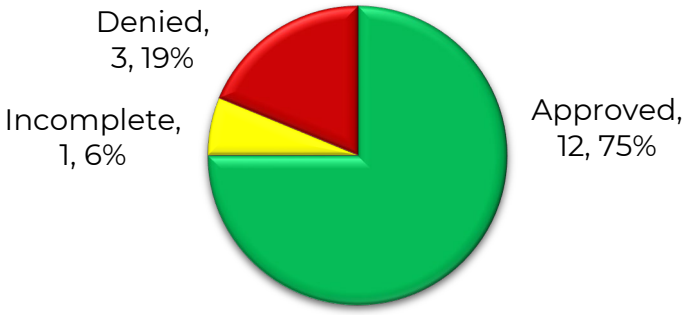
Top Prescriber Specialties of UCD Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of UCD Medications

There were 16 prior authorization requests submitted for UCD medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	9	56%	0	0%	3	19%	**12**
Aetna	1	6%	0	0%	0	0%	**1**
Humana	1	6%	0	0%	0	0%	**1**
OCH	1	6%	1	6%	0	0%	**2**
Total	**12**	**75%**	**1**	**6%**	**3**	**19%**	**16**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11]

Anticipated Patent Expiration(s):

- Ravicti® (glycerol phenylbutyrate): March 2032
- Olpruva® (sodium phenylbutyrate): October 2036

New U.S. Food and Drug Administration (FDA) Approval(s):

- **February 2026:** The FDA approved Loargys® (pegzilarginase-nbln) for the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with arginase 1 deficiency (ARG1-D), in conjunction with dietary protein restriction.

News:

- An internal literature review was conducted on the established evidence for the long-term use of Carbaglu® (carglumic acid), which indicated its safety and efficacy for long-term management in propionic acidemia (PA) or methylmalonic acidemia (MMA) beyond 7 days.

Pipeline:

- **DTX301:** DTX301 is an investigational Phase 3 intravenous (IV) gene therapy designed to improve ornithine transcarbamylase (OTC) functionality in patients 12 years of age and older with OTC deficiency. OTC, an enzyme produced by the liver, is responsible for ammonia degradation by enzymatically converting it to urea for excretion.

Ammonia is a byproduct of protein metabolism and is toxic to the central nervous system. If OTC functionality was restored, patients would no longer rely on protein restriction or chronic administration of nitrogen binders for ammonia regulation. The Phase 3 Enh3ance trial has completed enrollment and the trial is estimated to be completed in March 2031. DTX301 was granted Orphan Drug and Fast Track designations by the FDA.

Loargys® (Pegzilarginase-nbln) Product Summary[12,13,14,15,16]

Therapeutic Class: Human arginase 1 enzyme

Indication(s): Treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with ARG1-D, in conjunction with dietary protein restriction

- This indication is approved under accelerated approval based on reduction of plasma arginine. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

How Supplied: 2mg/0.4mL single-dose vial (SDV)

Dosing and Administration:

- Prior to initiating Loargys®, baseline plasma arginine (pArg) concentrations should be obtained.
- Pre-medication with antihistamines should be considered.
- The recommended starting dose is 0.1mg/kg administered once weekly via IV infusion.
- After 4 weeks of treatment, pre-dose pArg should be assessed for potential dosage adjustments. The maximum recommended dosage is 0.2mg/kg once weekly.
    - For pArg <50 micromolar, the weekly dosage should be reduced by 0.05mg/kg.
    - For pArg >150 micromolar, the weekly dosage should be increased by 0.05mg/kg.
- After 8 weeks of IV administration, a subcutaneous (sub-Q) route may be considered at the same dosage.
- Initial doses of Loargys® should be given in a health care setting equipped to manage hypersensitivity reactions. If maintenance doses are well tolerated, home administration under health care supervision can be considered.

Efficacy: The efficacy and safety of Loargys® were evaluated in the Phase 3, randomized, multicenter, double-blind, 24-week placebo-controlled PEACE trial.

- Key Inclusion Criteria:
  - Diagnosis of ARG1-D defined as elevated pArg, pathogenic variants in the *ARG1* gene, and/or diminished erythrocyte ARG1 activity
  - 2 years of age or older
  - Average pArg >250 micromolar
  - Impairment on any secondary functional mobility assessment
  - Currently receiving stabilized dosing or standards of care treatment with protein restriction
- Interventions:
  - Patients were randomized 2:1 to Loargys® or placebo at a starting dose of 0.1mg/kg weekly.
  - Weekly dosage was adjusted to achieve pArg within 50-150 micromolar/L measured at the end of the dosing interval (168 hours post-dose).
  - The PEACE trial utilized validated cerebral palsy assessments for clinical mobility response [Gross Motor Function Measure involving walking, running, and jumping (GMFM-E) and 2-minute walk test (2MWT)].
- Endpoints:
  - The primary endpoint was a change from baseline pArg at week 24.
  - The secondary endpoint was clinical improvement assessed through functional mobility scores (GMFM-E and 2MWT).
- Results:
  - The primary endpoint in the PEACE trial was met with a statistically significant decrease in pArg levels in the Loargys® group (baseline pArg of 365 micromolar to 92 micromolar at week 24) compared to placebo [baseline pArg of 472 micromolar to 449 micromolar at week 24; 95% confidence interval (CI): -72% (-89%, -55%); P<0.0001].
  - Additionally, 90% of patients on Loargys® had pArg levels <200 micromolar at the end of the 24-week study while none of the placebo-treated patients met this target.

Cost: The Wholesale Acquisition Cost (WAC) of Loargys® is $11,469.31 for (1) 2mg/0.4mL SDV. For a member weighing 80kg, this would result in a cost of $367,017.92 every 4 weeks of treatment and an estimated cost of $4,771,232.96 per year based on the FDA maximum dose of 0.2mg/kg every week.

Recommendations

The College of Pharmacy recommends the prior authorization of Loargys® (pegzilarginase-nbln) with the following criteria (shown in red):

Loargys® (Pegzilarginase-nbln) Approval Criteria:

1. An FDA approved diagnosis of arginase 1 deficiency (ARG1-D); and

a. Diagnosis of ARG1-D must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
    i. Persistently elevated plasma arginine levels; or
    ii. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *ARG1* gene; or
    iii. Diminished erythrocyte ARG1 activity; and
2. Member must be 2 years of age or older; and
3. Loargys® must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of ARG1-D; and
4. Loargys® must be administered under the direct supervision of a health care provider; and
5. Active management with a protein restricted diet; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
7. The maximum approvable dose of Loargys® is 0.2mg/kg once weekly; and
8. Initial approvals will be for 6 months. Subsequent approvals for the duration of 1 year will be approved if the prescriber documents the member is responding to treatment (i.e., reduction or normalization in plasma arginine levels); and
9. A quantity limit of 12mL per 28 days will apply. For members who require doses exceeding this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

Additionally, the College of Pharmacy recommends updating the approval criteria for Carbaglu® (carglumic acid) based on clinical practice (changes shown in red):

Carbaglu® (Carglumic Acid) Approval Criteria:

1. An indication of the treatment of acute or chronic hyperammonemia due to 1 of the following:
    a. N-acetylglutamate synthase (NAGS) deficiency; or
    b. Propionic acidemia (PA) or methylmalonic acidemia (MMA); and
~~2. An FDA approved indication of 1 of the following:~~
    ~~a. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; or~~
    ~~b. Maintenance therapy for the treatment of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; or~~

~~c. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA); and~~

3. Carbaglu® must be prescribed by a geneticist or in consultation with a geneticist; and
4. Carbaglu® is brand preferred; use of generic carglumic acid will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. For a diagnosis of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency:
    a. Documentation of active management with a low protein diet; and
    b. Initial approvals will be for the duration of 1 year. After that time, reauthorization will require the prescriber to verify the member is responding to therapy; or

~~6. For a diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA):~~

~~a. Documentation the member's plasma ammonia level is ≥50micromol/L; and~~

~~b. Prescriber must confirm Carbaglu® is being used concurrently with other ammonia-lowering therapies [e.g., intravenous (IV) glucose, insulin, L-carnitine, protein restriction, dialysis]; and~~

~~c. Number of days Carbaglu® was received while hospitalized must be provided; and~~

~~d. Approvals will be for no longer than 7 days total (including treatment days while hospitalized) as there is currently no evidence to support the use of Carbaglu® for acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) beyond 7 days.~~

7. For a diagnosis of hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA):
    a. Prescriber must confirm Carbaglu® is being used concurrently with standard of care treatment (e.g., L-carnitine, metronidazole, protein-restricted diet); and
    b. Initial approvals will be for the duration of 6 months. Subsequent approvals, for the durations of 1 year, may be granted if the prescriber attests that the member is tolerating and responding well to therapy.

Lastly, the College of Pharmacy recommends updating the approval criteria for Olpruva® (sodium phenylbutyrate pellets for oral suspension) and Pheburane® (sodium phenylbutyrate oral pellets) based on clinical practice and recommends updating the approval criteria for Ravicti® (glycerol

phenylbutyrate) based on clinical practice and net cost (changes shown in red):

Olpruva® (Sodium Phenylbutyrate Pellets for Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. Olpruva® must be prescribed by, or in consultation with, a geneticist; and
4. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
6. A maximum daily dose of 20g of sodium phenylbutyrate will apply.

Pheburane® (Sodium Phenylbutyrate Oral Pellets) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. Pheburane® must be prescribed by, or in consultation with, a geneticist; and
4. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
5. A maximum daily dose of 20g sodium phenylbutyrate will apply; and
6. A quantity limit of 1,218g of pellets (equivalent to 588g of sodium phenylbutyrate) per 29 days will apply.

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Active management with a protein restricted diet; and
3. ~~A patient-specific, clinically significant reason why member cannot use Buphenyl (sodium phenylbutyrate) must be provided; and~~
4. Ravicti® must be prescribed by, or in consultation with, a geneticist; and
5. Ravicti® is brand preferred; use of generic glycerol phenylbutyrate will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
6. A maximum daily dose of 17.5mL (19g) of glycerol phenylbutyrate will apply; and
7. A quantity limit of 525mL per 30 days will apply.

Utilization Details of UCD Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RAVICTI LIQ 1.1MG/ML	103	11	$4,208,921.59	$70,159.77	10.45	51.34%
CARBAGLU TAB 200MG	12	1	$3,017,534.52	$602,204.68	12	48.66%
TOTAL	**115**	**12***	**$7,226,456.11**	**$62,838.75**	**10.69**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members
PA = prior authorization; LIQ = liquid; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix R

Fiscal Year 2025 Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Cafergot® (Ergotamine/Caffeine Tablet), Desmoda™ (Desmopressin Oral Solution), Dicyclomine 40mg Tablet, Griseofulvin Ultramicrosize 165mg Tablet, Hydroxyzine Oral Solution Unit Dose Cups (UDCs), Khindivi™ (Hydrocortisone Oral Solution), Migergot® (Ergotamine/Caffeine Suppository), Ontralfy™ (Tizanidine Oral Solution), PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet, Quiofic™ (Folic Acid Oral Solution), Relgaabi™ (Gabapentin 200mg Capsule), and Vykoura™ (Leucovorin Injection)

Oklahoma Health Care Authority
June 2026

Introduction

Multiple formulations of medications are made for ease of administration, to increase bioavailability, or as new technologies are created, to provide a more efficient treatment response. Some of the new formulations incur greater costs for production, resulting in greater costs for the payer and consumer. A clinical review of each product and its comparative cost to other formulations is provided in the following report for reference. The data included in this report combines fee-for-service (FFS; SoonerCare) and managed care (SoonerSelect) utilization for fiscal year 2025 (07/01/2024 to 06/30/2025).

