OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
June 11, 2025
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
https://oklahoma.zoom.us/webinar/register/WN_94lCoSe9Ty2msgsLMqg2Ww
After registering, you will receive a confirmation email containing information about joining the webinar.

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 11, 2025

DATE: June 4, 2025

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.

Viewing Access Only via Zoom:
Please register for the meeting at:
https://oklahoma.zoom.us/webinar/register/WN_94lCoSe9Ty2msgsLMqg2Ww
After registering, you will receive a confirmation email containing information about joining the webinar.

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

Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Utilization Update – Appendix C

Action Item – Vote to Prior Authorize Daxxify® (DaxibotulinumtoxinA-lanm) and Update the Approval Criteria for the Botulinum Toxins – Appendix D

Action Item – Vote to Prior Authorize Brynovin™ (Sitagliptin Oral Solution), Glimepiride 3mg Tablet, Merilog™ (Insulin Aspart-szjj), Metformin 750mg Tablet, and Zituvimet™ XR [Sitagliptin/Metformin Extended-Release (ER)] and Update the Approval Criteria for the Anti-Diabetic Medications – Appendix E

Action Item – Vote to Prior Authorize Onyda™ XR [Clonidine Extended-Release (ER) Oral Suspension) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) Medications – Appendix F

Action Item – Vote to Prior Authorize Sofdra™ (Sofpironium) – Appendix G

Action Item – Vote to Prior Authorize Enzeevu™ (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications – Appendix H

Action Item – Vote to Prior Authorize Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsule], Onapgo™ (Apomorphine Injection for Continuous Infusion), and Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) and Update the Approval Criteria for the Parkinson's Disease Medications – Appendix I

Action Item – Vote to Prior Authorize Vanrafia® (Atrasentan) and Update the Approval Criteria for the Primary Immunoglobulin A Nephropathy (IgAN) Medications – Appendix J

Action Item – Vote to Prior Authorize Axtle™ (Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) and Update the Approval Criteria for the Lung Cancer Medications – Appendix K

Action Item – Annual Review of Antiviral Medications – Appendix L

Action Item – Annual Review of Daybue™ (Trofinetide) – Appendix M

Action Item – Annual Review of Strensiq® (Asfotase Alfa) – Appendix N

Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Avmapki™ Fakzynja ™ Co-Pack (Avutometinib and Defactinib) – Appendix O

Annual Review of the SoonerCare Pharmacy Benefit – Appendix P

Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Cobenfy™ (Xanomeline/Trospium), Erzofri® [Paliperidone Palmitate Extended-Release (ER) Injection], and Opipza™ (Aripiprazole Film) – Appendix Q

Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Carbamazepine 200mg Chewable Tablet, Femlyv™ [Norethindrone Acetate/Ethinyl Estradiol Orally Disintegrating Tablet (ODT)]; Focinvez™ (Fosaprepitant Injection), Imkeldi (Imatinib Oral Solution), IVRA (Melphalan 90mg/mL Injection), Myhibbin™ (Mycophenolate Mofetil Oral Suspension), Ondansetron 16mg ODT, Tezruly™ (Terazosin Oral Solution), Topiramate 50mg Sprinkle Capsule, Veltassa® (Patiromer) 1g Powder Packet, and Vigafyde™ (Vigabatrin Oral Solution) – Appendix R

Annual Review of Rezdiffra™ (Resmetirom) – Appendix S

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – June 11, 2025 @ 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
Mr. Kenneth Foster –	participating in person
Dr. Bret Haymore –	participating in person
Dr. Bethany Holderread –	participating in person
Dr. Craig Kupiec –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Jennifer Weakley –	participating in person

Viewing Access Only via Zoom:

Please register for the meeting at:
https://oklahoma.zoom.us/webinar/register/WN_94lCoSe9Ty2msgsLMqg2Ww
After registering, you will receive a confirmation email containing information about joining the webinar.

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 958 2294 2095
Passcode: 65079339

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.

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. May 14, 2025 DUR Board Meeting Minutes
   B. May 14, 2025 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 May 2025
   B. Medication Coverage Activity for May 2025

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

5. **Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Utilization Update – See Appendix C**
   A. Introduction
   B. DPP-4 Inhibitor Utilization in the SoonerCare Population
   C. Conclusions
   D. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Daxxify® (DaxibotulinumtoxinA-lanm) and Update the Approval Criteria for the Botulinum Toxins – See Appendix D**
   A. Market News and Updates
   B. Daxxify® (DaxibotulinumtoxinA-lanm) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Brynovin™ (Sitagliptin Oral Solution), Glimepiride 3mg Tablet, Merilog™ (Insulin Aspart-szjj), Metformin 750mg Tablet, and Zituvimet™ XR [Sitagliptin/Metformin Extended-Release (ER)] and Update the Approval Criteria for the Anti-Diabetic Medications – See Appendix E**
   A. Market News and Updates
   B. Cost Comparisons
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Onyda™ XR [Clonidine Extended-Release (ER) Oral Suspension) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) Medications – See Appendix F**
   A. Market News and Updates
   B. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Sofdra™ (Sofpironium) – See Appendix G**
   A. Market News and Updates
   B. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Enzeevu™ (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications – See Appendix H**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsule], Onapgo™ (Apomorphine Injection for Continuous Infusion), and Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) and Update the Approval Criteria for the Parkinson's Disease Medications – See Appendix I**
    A. Market News and Updates
    B. Product Summaries
    C. Cost Comparison: Oral Carbidopa/Levodopa Products
    D. College of Pharmacy Recommendations

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

12. **Action Item – Vote to Prior Authorize Vanrafia® (Atrasentan) and Update the Approval Criteria for the Primary Immunoglobulin A Nephropathy (IgAN) Medications – See Appendix J**
    A. Market News and Updates
    B. Vanrafia® (Atrasentan) Product Summary
    C. College of Pharmacy Recommendations

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

13. **Action Item – Vote to Prior Authorize Axtle™ (Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) and Update the Approval