Current Prior Authorization Criteria

Absorica LD® (Isotretinoin Capsule) Approval Criteria:

1. An FDA approved diagnosis of severe recalcitrant nodular acne in non-pregnant members 12 years of age and older with multiple inflammatory nodules with a diameter of 5mm or greater; and
2. Absorica LD® is not covered for members older than 20 years of age; and

3. Prescriber must verify member is enrolled in the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) program; and
4. Prescriber must verify lipid profile and liver function tests will be monitored prior to initiation of Absorica LD® and at regular intervals during treatment in accordance with the package labeling; and
5. A patient-specific, clinically significant reason why the member cannot use other isotretinoin capsules available without prior authorization must be provided; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of medication according to package labeling.

Alkindi Sprinkle® (Hydrocortisone Oral Granule) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed, must be provided.

Bucapsol™ (Buspirone Capsule) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use buspirone tablets, even when the tablets are crushed, must be provided.

Eohilia™ (Budesonide Oral Suspension) Approval Criteria:

1. An established diagnosis of eosinophilic esophagitis (EoE) defined as:
    a. The presence of clinical symptoms of EoE ≥2 times per week (i.e., dysphagia, emesis, epigastric pain); and
    b. Intraepithelial eosinophilia [≥15 eosinophils per high-power field (eos/hpf)] in the esophagus; and
2. Member must be 11 years of age or older; and
3. Must be prescribed by a gastroenterologist, allergist, or immunologist, or the member must have been evaluated by a gastroenterologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and
4. Member must have a documented trial for a minimum of 8 weeks that resulted in failure with 1 high-dose proton pump inhibitor (i.e., omeprazole 20-40mg twice daily or equivalent in adults or 1-2mg/kg of omeprazole daily or equivalent in children) or have a contraindication or documented intolerance; and
5. A patient specific, clinically significant reason why the member cannot use a swallowed respiratory corticosteroid (e.g., budesonide, fluticasone) must be provided; and
6. Approvals will be for (1) 3-month treatment course; and

7. A quantity limit of 600mL per 30 days will apply; and
8. Eohilia™ will not be approved for maintenance treatment. Reauthorization for additional 3-month treatment course(s) may be considered if the prescriber documents the following:
    a. The member had a positive initial response to Eohilia™; and
    b. Is now experiencing recurrent worsening symptoms of EoE after completing the treatment course with Eohilia™; and
    c. A patient specific, clinically significant reason why the member still cannot use a swallowed respiratory corticosteroid (e.g., budesonide, Flovent) must be provided.

Ermeza™ (Levothyroxine Oral Solution) and Thyquidity® (Levothyroxine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
    b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the oral solutions, a reason why the member cannot use the levothyroxine tablet formulation, even when the tablets are crushed, must be provided; and
3. Prescriber must verify member has been compliant with levothyroxine tablets at a greatly increased dose for at least 8 weeks; and
4. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite a greatly increased dose and compliance with levothyroxine tablets.

Femlyv™ [Norethindrone Acetate and Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Nextstellis® (Drospirenone/Estetrol Tablet), and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without prior authorization must be provided.

Gimoti® (Metoclopramide Nasal Spray) Approval Criteria:

1. An FDA approved indication of acute or recurrent diabetic gastroparesis in adult members; and
2. A patient-specific, clinically significant reason why the member cannot use metoclopramide oral tablets and metoclopramide oral solution must be provided; and

3. For members 65 years of age or older, approvals will not be granted for initiation of metoclopramide therapy; and
4. For members 65 years of age or older requesting to switch from an alternative metoclopramide product to Gimoti®:
    a. Member must be taking a stable dose of metoclopramide 10mg 4 times daily for at least 10 days; and
    b. Duration of current metoclopramide treatment must be provided; and
5. A maximum approval duration of 8 weeks total from all sources will apply; and
6. A quantity limit of 9.8mL per 28 days will apply.

Gralise® [Gabapentin Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved indication of postherpetic neuralgia (PHN); and
2. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
    a. Tricyclic antidepressants; or
    b. Anticonvulsants; or
    c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Horizant® [Gabapentin Enacarbil Extended-Release (ER) Tablet] Approval Criteria:

1. For the FDA approved indication of restless leg syndrome:
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts at recommended dosing with at least 2 of the following medications that did not yield adequate relief:
        i. Carbidopa/levodopa; or
        ii. Pramipexole; or
        iii. Ropinirole; and
    c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.
2. For the FDA approved indication of postherpetic neuralgia (PHN):
    a. Member must be 18 years of age or older; and
    b. Documented treatment attempts, at recommended dosing, with at least 1 agent from 2 of the following drug classes that did not yield adequate relief:
        i. Tricyclic antidepressants; or
        ii. Anticonvulsants; or

iii. Topical or oral analgesics; and

c. A patient-specific, clinically significant reason why the member cannot take the immediate-release formulation of gabapentin must be provided.

Jylamvo® (Methotrexate Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Treatment of adults and pediatric members with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen; or
   b. Treatment of adults with mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or
   c. Treatment of pediatric members with polyarticular juvenile idiopathic arthritis (pJIA); or
   d. Treatment of adults with relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or
   e. Treatment of adults with rheumatoid arthritis; or
   f. Treatment of adults with severe psoriasis; and
2. A patient-specific clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.

Khapzory® (Levoleucovorin Injection) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Rescue after high-dose methotrexate (MTX) therapy in members with osteosarcoma; or
   b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or
   c. Treatment of members with metastatic colorectal cancer in combination with fluorouracil; and
2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection must be provided.

Klor-Con® (Potassium Chloride 20mEq Packet) and PoKonza™ (Potassium Chloride 10mEq Packet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all the following must be provided:
   a. Potassium chloride tablet; and
   b. Potassium chloride extended-release (ER) dispersible tablet; and
   c. Potassium chloride ER sprinkle capsule; and
   d. Potassium chloride oral solution.

Kristalose® (Lactulose Packet for Oral Solution) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the liquid lactulose formulation must be provided.

Lodoco® (Colchicine) Approval Criteria:

1. An FDA approved indication to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death; and
2. Member must be 18 years of age or older; and
3. Member must have a diagnosis history of clinical atherosclerotic cardiovascular disease (ASCVD); and
    a. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD must be provided;
4. Member must already be receiving guideline-directed therapy for atherosclerotic disease, as documented in the member's pharmacy claims history, unless contraindicated; and
5. Lodoco® must be prescribed by a cardiologist or other specialist with expertise in the treatment and management of ASCVD; and
6. Member must not have kidney failure, severe liver disease, or pre-existing blood dyscrasias; and
7. The member must not be taking any P-gp inhibitors (e.g., cyclosporine, ranolazine) or strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, ketoconazole) concurrently with Lodoco®; and
8. A patient-specific, clinically significant reason why the member cannot use the 0.6mg tablet, which is available without a prior authorization, must be provided; and
9. A quantity limit of 30 tablets per 30 days will apply.

Lyrica® CR [Pregabalin Extended-Release (ER) Capsule] Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Neuropathic pain associated with diabetic peripheral neuropathy (DPN); or
    b. Neuropathic pain associated with postherpetic neuralgia (PHN); and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation of pregabalin must be provided; and
3. Requests exceeding once daily dosing will not be approved.

Metozolv® ODT [Metoclopramide Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the metoclopramide oral tablet formulation must be provided.

Millipred™ (Prednisolone 5mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use prednisone 5mg tablets, methylprednisolone 4mg tablets, or alternative oral corticosteroids that are available without a prior authorization must be provided.

Millipred™ (Prednisolone Sodium Phosphate 10mg/5mL Oral Solution) and Veripred™ 20 (Prednisolone Sodium Phosphate 20mg/5mL Oral Solution) Approval Criteria:

1. Approval of Millipred™ or Veripred™ 20 requires a patient-specific, clinically significant reason why the member cannot use an alternative strength liquid formulation of generic prednisolone oral solution including the 5mg/5mL, 15mg/5mL, and 25mg/5mL strengths which are available without a prior authorization.

Myhibbin® (Mycophenolate Mofetil Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use generic Cellcept® (mycophenolate mofetil for oral suspension), which is available without a prior authorization, must be provided.

Orapred ODT® [Prednisolone Sodium Phosphate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use an alternative oral corticosteroid tablet or generic prednisolone oral solutions (5mg/5mL, 15mg/5mL, and 25mg/5mL strengths) that are available without a prior authorization; and
2. A quantity of 10 ODTs will be available without prior authorization for members 10 years of age or younger.

Otrexup® and Rasuvo® (Methotrexate Injection Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Severe, active rheumatoid arthritis (RA) in adult members; or
    b. Active polyarticular juvenile idiopathic arthritis (pJIA) in pediatric members; or
    c. Severe, recalcitrant, disabling psoriasis confirmed by biopsy or dermatologic consultation; and
2. A patient-specific, clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.

Phexxi® (Lactic Acid/Citric Acid/Potassium Bitartrate Vaginal Gel) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use an over-the-counter (OTC) spermicide and all other forms of contraception (e.g., condoms, oral contraceptives) must be provided.

Various OTC spermicides containing nonoxynol 9 are covered by SoonerCare without prior authorization.

Pyridostigmine 30mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use pyridostigmine 60mg tablets, which are available without prior authorization, must be provided.

Rayos® (Prednisone Delayed-Release Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use immediate-release corticosteroid medications must be provided.

TaperDex™ (Dexamethasone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use dexamethasone 1.5mg individual tablets, which are available without a prior authorization, must be provided.

Taytulla® (Norethindrone Acetate/Ethinyl Estradiol Capsule and Ferrous Fumarate Capsule) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use all other generic formulations of norethindrone acetate/ethinyl estradiol tablets with ferrous fumarate tablets must be provided.

Vuity® (Pilocarpine Hydrochloride 1.25% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication of the treatment of presbyopia in adults; and
2. Must be prescribed by an ophthalmologist or optometrist; and
3. Prescriber must verify the member does not have iritis; and
4. Prescriber must verify the member has been counseled on the risk of retinal detachment with use of Vuity® and when to seek immediate medical care; and
5. Prescriber must verify the member has been advised to use caution with night driving and hazardous occupations in poor illumination as vision may not be clear in these conditions while using Vuity®; and
6. A patient-specific, clinically significant reason why the member cannot use corrective lenses must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use generic pilocarpine ophthalmic solution (Isopto® Carpine) must be provided.

Xatmep® (Methotrexate 2.5mg/mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:

a. Treatment of pediatric members with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen; or
b. Management of pediatric members with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy; and

2. A patient-specific, clinically significant reason why the oral tablets or generic injectable formulation cannot be used must be provided.

Zilretta® [Triamcinolone Acetonide Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of osteoarthritis (OA) pain of the knee; and
2. Zilretta® will only be approvable for use in the knee(s) for OA pain; and
3. A patient-specific, clinically significant reason why the member cannot use Kenalog-40® (triamcinolone acetonide 40mg injection) and Depo-Medrol® (methylprednisolone injection) must be provided; and
4. A quantity limit of 1 injection per knee per 12 weeks will apply.

Utilization of Various Special Formulations: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	694	1,385	$283,641.46	$204.80	$8.99	31,085	31,535
Aetna	90	120	$21,775.56	$181.46	$7.82	3,240	2,783
Humana	87	112	$22,264.65	$198.79	$7.50	3,252	2,968
OCH	157	209	$62,466.28	$298.88	$7.83	8,862	7,976
2024 Total	**958**	**1,826**	**$390,147.95**	**$213.66**	**$8.62**	**46,438**	**45,262**
Fiscal Year 2025							
FFS	92	260	$89,332.03	$343.58	$9.90	14,518	9,021
Aetna	146	349	$112,693.79	$322.90	$10.83	15,321	10,406
Humana	143	372	$115,054.44	$309.29	$8.20	17,842	14,037
OCH	179	399	$137,380.27	$344.31	$9.67	19,136	14,214
2025 Total	**548**	**1,380**	**$454,460.53**	**$329.32**	**$9.53**	**66,817**	**47,678**
% Change	**-42.80%**	**-24.40%**	**16.50%**	**54.10%**	**10.60%**	**43.90%**	**5.30%**
Change	**-410**	**-446**	**$64,312.58**	**$115.66**	**$0.91**	**20,379**	**2,416**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

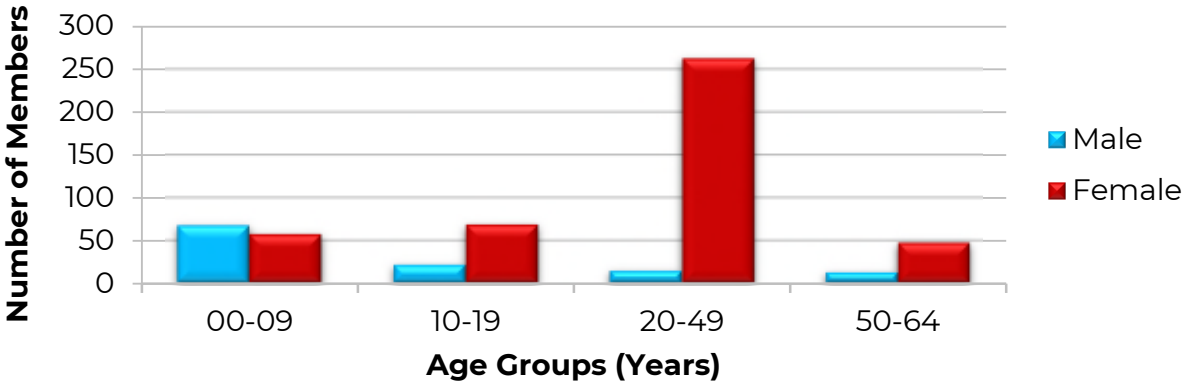
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	16	21	$15,528.84	$739.47	1.31
Aetna	1	1	$1,119.36	$1,119.36	1
Humana	1	1	$561.28	$561.28	1
OCH	2	2	$2,238.72	$1,119.36	1
2024 Total	**19**	**25**	**$19,448.20**	**$777.93**	**1.32**
Fiscal Year 2025					
FFS	7	13	$10,312.32	$793.26	1.86
Aetna	3	4	$2,485.14	$621.29	1.33
Humana	5	5	$2,824.07	$564.81	1
OCH	3	3	$3,440.00	$1,146.67	1
2025 Total	**18**	**25**	**$19,061.53**	**$762.46**	**1.39**
% Change	**-5.26%**	**0.00%**	**-1.99%**	**-1.99%**	**5.30%**
Change	**-1**	**0**	**-$386.67**	**-$15.47**	**0.07**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

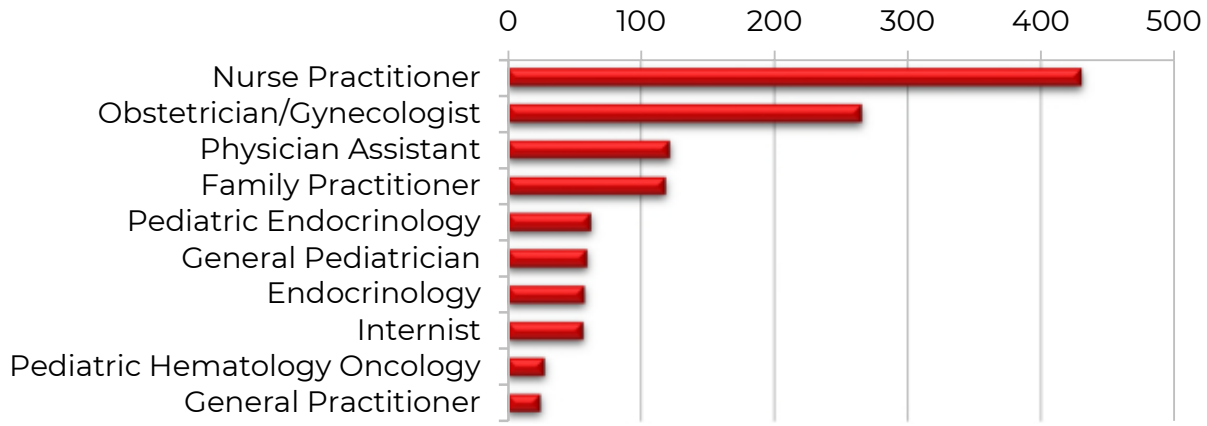
- Due to the evolving nature of this category, fiscal year comparisons may not reflect the same product utilization from year to year.
- Aggregate drug rebates collected during fiscal year 2025 for the various special formulations totaled $179,800.87.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Various Special Formulations: Pharmacy Claims (All Plans)



[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

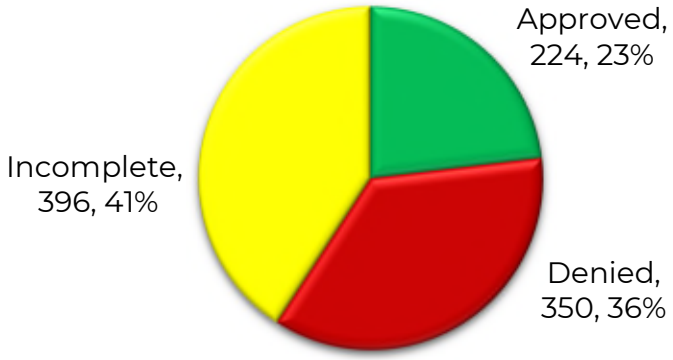
Top Prescriber Specialties of Various Special Formulations by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Various Special Formulations

There were 970 prior authorization requests submitted for various special formulations during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	88	17%	316	60%	119	23%	**523**
Aetna	28	19%	62	42%	59	40%	**149**
Humana	66	45%	0	0%	82	55%	**148**
OCH	42	28%	18	12%	90	60%	**150**
Total	**224**	**23%**	**396**	**41%**	**350**	**36%**	**970**

FFS = fee-for-service; OCH = OK Complete Health

Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate) Product Summary[1,2]

Therapeutic Class: Contraceptives

Indication(s): For use by females of reproductive potential to prevent pregnancy

How Supplied:

- 21 orange tablets each containing 0.15mg desogestrel and 0.03mg ethinyl estradiol
- 7 blue tablets each containing ferrous bisglycinate 36.5mg

Dosing and Administration:

- Take 1 tablet by mouth at the same time daily

Other Formulation(s) Available:

- Branded generics Apri®, Cyred EQ®, Enskyce™, Isibloom®, Juleber™, Kalliga™, Reclipsen™ (Desogestrel/Ethinyl Estradiol 0.15mg/0.03mg Tablets):
  - These branded generics are supplied as 21 active tablets each containing 0.15mg desogestrel and 0.03mg ethinyl estradiol and 7 tablets containing inert ingredients.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per Year*
Averi™ (desogestrel/ethinyl estradiol/ferrous bisglycinate 0.15mg/0.03mg/36.5mg tablets)	**$7.41**	**$2,697.24**
Apri® (desogestrel/ethinyl estradiol 0.15mg/0.03mg tablets)	$0.13	$47.32

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per year based on the U.S. Food and Drug Administration (FDA) approved dose of 1 tablet daily.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of Averi™ during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
ISIBLOOM TAB 0.15MG/0.03MG	427	152	$7,824.51	2.81	$18.32
APRI TAB 0.15MG/0.03MG	171	57	$3,044.31	3	$17.80
ENSKYCE TAB 0.15MG/0.03MG	130	60	$3,014.74	2.17	$23.19
JULEBER TAB 0.15MG/0.03MG	63	28	$1,191.39	2.25	$18.91
RECLIPSEN TAB 0.15MG/0.03MG	29	14	$500.18	2.07	$17.25
TOTAL	**820**	**281***	**$15,575.13**	**2.92**	**$18.99**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet

Cafergot® (Ergotamine/Caffeine Tablet) and Migergot® (Ergotamine/Caffeine Suppository) Product Summary[3,4,5]

Therapeutic Class: Ergot alkaloids/stimulant

Indication(s): Therapy to abort or prevent vascular headache in adults (e.g., migraine, migraine variants or so-called "histaminic cephalalgia")

How Supplied:

- Cafergot®: Tablet containing 1mg of ergotamine and 100mg of caffeine
- Migergot®: Suppository containing 2mg of ergotamine and 100mg of caffeine

Dosing and Administration:

- For the best results, dosage should start at the first sign of an attack.
- Cafergot®: Take 2 tablets at the start of attack, and 1 additional tablet every half hour may be taken if needed for full relief with a maximum of 6 tablets per attack and 10 tablets per week.
- Migergot®: Insert 1 suppository rectally at the start of the attack, and 1 additional suppository may be used after 1 hour, if needed for full relief with a maximum of 5 suppositories per week (10mg of ergotamine).

Other Formulation(s) Available:

- Ergomar® (Ergotamine) 2mg Sublingual (SL) Tablet:
  - Ergomar® has the same indication as Cafergot and Migergot®; however, it is available without caffeine and should be administered SL.
  - The FDA maximum dose per week is 10mg of ergotamine, which is the same as Cafergot® and Migergot®.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days*
Migergot® (ergotamine/caffeine 2mg/100mg suppository)	**$225.74**	**$4,514.80**
Cafergot® (ergotamine/caffeine 1mg/100mg tablet)	**$37.71**	**$1,508.40**
Ergomar® (ergotamine 2mg SL tablet)	$41.32	$826.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 28 days is based on the FDA maximum dose of ergotamine which is 10mg per week.
Unit = tablet or suppository
SL = sublingual

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of Cafergot®, Ergomar®, or Migergot® during fiscal year 2025.

Desmoda™ (Desmopressin Oral Solution) Product Summary[6,7,8,9,10]

Therapeutic Class: Vasopressin analog

Indication(s):

- Management of arginine vasopressin deficiency (AVP-D), also known as central diabetes insipidus, as antidiuretic replacement therapy for adults and pediatric patients
  - Limitations of Use: Desmoda™ is not indicated for the treatment of AVP-resistance (AVP-R), also known as nephrogenic diabetes insipidus.

How Supplied: 0.05mg/1mL oral solution in a 145mL bottle

Dosing and Administration:

- The recommended starting dose for adults and pediatric patients is 0.05mg (50mcg) twice daily.
- Titrate the daily dose as needed to obtain an adequate antidiuretic response.
- Desmoda™ should be taken on an empty stomach, at least 1 hour before or 2 hours after food.

Other Formulation(s) Available:

- Desmopressin 10mcg/0.1mL Nasal Spray:
  - Desmopressin nasal spray has the same indication as Desmoda™; however, the dosing is different. The intranasal desmopressin formulation is approximately 10 to 40-fold more potent than the oral formulation.
  - The recommended starting dose in adults is 10mcg once daily into 1 nostril up to 40mcg once daily (or 40mcg divided into 2 or 3 daily doses).
- Desmopressin 0.1mg and 0.2mg Tablets:
  - Desmopressin tablets are indicated for AVP-D and primary nocturnal enuresis.
  - Dosing for the tablets is similar to Desmoda™ with a starting daily dose of 0.05mg (half of the 0.1mg tablet) twice daily. The optimal dose ranged from 0.1mg to 0.8mg daily, administered in divided doses.
  - Tablets should be swallowed whole, but they can be crushed for those who cannot swallow the tablets.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Desmoda™ (desmopressin 0.05mg/mL oral sol)	**$122.50**	**$58,800.00***	**$705,600.00**

desmopressin 10mcg/0.1mL nasal spray (generic)	$8.72	$104.64[+]	$1,255.68
desmopressin 0.2mg tablet (generic)	$0.35	$42.00*	$504.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
sol = solution; unit= tablet or mL
*Cost per 30 days is based on the FDA approved maximum dose of 0.8mg daily.
[+]Cost per 30 days is based on the FDA approved maximum dose of 40mcg/day.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of Desmoda™ during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
DESMOPRESSIN TAB 0.2MG	7,748	1,636	$260,580.57	4.74	$33.63
DESMOPRESSIN TAB 0.1MG	1,651	427	$47,159.53	3.87	$28.56
DESMOPRESSIN SPR 0.01%	236	56	$11,034.91	4.21	$46.76
DDAVP TAB 0.1MG	10	1	$11,556.42	10	$1,155.64
TOTAL	**9,645**	**2,019***	**$330,331.43**	**4.78**	**$34.25**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet; SPR = spray

Dicyclomine 40mg Tablet Product Summary[11,12]

Therapeutic Class: Anticholinergic

Indication(s): Treatment of patients with functional bowel/irritable bowel syndrome

How Supplied: 40mg tablet

Dosing and Administration:

- The recommended initial dose is 20mg 4 times per day.
- After 1 week of treatment with the initial dose, the dose may be increased to 40mg 4 times per day unless side effects limit dosage escalation.
- If efficacy is not achieved within 2 weeks or side effects require doses below 80mg per day, the drug should be discontinued.
- Documented safety data are not available for doses above 80mg daily for periods longer than 2 weeks.

Other Formulation(s) Available:

- Dicyclomine 20mg tablet
- Dicyclomine 10mg capsule

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
dicyclomine 40mg tablet (generic)	**$17.62**	**$2,114.40**	**$25,372.80**

dicyclomine 20mg tablet (generic)	$0.06	$14.40	$172.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the FDA approved maximum dose of 40mg 4 times daily.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of dicyclomine 40mg tablet during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
DICYCLOMINE TAB 20MG	5,970	3,567	$94,175.67	1.67	$15.77
DICYCLOMINE CAP 10MG	4,582	2,521	$76,374.16	1.82	$16.67
TOTAL	**10,552**	**5,958***	**$170,549.83**	**1.77**	**$16.16**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet

Griseofulvin Ultramicrosize 165mg Tablet Product Summary[13,14,15,16]

Therapeutic Class: Antifungal

Indication(s): Treatment of ringworm infections of the skin, hair, and nails, namely: tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis, tinea unguium (onychomycosis) when caused by 1 or more genera of fungi

How Supplied: 165mg ultramicrosize tablet

Dosing and Administration:

- Accurate diagnosis of the infecting organism is essential and should be identified.
- Medication should be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination.
- Treatment period lengths depend on the type of the infection but can range from 4 weeks up to 6 months.
- Adults: 330mg (as a single dose or in divided amounts) for tinea corporis, tinea cruris, and tinea capitis. For infections that are more difficult to eradicate, such as tinea pedis and tinea unguium, a divided daily dose of 660mg is recommended.
- Children (>2 years): Approximately 3.3mg per pound of body weight per day is an effective dose for most children. On this basis, the following dosing schedule is suggested:
  - 30-50lbs: 82.5mg (one-half tablet) to 165mg daily
  - >50lbs: 165mg to 330mg daily

Other Formulation(s) Available:

- Griseofulvin Ultramicrosize 125mg and 250mg Tablets:

- The ultramicrosize 125mg tablet and 250mg tablet have the same indications and similar dosing to the ultramicrosize 165mg tablet.
- Adults: 375mg (as a single dose or in divided doses) for tinea corporis, tinea cruris, and tinea capitis. For infections that are more difficult to eradicate, such as tinea pedis and tinea unguium, a divided daily dose of 750mg is recommended.
- Children (>2 years): Approximately 7.3mg per kg of body weight per day. On this basis, the following dosing schedule is suggested:
    - 16-27kg: 125mg to 187.5mg daily
    - >27kg: 187.5mg to 375mg daily

- Griseofulvin 500mg Microsize Tablet and Griseofulvin 125mg/5mL Suspension:
    - The microsize tablet and suspension have the same indications as the ultramicrosize tablets; however, the recommended dosing is different.
    - Adults: 500mg daily (125mg 4 times daily, 250mg 2 times daily, or 500mg/day). Patients with less severe or extensive infections may require less, whereas those with widespread lesions may require a starting dose of 0.75-1g/day. This may be reduced gradually to 500mg or less after a response has been noted. In all cases, the dose should be individualized.
    - Children (>2 years): A dose of 10mg/kg daily is usually adequate. Dose should be individualized, as with adults. Clinical relapses will occur if the medication is not continued until the infecting organism is eradicated.
        - 30-50lbs: 125mg to 250mg daily
        - >50lbs: 250mg to 500mg daily, in divided doses

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Day	Cost Per Treatment*
griseofulvin ultramicrosize 165mg tab (generic)	**$33.07**	**$132.28**	**$23,810.40**
griseofulvin microsize 500mg tab (generic)	$6.19	$12.38	$2,228.40
griseofulvin ultramicrosize 250mg tab (generic)	$3.41	$10.23	$1,841.40
griseofulvin 125mg/5mL sus (generic)	$0.26	$10.40	$1,872.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
tab = tablet; sus = suspension
*Cost per treatment is based on a 6-month treatment course for tinea pedis with the FDA approved maximum dosing of 660mg daily for the ultramicrosize 165mg tablet, 1,000mg daily for the microsize tablet and suspension, and 750mg daily for the ultramicrosize 250mg tablet.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of griseofulvin ultramicrosize 165mg tablet during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
GRISEOFULVIN SUS 125MG/5ML	1,005	777	$159,946.36	1.29	$159.15
GRISEOFULVIN TAB MICR 500MG	360	267	$87,049.42	1.35	$241.80
GRISEOFULVIN TAB ULTR 250MG	96	85	$14,467.53	1.13	$150.70
GRISEOFULVIN TAB ULTR 125MG	24	23	$4,432.13	1.04	$184.67
TOTAL	**1,485**	**1,138***	**$265,895.44**	**1.3**	**$179.05**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
MICR = microsize; SUS = suspension; TAB = tablet, ULTR = ultramicrosize

Hydroxyzine Oral Solution Unit Dose Cups (UDCs) Product Summary[17,18]

Therapeutic Class: Antihistamine

Indication(s):

- Symptomatic relief of anxiety and tension
- Management of pruritus due to allergic conditions
- Sedative when used as premedication following general anesthesia

How Supplied:

- UDC containing 5mL of hydroxyzine 10mg/5mL
- UDC containing 25mL of hydroxyzine 50mg/25mL

Dosing and Administration:

- Anxiety: 50mg to 100mg orally 4 times daily
- Pruritus: 25mg orally 3 to 4 times daily
- Sedation: 50mg to 100mg orally 1 time used with premedication following general anesthesia

Other Formulation(s) Available:

- Hydroxyzine 10mg/5mL oral solution stock bottle

Formulation Cost Comparison:

Product	Cost Per mL	Cost Per 30 Days*	Cost Per Year
hydroxyzine 50mg/25mL UDC (generic)	**$4.06**	**$12,180.00**	**$146,160.00**
hydroxyzine 10mg/5mL UDC (generic)	**$0.58**	**$1,740.00**	**$20,880.00**
hydroxyzine 10mg/5mL oral solution (generic)	$0.12	$360.00	$4,320.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
UDC = unit dose cup
*Cost per 30 days is based on the FDA approved dose for anxiety of 50mg orally 4 times daily.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of hydroxyzine oral solution UDCs during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
HYDROXYZINE HCL SYP 10MG/5ML	3,532	1,815	$119,874.81	1.95	$33.94
HYDROXYZINE SYP 10MG/5ML	292	208	$11,066.11	1.4	$37.90
TOTAL	**3,824**	**1,941***	**$130,940.92**	**1.97**	**$34.24**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
HCL = hydrochloride; SYP = syrup

Khindivi™ (Hydrocortisone Oral Solution) Product Summary[19,20,21,22]

Therapeutic Class: Corticosteroid

Indication(s): Replacement therapy in pediatric patients 5 years of age and older with adrenocortical insufficiency

How Supplied: 1mg/mL berry flavored oral solution

Dosing and Administration:

- Individualize the dose, using the lowest possible dosage.
- When stress dosing is needed, a different hydrocortisone-containing drug product should be used.
- The recommended starting dose is 8 to 10mg/m^2 daily. Higher doses may be needed based on the patient's age and symptoms of the disease. Use of lower starting doses may be sufficient in patients with residual but decreased endogenous cortisol production.
- The dose should be rounded to the nearest 0.5mg or 1mg.
- Divide the total daily dose into 3 doses and administer 3 times daily. Older patients may have their daily dose divided by 2 and administered twice daily.
- Khindivi™ should be administered using the oral syringe provided by the pharmacy. Khindivi™ may be administered through a gastric tube. Flush gastric tube with 20mL of water to ensure the entire dose is delivered.
- When switching from other oral hydrocortisone formulations, the same total daily hydrocortisone dosage should be used. If symptoms of adrenal insufficiency occur, increase total daily dosage.

Other Formulation(s) Available:

- Alkindi Sprinkle® (Hydrocortisone Oral Granules):
  - Alkindi Sprinkle® and Khindivi™ have the same indication and recommended dosing.
  - Alkindi Sprinkle® is supplied as oral granules contained within capsules available as 0.5mg, 1mg, 2mg, and 5mg strengths.
  - The capsules should not be swallowed, nor the granules chewed or crushed. The capsule should be opened and its contents placed directly into the patient's mouth or sprinkled onto soft food (such

as yogurt or fruit puree) and given immediately. The granules should not be added to liquid as this can reduce the dose and result in a bitter taste.
    - Alkindi Sprinkle® should not be used in nasogastric or gastric tubes as they may cause tube blockage.
- Hydrocortisone Tablet:
    - Hydrocortisone tablets have various indications including endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic disorders, neoplastic diseases, and others.
    - The initial dosage of hydrocortisone tablets varies from 20mg to 240mg per day depending on the specific disease entity being treated. In situations of less severity, lower doses will generally suffice while in selected patients, higher initial doses may be required.
    - Hydrocortisone tablets are scored and available in 3 strengths: 5mg, 10mg, and 20mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Khindivi™ (hydrocortisone 1mg/mL solution)	**$26.54**	**$4,777.20**	**$57,326.40**
Alkindi Sprinkle® (hydrocortisone 2mg granule)	$42.47	$3,822.30	$45,867.60
hydrocortisone 5mg tablet (generic)	$0.15	$6.75	$81.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = granule-filled capsule, mL, or tablet
*Cost per 30 days is based on the FDA recommended starting dose of 8mg/m^2 (divided into 3 doses/day and rounded to the nearest 0.5mg or 1mg dose) for hydrocortisone for a pediatric patient with a body surface area of 0.8m^2. This would result in a dose of 2mg 3 times daily (using one-half tablet to achieve a 2.5mg dose for the hydrocortisone tablets).

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of Khindivi™ during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
HYDROCORTISONE TAB 5MG	1,542	305	$41,401.64	5.06	$26.85
HYDROCORTISONE TAB 10MG	836	239	$24,461.36	3.5	$29.26
HYDROCORTISONE TAB 20MG	345	101	$11,380.59	3.42	$32.99
CORTEF TAB 5MG	67	11	$9,511.24	6.09	$141.96
ALKINDI SPRI CAP 1MG	1	1	$591.01	1	$591.01
ALKINDI SPRI CAP 0.5MG	1	1	$301.21	1	$301.21
TOTAL	**2,792**	**567***	**$87,647.05**	**4.92**	**$31.39**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet; SPRI = sprinkle

Ontralfy™ (Tizanidine Oral Solution) Product Summary[23,24,25]

Therapeutic Class: Muscle relaxant

Indication(s): Treatment of spasticity in adults

How Supplied: 2mg/5mL strawberry flavored oral solution in a 473mL bottle

Dosing and Administration:

- The recommended starting dose is 2mg (5mL) orally every 6-8 hours, as needed, to a maximum of 3 doses in 24 hours.
- The dose should gradually be increased every 1-4 days by 2-4mg (5-10mL) at each dose based on clinical response and tolerability.
- The maximum total daily dose is 36mg (90mL). Single doses greater than 16mg (40mL) have not been studied.

Other Formulation(s) Available:

- Tizanidine 2mg, 4mg tablets
- Tizanidine 2mg, 4mg, 6mg, 8mg capsules

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Ontralfy™ (tizanidine 2mg/5mL solution)	**$1.59**	**$4,293.00**	**$51,516.00**
tizanidine 6mg capsule (generic)	$0.14	$25.20	$302.40
tizanidine 4mg tablet (generic)	$0.03	$8.10	$97.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on usage up to the maximum daily dose of 36mg per day for each product.
Unit = capsule, mL, or tablet

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of Ontralfy™ during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TIZANIDINE TAB 4MG	37,303	11,864	$493,061.45	3.14	$13.22
TIZANIDINE TAB 2MG	7,412	3,305	$94,517.05	2.24	$12.75
TIZANIDINE CAP 4MG	158	123	$3,036.85	1.28	$19.22
TIZANIDINE CAP 6MG	92	39	$2,386.86	2.36	$25.94
TIZANIDINE CAP 2MG	66	49	$1,008.60	1.35	$15.28
TOTAL	**45,031**	**14,755***	**$594,010.81**	**3.05**	**$13.19**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet

PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet Summary[26,27,28,29,30,31,32,33,34]

Therapeutic Class: Electrolyte

Indication(s): Treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient

How Supplied:

- PoKonza™ 10mEq/15mL solution is available in an orange flavored solution in a 237mL bottle.
- PoKonza™ 15mEq packet is available in an orange flavored powder in single-dose pouches.
- Potassium chloride 40mEq packet is available in an orange flavored powder in single-dose pouches.

Dosing and Administration:

- Treatment of Hypokalemia:
  - Adults: Initial doses range from 40-100mEq/day in 2-5 divided doses; doses should be limited to 40mEq per dose and total daily doses should not exceed 200mEq.
  - Pediatric Patients (Birth to 16 Years of Age): 2-4mEq/kg/day in divided doses; doses should not exceed 1mEq/kg as a single dose or 40mEq whichever is lower and total daily doses should not exceed 100mEq.
- Maintenance or Prophylaxis of Hypokalemia:
  - Adults: 20mEq per day
  - Pediatric Patients (Birth to 16 Years of Age): 1mEq/kg/day; doses should not exceed 3mEq/kg/day.
- The contents of 1 packet of PoKonza™, 1 packet of potassium 40mEq, or 1 dose of PoKonza™ oral solution should be diluted in at least 4oz of cold water and taken with meals or immediately after eating.

Other Formulation(s) Available:

- Potassium Chloride ER Tablet, Potassium Chloride ER Dispersible Tablet, Potassium Chloride ER Sprinkle Capsule, Potassium Chloride Oral Solution, and Potassium Chloride Packet for Oral Solution:
  - All formulations have the same indications and recommended dose; however, the administration is different.
  - Potassium chloride ER tablet is a film coated tablet and must be swallowed whole. It is available in 8mEq, 10mEq, and 20mEq strengths.

- For those who have difficulties swallowing, potassium chloride ER dispersible tablet, potassium chloride ER sprinkle capsules, potassium chloride oral solution, and potassium chloride packet for oral solution are available.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
PoKonza™ (potassium chloride 10mEq/15mL solution)	**$10.08**	**$4,536.00⁺**
potassium chloride 40mEq packet (generic)	**$86.07**	**$2,582.10***
PoKonza™ (potassium chloride 15mEq packet)	**$43.04**	**$1,291.20***
PoKonza™ (potassium chloride 10mEq packet)	$28.42	$852.60*
potassium chloride 40mEq/15mL oral solution (generic)	$0.05	$22.50⁺
potassium chloride 20mEq packet (generic)	$0.61	$18.30*
potassium chloride 20mEq ER tablet (generic)	$0.16	$4.80*
potassium chloride 10mEq ER sprinkle capsule (generic)	$0.13	$3.90*
potassium chloride 20mEq dispersible tablet (generic)	$0.12	$3.60*

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit= capsule, mL, packet, or tablet; ER = extended-release
⁺Cost per 30 days is based on 15mL daily.
*Cost per 30 days is based on 1 capsule, packet, or tablet daily.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of PoKonza™ or potassium chloride 40mEq packet during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
POT CHLORIDE MICRO TAB 20MEQ ER	10,686	3,824	$171,016.52	$0.45	2.79	$16.00
POT CHLORIDE TAB 10MEQ ER	7,039	2,598	$96,667.31	$0.35	2.71	$13.73
POT CHLORIDE TAB 20MEQ ER	3,787	1,580	$64,153.51	$0.43	2.4	$16.94
POT CHLORIDE MICRO TAB 10MEQ ER	3,216	1,217	$51,763.41	$0.45	2.64	$16.10
POT CHLORIDE CAP 10MEQ ER	2,999	1,047	$52,182.39	$0.45	2.86	$17.40
POT CHLORIDE SOL 20MEQ/15ML	590	168	$21,366.21	$1.28	3.51	$36.21
POT CHLORIDE TAB 8MEQ ER	527	168	$11,674.85	$0.52	3.14	$22.15
KLOR-CON M20 TAB 20MEQ ER	314	174	$5,070.69	$0.43	1.8	$16.15
POT CHLORIDE CAP 8MEQ ER	222	62	$3,524.39	$0.42	3.58	$15.88
POT CHLORIDE SOL 40MEQ/15ML	120	42	$5,552.63	$1.70	2.86	$46.27
KLOR-CON PAK 20MEQ	50	25	$3,168.21	$2.49	2	$63.36
KLOR-CON M10 TAB 10MEQ ER	24	17	$391.26	$0.41	1.41	$16.30
KLOR-CON 10 TAB 10MEQ ER	18	10	$281.21	$0.55	1.8	$15.62
POT CHLORIDE MICRO TAB 15MEQ ER	15	3	$600.51	$1.33	5	$40.03
POT CHLORIDE POW 20MEQ	14	10	$720.74	$2.49	1.4	$51.48
KLOR-CON M15 TAB 15MEQ ER	4	3	$276.94	$1.54	1.33	$69.24
KLOR-CON 8 TAB 8MEQ ER	4	4	$66.65	$0.42	1	$16.66
POT CHLORIDE TAB 15MEQ ER	2	2	$55.45	$1.58	1	$27.73

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	CLAIMS/ MEMBER	COST/ CLAIM
POT CHLORIDE MICRO TAB 10MEQ CR	1	1	$22.23	$0.74	1	$22.23
TOTAL	**29,632**	**9,687***	**$488,555.11**	**$0.44**	**3.06**	**$16.49**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CR = controlled-release; ER = extended-release; MEQ = milliequivalent; MICRO = microencapsulated; PAK = packet; POT = potassium; POW = powder; SOL = solution; TAB = tablet

Quiofic™ (Folic Acid Oral Solution) Product Summary[35,36,37]

Therapeutic Class: Folate analog

Indication(s): Treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients

How Supplied: 0.2mg/mL mixed berry flavored oral solution in a 75mL bottle

Dosing and Administration:

- The recommended starting dose of Quiofic™ in pediatric and adult patients is up to 1mg orally daily.
- Quiofic™ may be taken with or without food.
- The recommended maintenance dosing, after clinical symptoms have subsided and the blood picture has become normal, use a daily maintenance dosing as follows:
  - Birth to 23 months: 0.1mg orally daily
  - 2 years to less than 4 years: up to 0.3mg orally daily
  - ≥4 years and adults: 0.4mg orally daily
  - Pregnant and lactating women: 0.8mg daily; but never less than 0.1mg orally per day
- Higher maintenance doses may be needed in the presence of alcoholism, hemolytic anemia, anticonvulsant therapy, or chronic infection.
- Monitor patients frequently for relapses and adjust doses accordingly.

Other Formulation(s) Available:

- Folic Acid 1mg Tablets:
  - Folic acid tablets and solution have the same indication and recommended dosing.
  - There are other strengths of folic acid available over the counter including the 400mcg and 800mcg strengths, which are not covered by SoonerCare.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 days*	Cost Per Year
Quiofic™ (folic acid 0.2mg/mL oral solution)	**$20.78**	**$3,117.00**	**$37,404.00**

folic acid 1mg tablet (generic)	$0.02	$0.60	$7.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days is based on the FDA maximum approved dose of 1mg daily.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of Quiofic™ during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
FOLIC ACID 1MG TAB	25,404	6,727	$261,086.91	3.78	$10.28
TOTAL	**25,404**	**6,727***	**$261,086.91**	**3.78**	**$10.28**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet

Relgaabi™ (Gabapentin 200mg Capsule) Product Summary[38,39,40]

Therapeutic Class: Anticonvulsant

Indication(s):
- Management of postherpetic neuralgia in adults
- Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years of age or older

How Supplied: 200mg capsule, 300mg capsule, and 400mg capsule

Dosing and Administration:
- Postherpetic Neuralgia: In adults, may be initiated on day 1 as a single 300mg dose, on day 2 as 600mg/day (300mg 2 times a day), and on day 3 as 900mg/day (300 mg 3 times a day). The dose can subsequently be titrated up as needed for pain relief to a dose of 1,800mg/day (600mg 3 times a day).
- Partial Onset Seizures:
  - Patients ≥12 years of age: The starting dose is 300mg 3 times daily, and the maintenance dose is 300mg to 600mg 3 times daily with a maximum dose up to 2,400mg/day.
  - Pediatric patients 3 to 11 years old: The starting dose range is 10mg/kg/day to 15mg/kg/day, given in 3 divided doses, and the recommended maintenance dose reached by upward titration over a period of approximately 3 days. The recommended maintenance dose is based on age and weight, see package labeling for more information.

Other Formulation(s) Available:
- Gabapentin 100mg, 300mg, 400mg capsules
- Gabapentin 600mg and 800mg tablets

Formulation Cost Comparison:

Product	Cost Per Capsule	Cost Per 30 Days*	Cost Per Year
Relgaabi™ (gabapentin 200mg capsule)	**$15.30**	**$1,377.00**	**$16,524.00**
gabapentin 100mg capsule (generic)	$0.02	$3.60	$43.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on a dose of 200mg 3 times daily.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of Relgaabi™ during fiscal year 2025.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
GABAPENTIN CAP 300MG	55,333	19,111	$828,560.67	2.9	$14.97
GABAPENTIN TAB 600MG	28,448	7,110	$554,656.21	4	$19.50
GABAPENTIN CAP 100MG	21,950	9,413	$284,712.20	2.33	$12.97
GABAPENTIN TAB 800MG	21,729	4,527	$498,948.77	4.8	$22.96
GABAPENTIN CAP 400MG	9,301	2,674	$149,621.14	3.48	$16.09
NEURONTIN CAP 300MG	7	2	$10,650.04	3.5	$1,521.43
TOTAL	**136,768**	**36,627***	**$2,327,149.03**	**3.73**	**$17.02**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet

Vykoura™ (Leucovorin Injection) Product Summary[41,42,43,44,45,46,47]

Therapeutic Class: Folate analog

Indication(s):

- Rescue after high-dose methotrexate (MTX) therapy in adult and pediatric patients
- Reducing the toxicity of MTX in adult and pediatric patients with impaired MTX elimination or folic acid antagonists or dihydrofolate reductase (DHFR) inhibitors following an overdose in adult and pediatric patients
- Treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients when oral therapy is not feasible
- Treatment of patients with metastatic colorectal cancer in combination with fluorouracil
    - Limitations of Use: Vykoura™ is not indicated for pernicious anemia and megaloblastic anemia secondary to the lack of vitamin B_{12}, because of the risk of progression of neurologic manifestations despite hematologic remission.

How Supplied: Vykoura™ is supplied in single-dose vials delivering 10mg/mL of leucovorin in the following vial sizes: 50mg/5mL, 350mg/35mL, 500mg/50mL.

Dosing and Administration:

- Vykoura™ is indicated for IV and intramuscular (IM) administration only. It should not be given intrathecally. It may be harmful or fatal if given intrathecally.
- The recommended dosing is based on diagnosis, as follows (additional information available in the full *Prescribing Information*):
  - Rescue After High-Dose MTX Therapy: The dose is based on serum MTX levels obtained 24 hours following the MTX infusion. The recommended dose for patients who receive a dose of 12-15g/m^2 of MTX with normal MTX elimination is 15mg IV or IM every 6 hours for 60 hours for a total of 10 doses.
  - Reduce Toxicity of Folic Acid Antagonists, DHFR inhibitors, or Impaired MTX Elimination: Administer Vykoura™ 10mg/m^2 IV or IM every 6 hours until the serum MTX level is less than 0.01 micromolar (1×10^{-8} M).
  - Advanced Colorectal Cancer in Combination with Fluorouracil: Dosage of Vykoura™ in combination with fluorouracil varies by regimen and ranges from 20mg/m^2 to 500mg/m^2. Consult institutional guidelines for recommended dosing, dosing frequency, and duration of therapy.
  - Megaloblastic Anemia Due to Folic Acid Deficiency: Up to 1mg daily administered IV until adequate hematologic response is achieved. There is no evidence that doses greater than 1mg/day have greater efficacy than those of 1mg; additionally, loss of folate in urine becomes roughly logarithmic as the amount administered exceeds 1mg.

Other Formulation(s) Available:

- Leucovorin Injection Powder for Solution:
  - Leucovorin injection powder has the same indications and recommended dosing as Vykoura™; however, it must be reconstituted before administration.
  - It is available in 50mg, 100mg, 200mg, 350mg, and 500mg vials.
- Leucovorin Injection Solution:
  - Leucovorin injection solution has the same indications and recommended dosing as Vykoura™. Both products are available in ready-to-use vials that do not need to be reconstituted; however, leucovorin injection solution is only available in a 100mg/10mL vial.
- Khapzory® (Levoleucovorin Injection) and Levoleucovorin Calcium 50mg Vial and 10mg/mL Solution:

- The indications for levoleucovorin calcium and Khapzory® are the same as leucovorin except leucovorin has an additional indication for treatment of megaloblastic anemias due to folic acid deficiency when oral therapy is not feasible.
- The recommended dosing for levoleucovorin is half that of leucovorin for all overlapping indications.
- Levoleucovorin is for IV administration only.
- Levoleucovorin calcium is available in a 50mg vial that must be reconstituted and then in a 175mg/17.5mL and 250mg/25mL ready-to-use solution.
- Khapzory® is available in a 175mg vial that must be reconstituted. Khapzory® is the only sodium-based levoleucovorin formulation.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment*
Vykoura™ (leucovorin inj) 350mg/35mL	**$25.00**	**$4,375.00**
Khapzory® (levoleucovorin inj) 175mg vial	$775.88	$3,879.40
levoleucovorin inj solution 175mg/17.5mL (generic)	$6.29	$550.38
leucovorin inj solution 100mg/10mL (generic)	$2.20	$385.00
leucovorin inj powder 350mg vial (generic)	$70.00	$350.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or vial; inj = injection
*Cost per treatment is based on the recommended dosing for advanced colorectal cancer in combination with fluorouracil at 100mg/m^2 for levoleucovorin and 200mg/m^2 for leucovorin in a patient with a body surface area of 1.75m^2 for 5 total doses.

Fiscal Year 2025 Utilization: There was no SoonerCare utilization of levoleucovorin injection, Khapzory®, or Vykoura™ during fiscal year 2025.

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LEUCOVORIN INJ J0640	2,235	284	$23,233.50	$10.40	7.87
TOTAL	**2,235**	**284**	**$23,233.50**	**$10.40**	**7.87**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = Injection

Recommendations

The College of Pharmacy recommends the prior authorization of Averi™ (desogestrel/ethinyl estradiol/ferrous sulfate) with criteria similar to Femlyv™ [norethindrone acetate/ethinyl estradiol orally disintegrating tablet (ODT)], Nextstellis® (drospirenone/estetrol tablet) and Slynd® (drospirenone tablet) with the following criteria (shown in red):

Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Femlyv™ [Norethindrone Acetate and Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Nextstellis® (Drospirenone/Estetrol Tablet), and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without prior authorization must be provided.

Next, the College of Pharmacy recommends the prior authorization of Cafergot® (ergotamine/caffeine tablets) and Migergot® (ergotamine/caffeine suppository) with placement into the Special PA Tier of the Anti-Migraine Product Based Prior Authorization (PBPA) category with the following additional criteria (changes shown in red):

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Cafergot® (ergotamine/caffeine tablets), Ergomar® (ergotamine sublingual tablets), and Migergot® (ergotamine/caffeine suppository) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Cafergot®, Ergomar®, and Migergot® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and
    b. The following ~~A~~ quantity limits ~~of 20 tablets per 28 days~~ will apply~~.~~:
        i. Cafergot®: 40 tablets per 28 days; or
        ii. Ergomar®: 20 tablets per 28 days; or
        iii. Migergot®: 20 suppositories per 28 days.
2. Use of Brekiya® [dihydroergotamine (DHE) autoinjector] or D.H.E. 45® (DHE injection) will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray) and lower-tiered triptan medications.
3. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]+:
    a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
    b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
    c. A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.

    *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to

be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.
†Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.

4. Use of Reyvow® (lasmiditan) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor
5. Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use Treximet® (sumatriptan/naproxen) and a different combination of a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID) (i.e., rizatriptan with ibuprofen).
6. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.
7. Use of Imitrex® STATdose System (sumatriptan injection), Tosymra® (sumatriptan nasal spray), or Zembrace® SymTouch® (sumatriptan injection) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
8. Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.

The College of Pharmacy also recommends the prior authorization of Desmoda™ (desmopressin oral solution), dicyclomine 40mg tablet, griseofulvin ultramicrosize 165mg tablet, and hydroxyzine oral solution UDCs with the following criteria (shown in red):

Desmoda™ (Desmopressin Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of arginine vasopressin deficiency (AVP-D), also known as central diabetes insipidus; and
2. A patient specific, clinically significant reason why the member cannot use desmopressin nasal spray and desmopressin oral tablets, even when tablets are crushed, which are both available without a prior authorization, must be provided.

Dicyclomine 40mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason why the member cannot use the 20mg tablet, which is available without a prior authorization, to achieve the dose must be provided.

Griseofulvin Ultramicrosize 165mg Tablet Approval Criteria:

1. An FDA approved indication for the treatment of ringworm infections of the skin, hair, and nails; and
2. The infection must be caused by 1 or more of the genera of fungi listed in the package labeling; and
3. A patient specific, clinically significant reason why the member cannot use other formulations of griseofulvin available without a prior authorization (i.e., griseofulvin microsize 500mg tablet, griseofulvin 125mg/5mL suspension, and griseofulvin ultramicrosize 125mg and 250mg tablets) must be provided.

Hydroxyzine 10mg/5mL and 50mg/25mL Oral Solution Unit-Dose Cups (UDCs) Approval Criteria:

1. A patient-specific, clinically significant reason why the member requires the UDCs in place of the bulk solution, which is available without a prior authorization, must be provided.

Next, the College of Pharmacy recommends the prior authorization of Khindivi™ (hydrocortisone oral solution) with criteria similar to Alkindi Sprinkle® (hydrocortisone oral granule) (changes shown in red):

Alkindi Sprinkle® (Hydrocortisone Oral Granule) and Khindivi™ (Hydrocortisone Oral Solution) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed or split, which are available without prior authorization, must be provided (e.g., clinically indicated dose cannot be achieved with available tablet formulation); and
3. For Khindivi™, a patient-specific, clinically significant reason why the member cannot use Alkindi Sprinkle® must be provided.

The College of Pharmacy also recommends the prior authorization of Ontralfy™ (tizanidine oral solution) with placement into the Special PA Tier of the Muscle Relaxant PBPA category with the following additional criteria (changes shown in red).

Ontralfy™ (Tizanidine Oral Solution) Approval Criteria:

1. An FDA approved indication for the treatment of spasticity; and

2. A patient-specific, clinically significant reason why the member cannot use Tier-1 tizanidine tablets, even when tablets are crushed or split, which are available without prior authorization, must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use generic tizanidine 2mg, 4mg, or 6mg capsules to achieve the requested dose, even when the capsules are opened and sprinkled on applesauce, must be provided.

The College of Pharmacy also recommends the prior authorization of PoKonza™ 10mEq/15mL solution, PoKonza™ 15mEq packet, and potassium chloride 40mEq packet with criteria similar to the other potassium chloride products (changes shown in red):

Klor-Con® (Potassium Chloride 20mEq Packet), ~~and~~ PoKonza™ (Potassium Chloride ~~10mEq~~ Oral Solution and Packet), and Potassium Chloride 40mEq Packet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all the following must be provided:
   a. Potassium chloride tablet; and
   b. Potassium chloride extended-release (ER) dispersible tablet; and
   c. Potassium chloride ER sprinkle capsule; and
   d. Potassium chloride oral solution.

The College of Pharmacy recommends the prior authorization of Quiofic™ (folic acid solution) and Relgaabi™ (gabapentin 200mg capsule) with the following criteria (shown in red):

Quiofic™ (Folic Acid Oral Solution) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the tablet formulation, even when the tablets are crushed, which is available without prior authorization, must be provided; and
2. A quantity limit of 150mL per 30 days will apply.

Relgaabi™ (Gabapentin 200mg Capsule) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use 2 of the 100mg gabapentin capsules, which are available without prior authorization, to achieve the 200mg dose must be provided; and
2. A quantity limit of 270 capsules per 30 days will apply.

The College of Pharmacy also recommends the prior authorization of Vykoura™ (leucovorin injection) with criteria similar to Khapzory® (levoleucovorin injection) approval criteria (changes shown in red):

Khapzory® (Levoleucovorin Injection) and Vykoura™ (Leucovorin Injection) Approval Criteria:

1. An FDA approved indication; and ~~of 1 of the following:~~

~~a. Rescue after high-dose methotrexate (MTX) therapy in members with osteosarcoma; or~~
~~b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or~~
~~c. Treatment of members with metastatic colorectal cancer in combination with fluorouracil; and~~

2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection, which are both available without prior authorization, must be provided.

Finally, the College of Pharmacy recommends the prior authorization of Annovera™ (segesterone acetate/ethinyl estradiol vaginal system) based on net cost with the following criteria (shown in red):

Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) and all other available formulations of estrogen/progestin contraception available without prior authorization must be provided; and
3. A quantity limit of 1 vaginal system per year will apply.

Utilization Details of Various Special Formulations: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DROSPIRENONE PRODUCTS						
SLYND TAB 4MG	479	180	$152,633.72	$318.65	2.66	33.59%
SUBTOTAL	**479**	**180**	**$152,633.72**	**$318.65**	**2.66**	**33.59%**
LEVOTHYROXINE PRODUCTS						
THYQUIDITY SOL 100MCG/5ML	32	12	$7,884.83	$246.40	2.67	1.73%
TIROSINT CAP 100MCG	18	6	$2,948.42	$163.80	3	0.65%
TIROSINT-SOL 75MCG/ML	18	5	$2,745.46	$152.53	3.6	0.60%
LEVOTHYROXINE CAP 200MCG	16	3	$3,505.43	$219.09	5.33	0.77%
TIROSINT CAP 75MCG	15	8	$3,533.70	$235.58	1.88	0.78%
LEVOTHYROXINE CAP 75MCG	12	3	$1,472.95	$122.75	4	0.32%
TIROSINT CAP 112MCG	11	5	$1,716.15	$156.01	2.2	0.38%
TIROSINT CAP 125MCG	10	4	$1,748.81	$174.88	2.5	0.38%
TIROSINT CAP 175MCG	9	5	$1,316.69	$146.30	1.8	0.29%
TIROSINT CAP 88MCG	9	3	$1,312.40	$145.82	3	0.29%
TIROSINT CAP 150MCG	9	6	$1,584.46	$176.05	1.5	0.35%
TIROSINT CAP 200MCG	9	4	$1,886.19	$209.58	2.25	0.42%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIROSINT-SOL 150MCG/ML	9	3	$1,862.63	$206.96	3	0.41%
TIROSINT CAP 25MCG	9	3	$3,370.09	$374.45	3	0.74%
TIROSINT-SOL 137MCG/ML	8	3	$1,168.24	$146.03	2.67	0.26%
LEVOTHYROXINE CAP 125MCG	8	3	$1,051.71	$131.46	2.67	0.23%
LEVOTHYROXINE CAP 112MCG	8	3	$907.23	$113.40	2.67	0.20%
LEVOTHYROXINE CAP 88MCG	8	4	$892.05	$111.51	2	0.20%
TIROSINT-SOL 37.5MCG/ML	7	4	$961.14	$137.31	1.75	0.21%
TIROSINT CAP 50MCG	7	4	$1,026.27	$146.61	1.75	0.23%
LEVOTHYROXINE CAP 100MCG	7	5	$1,018.21	$145.46	1.4	0.22%
TIROSINT CAP 137MCG	7	3	$1,153.28	$164.75	2.33	0.25%
LEVOTHYROXINE CAP 137MCG	6	4	$501.02	$83.50	1.5	0.11%
LEVOTHYROXINE CAP 25MCG	6	3	$971.33	$161.89	2	0.21%
TIROSINT-SOL 44MCG/ML	6	3	$932.46	$155.41	2	0.21%
TIROSINT-SOL 25MCG/ML	6	4	$900.01	$150.00	1.5	0.20%
TIROSINT-SOL 200MCG/ML	6	4	$899.74	$149.96	1.5	0.20%
TIROSINT-SOL 50MCG/ML	6	3	$893.71	$148.95	2	0.20%
TIROSINT-SOL 88MCG/ML	5	3	$733.75	$146.75	1.67	0.16%
TIROSINT-SOL 62.5MCG/ML	4	2	$597.24	$149.31	2	0.13%
LEVOTHYROXINE CAP 50MCG	4	4	$478.87	$119.72	1	0.11%
TIROSINT-SOL 100MCG/ML	3	3	$449.97	$149.99	1	0.10%
TIROSINT CAP 37.5MCG	3	1	$449.65	$149.88	3	0.10%
TIROSINT CAP 62.5MCG	3	1	$443.67	$147.89	3	0.10%
ERMEZA SOL 150MCG/5ML	3	3	$573.99	$191.33	1	0.13%
TIROSINT-SOL 125MCG/ML	2	1	$293.26	$146.63	2	0.06%
TIROSINT CAP 13MCG	2	2	$292.82	$146.41	1	0.06%
LEVOTHYROXINE CAP 13MCG	2	2	$273.37	$136.69	1	0.06%
LEVOTHYROXINE CAP 175MCG	2	1	$199.79	$99.90	2	0.04%
TIROSINT CAP 44MCG	1	1	$148.41	$148.41	1	0.03%
TIROSINT-SOL 112MCG	1	1	$146.32	$146.32	1	0.03%
SUBTOTAL	**317**	**145**	**$55,245.72**	**$174.28**	**2.19**	**12.16%**
METHOTREXATE PRODUCTS						
XATMEP SOL 2.5MG/ML	86	21	$55,095.45	$640.64	4.1	12.12%
RASUVO INJ 25MG	25	8	$14,035.92	$561.44	3.13	3.09%
RASUVO INJ 15MG	16	3	$8,934.81	$558.43	5.33	1.97%
RASUVO INJ 12.5MG	14	2	$7,844.97	$560.36	7	1.73%
RASUVO INJ 10MG	13	3	$7,346.65	$565.13	4.33	1.62%
OTREXUP INJ 25MG	10	2	$6,956.30	$695.63	5	1.53%
RASUVO INJ 7.5MG	7	3	$4,023.21	$574.74	2.33	0.89%
OTREXUP INJ 10MG	7	1	$5,481.35	$783.05	7	1.21%
RASUVO INJ 20MG	2	1	$1,116.00	$558.00	2	0.25%
OTREXUP INJ 15MG	1	1	$779.55	$779.55	1	0.17%
SUBTOTAL	**181**	**45**	**$111,614.21**	**$616.65**	**4.02**	**24.56%**
PREDNISONE AND PREDNISOLONE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PREDNISOLONE TAB 15MG ODT	58	53	$5,982.84	$103.15	1.09	1.32%
PREDNISOLONE TAB 30MG ODT	18	16	$2,013.00	$111.83	1.13	0.44%
PREDNISOLONE TAB 10MG ODT	16	15	$567.22	$35.45	1.07	0.12%
PREDNISOLONE SOL 10MG/5ML	9	7	$612.34	$68.04	1.29	0.13%
PREDNISOLONE TAB 5MG	8	8	$2,539.01	$317.38	1	0.56%
PREDNISOLONE SOL 20MG/5ML	3	3	$182.43	$60.81	1	0.04%
RAYOS TAB 2MG	1	1	$2,662.04	$2,662.04	1	0.59%
RAYOS TAB 1MG	1	1	$453.25	$453.25	1	0.10%
SUBTOTAL	**114**	**104**	**$15,012.13**	**$131.69**	**1.10**	**3.30%**
DROSPIRENONE/ESTETROL PRODUCTS						
NEXTSTELLIS TAB 3MG/14.2MG	105	34	$31,661.95	$301.54	3.09	6.97%
SUBTOTAL	**105**	**34**	**$31,661.95**	**$301.54**	**3.09**	**6.97%**
POTASSIUM CHLORIDE PRODUCTS						
KLOR-CON PAK 20MEQ	50	25	$3,168.21	$63.36	2	0.70%
POT CHLORIDE POW 20MEQ	14	10	$720.74	$51.48	1.4	0.16%
SUBTOTAL	**64**	**35**	**$3,888.95**	**$60.76**	**1.83**	**0.44%**
GABAPENTIN PRODUCTS						
HORIZANT TAB 600MG ER	13	3	$6,882.06	$529.39	4.33	1.51%
HORIZANT TAB 300MG ER	9	2	$4,822.61	$535.85	4.5	1.06%
GABAPENT DLY TAB 600MG ER	7	4	$1,095.37	$156.48	1.75	0.24%
GRALISE TAB 900MG	2	1	$1,629.52	$814.76	2	0.36%
GRALISE TAB 450MG	1	1	$1,926.85	$1,926.85	1	0.42%
GABAPENT DLY TAB 300MG ER	1	1	$211.76	$211.76	1	0.05%
SUBTOTAL	**33**	**12**	**$16,568.17**	**$502.07**	**2.75**	**1.51%**
BUDESONIDE PRODUCTS						
EOHILIA SUS 2MG/10ML	21	14	$37,735.98	$1,796.95	1.5	8.30%
SUBTOTAL	**21**	**14**	**$37,735.98**	**$1,796.95**	**1.5**	**8.30%**
LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE PRODUCTS						
PHEXXI GEL 1.8/1/0.4%	21	10	$9,015.34	$429.30	2.1	1.98%
SUBTOTAL	**21**	**10**	**$9,015.34**	**$429.30**	**2.1**	**1.98%**
LACTULOSE PRODUCTS						
KRISTALOSE PAK 20GM	9	7	$2,068.23	$229.80	1.29	0.46%
KRISTALOSE PAK 10GM	6	4	$1,814.09	$302.35	1.5	0.40%
LACTULOSE PAK 10GM	1	1	$267.01	$267.01	1	0.06%
LACTULOSE PAK 20GM	1	1	$267.01	$267.01	1	0.06%
SUBTOTAL	**17**	**13**	**$4,416.34**	**$259.78**	**1.31**	**0.97%**
PREGABALIN PRODUCTS						
PREGABALN ER TAB 165MG	10	3	$927.21	$92.72	3.33	0.20%
PREGABALN ER TAB 330MG	5	2	$571.77	$114.35	2.5	0.13%
SUBTOTAL	**15**	**5**	**$1,498.98**	**$99.93**	**3**	**0.33%**
ISOTRETINOIN PRODUCTS						
ABSORICA LD CAP 24MG	6	2	$13,859.69	$2,309.95	3	3.05%
SUBTOTAL	**6**	**2**	**$13,859.69**	**$2,309.95**	**3**	**3.05%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NORETHINDRONE ACE/ETHINYL ESTRADIOL/FE PRODUCTS						
GEMMILY CAP 1MG/20MCG	2	1	$161.91	$80.96	2	0.04%
NORE/ETH/FE CAP 1MG/20MCG	2	1	$95.50	$47.75	2	0.02%
SUBTOTAL	**4**	**2**	**$257.41**	**$64.35**	**2**	**0.06%**
HYDROCORTISONE PRODUCTS						
ALKINDI SPRI CAP 1MG	1	1	$591.01	$591.01	1	0.13%
ALKINDI SPRI CAP 0.5MG	1	1	$301.21	$301.21	1	0.07%
SUBTOTAL	**2**	**2**	**$892.22**	**$446.11**	**1**	**0.20%**
PILOCARPINE PRODUCTS						
VUITY SOL 1.25% OP 30MG	1	1	$159.72	$159.72	1	0.04%
SUBTOTAL	**1**	**1**	**$159.72**	**$159.72**	**1**	**0.04%**
TOTAL	**1,380**	**548***	**$454,460.53**	**$329.32**	**2.52**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACE = acetate; CAP = capsule; DLY = daily; ER = extended release; ETH = ethinyl estradiol; FE = iron; GABAPENT = gabapentin; INJ = injection; LD = low-dose; NORE = norethindrone; OP = ophthalmic; PAK = packet; POT = potassium; POW = powder; SPRI = sprinkle; SOL = solution; SUS = suspension; TAB = tablet

Medical Claims (All Plans)

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZILRETTA INJ 32MG J3304	25	18	$19,061.53	$762.46	1.39
TOTAL	**25**	**18**	**$19,061.53**	**$762.46**	**1.39**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = Injection

[1] Averi™ (Desogestrel and Ethinyl Estradiol) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=91359e20-0de1-4995-b525-58b7544e34dc. Last revised 06/05/2025. Last accessed 05/26/2026.
[2] Apri® (Desogestrel and Ethinyl Estradiol) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a9e08f9b-9862-4c2c-8302-53dc82d85126. Last revised 12/15/2021. Last accessed 05/26/2026.
[3] Cafergot® (Ergotamine/Caffeine Tablet) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4db7eece-2eef-bc1b-e063-6394a90a98cb. Last revised 03/23/2026. Last accessed 05/26/2026.
[4] Migergot® (Ergotamine/Caffeine Suppository) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3a31ad0c-7bdd-544b-f5df-a99d04cf541c. Last revised 11/29/2022. Last accessed 06/03/2026.
[5] Ergomar® (Ergotamine Sublingual Tablet) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a9582fdb-7ddd-4f69-aa7a-66247cdb8c92. Last revised 02/25/2025. Last accessed 05/26/2026.
[6] Desmoda™ (Desmopressin Oral Solution) Prescribing Information. Eton Pharmaceuticals, Inc. Available online at: https://desmoda.com/PI.pdf. Last revised 02/2026. Last accessed 05/26/2026.

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Appendix S

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates*

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: May 22, 2026

FDA Approves First Treatment for Chronic Hepatitis Delta Virus (HDV) Infection

The FDA approved Hepcludex® (bulevirtide-gmod) injection to treat chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis. Bulevirtide is the first FDA-approved treatment for chronic HDV infection, a serious and life-threatening condition that can cause rapid development of liver fibrosis, liver cancer, liver failure, and even death.

HDV infection only occurs in individuals who have hepatitis B virus (HBV) infection. Some risk factors for contracting HDV include unprotected sex, injecting drugs, and occupational exposure to blood. HBV vaccination protects against HBV and HDV as well.

The efficacy of Hepcludex® was demonstrated in a multi-center, randomized, open-label, parallel-arm phase 3 trial. In Trial MYR301, participants were randomly assigned to immediate treatment with Hepcludex® 8.5 mg once daily for 144 weeks or to delayed treatment with an observational period of 48 weeks followed by Hepcludex® 8.5 mg once daily for 96 weeks.

The primary efficacy endpoint was combined response, defined as undetectable HDV ribonucleic acid (RNA), defined as less than the lower limit of quantification (LLOQ) (50 IU/mL) with target not detected or greater than 2 $\log_{10}$ IU/mL decline from baseline and aminotransferase (ALT) normalization, at week 48. At this time, the combined response was 48% in the Hepcludex® group compared with 2% in the delayed treatment group. At week 48, the rate of undetectable HDV RNA was 20% in the Hepcludex® group compared with 0% in the delayed treatment group. At weeks 96 and 144, the rate of undetectable HDV RNA increased to 36% and 50%, respectively, in the Hepcludex® group.

Possible side effects associated with Hepcludex® include hypersensitivity reactions, including anaphylaxis, injection site reactions, headache, abdominal pain, fatigue, and pruritus. The labeling includes a *Boxed Warning* that discontinuation of Hepcludex® may result in severe acute exacerbations of HDV and HBV infection.

The FDA granted Hepcludex® Breakthrough Therapy designation and Orphan Drug designation. Hepcludex® received priority review and was approved under the Accelerated Approval pathway. The FDA granted the approval to Gilead Sciences, Inc.

FDA NEWS RELEASE

For Immediate Release: May 1, 2026

FDA Permits Expanded Access for Investigational Pancreatic Cancer Drug

The FDA announced that it issued a "safe to proceed" letter to Revolution Medicines, allowing the sponsor to initiate an expanded access treatment protocol (EAP) for its experimental pancreatic cancer drug, daraxonrasib.

The EAP is for patients with previously treated metastatic pancreatic ductal adenocarcinoma (PDAC). The FDA received the expanded access request from Revolution Medicines on April 28th and signed it on April 30th.

FDA regulations allow expanded access to investigational drugs for treatment purposes for larger populations under a treatment protocol or treatment investigational new drug application (INDA). Per EAP guidelines, requests for expanded access must be submitted to the sponsor by physicians licensed in the United States on behalf of eligible patients.

Daraxonrasib is a RAS inhibitor designed to inhibit a protein (RAS) that is mutated in most pancreatic cancer tumors.

The company said on April 13th that it intends to submit a new drug application for daraxonrasib under the Commissioner's National Priority Voucher (CNPV) pilot program. The FDA granted a national priority voucher to daraxonrasib, also called RMC-6236, in October 2025. The FDA previously granted Breakthrough Therapy and Orphan Drug designations to daraxonrasib.

FDA NEWS RELEASE

For Immediate Release: April 30, 2026

FDA Approves First Non-Antipsychotic Drug to Treat Agitation Associated with Dementia

The FDA approved an expanded use for Auvelity® (dextromethorphan hydrobromide and bupropion hydrochloride) extended-release tablets to treat agitation associated with dementia due to Alzheimer's disease in adults. The drug is the first FDA-approved treatment for this condition that is not an antipsychotic. FDA initially approved Auvelity® in 2022 to treat major depressive disorder in adults.

Agitation is a common and distressing symptom in patients with Alzheimer's disease dementia, characterized by excessive motor activity and verbal or physical aggression. It can significantly impact quality of life for patients and caregivers.

The first randomized study was a 5-week trial in which participants received either Auvelity® or a placebo. The primary endpoint was the change from baseline to week 5 in the total score of the Cohen-Mansfield Agitation Inventory (CMAI), a survey that assesses the frequency of manifestations of agitated behaviors in elderly patients based on caregiver reports. Auvelity® was significantly superior to placebo in the CMAI score improvements.

The second randomized study was a withdrawal study in participants who responded to Auvelity®. Upon reaching a sustained clinical response to Auvelity®, patients were randomly assigned to continue treatment with Auvelity® or switch to placebo. The primary endpoint was time to relapse. Participants who continued Auvelity® treatment had a significantly longer time to relapse of agitation symptoms compared to patients receiving the placebo.

The most common side effects include dizziness, upset stomach, headache, diarrhea, drowsiness, dry mouth, sexual dysfunction, and uncontrolled sweating. Auvelity® has a *Boxed Warning* about increased risk of suicidal thoughts and behaviors in adolescents and young adults taking antidepressants. Health care providers should monitor patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during initial treatment. The seizure risk associated with Auvelity® increases with higher doses. It can also cause hypertension and may activate mania or hypomania in susceptible patients.

Before starting Auvelity®, health care providers should assess blood pressure, screen for personal and family history of bipolar disorder, and determine if patients are taking other medications containing bupropion or dextromethorphan.

The FDA granted breakthrough therapy and priority review designations to Axsome Therapeutics which ultimately led to the approval of Auvelity® for agitation associated with dementia due to Alzheimer's disease.

FDA NEWS RELEASE

For Immediate Release: April 30, 2026

FDA Proposes to Exclude Semaglutide, Tirzepatide, and Liraglutide on 503B Bulks List

The FDA announced it is proposing to exclude semaglutide, tirzepatide, and liraglutide on the 503B bulks list, finding no clinical need for outsourcing facilities to compound these drugs from bulk substances.

The 503B bulks list identifies bulk drug substances that outsourcing facilities may use in compounding under the conditions of section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In most cases, outsourcing facilities cannot compound drugs using bulk drug substances unless the substance appears on the 503B bulks list, or the compounded drug is on the FDA’s drug shortage list at the time of compounding, distribution, and dispensing.

After evaluating the nominations for these 3 substances, the FDA did not identify sufficient evidence or clinical need for outsourcing facilities to compound semaglutide, tirzepatide, and liraglutide from 503B bulk drug substance list. A determination of clinical need is based on patient safety and medical necessity under the law.

The FDA is now inviting interested parties to submit comments electronically through the docket by June 29, 2026. The FDA will consider submitted comments before making a final determination.

FDA NEWS RELEASE

For Immediate Release: April 23, 2026

FDA Approves First-Ever Gene Therapy for Treatment of Genetic Hearing Loss Under National Priority Voucher Program

The FDA approved Otarmeni™ (lunsotogene parvec-cwha), the first-ever dual adeno-associated virus (AAV) vector-based gene therapy. Otarmeni™ is indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (HL) (any frequency >90 decibels dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene.

Prior to today's approval, no disease modifying treatments existed for *OTOF*-related deafness. Otarmeni™ is for patients with preserved outer hair cell function and no prior cochlear implant in the same ear.

Genetic mutations cause about half of congenital HL. Variants in the *OTOF* gene account for 2% to 8% of inherited, non-syndromic cases. Patients with 2 nonworking copies do not produce otoferlin, disrupting sound signal transmission. Delayed diagnosis can lead to missed treatment windows and lasting speech and language delays.

Otarmeni™ and the administration kit are a one-time biologic-device combination product. It includes a dual adeno-associated virus serotype 1 (AAV1) vector gene therapy surgically administered as a single dose per ear into the cochlea via a syringe and catheter provided in the administration kit and connected to an infusion pump. Otarmeni™ delivers a functional copy of the *OTOF* gene to inner hair cells to restore otoferlin production and auditory signaling.

The safety and effectiveness of Otarmeni™ were based on results from a single, ongoing, multi-center, single-arm (compared to the natural history of untreated HL) clinical trial in 24 pediatric patients aged 10 months to 16 years with *OTOF* gene-associated severe-to-profound and profound sensorineural HL with confirmatory evidence including mechanistic nonclinical data and sustained otoferlin protein expression post-Otarmeni™ administration. Of the 20 patients who were evaluable for efficacy, 80% experienced improved hearing, which is not expected in the natural history of the disease without intervention.

Common side effects included middle ear infection, nausea, dizziness, and procedural pain. Providers should monitor for possible surgical complications. The therapy is not recommended for patients with anatomy that prevents safe access to the inner ear.

The application was granted orphan drug, rare pediatric disease, fast track, and regenerative medicine advanced therapy (RMAT) designations. The

FDA granted accelerated approval of Otarmeni™ to Regeneron Pharmaceuticals, Inc. Continued approval may be contingent upon assessment of durability of hearing improvement along with verification of treatment effects on clinical measures of speech development and quality of life.

Current Drug Shortages Index (as of May 27, 2026):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bacitracin Ophthalmic Ointment	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***

Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Furosemide Oral Solution	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Isocarboxazid Tablet	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***

Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***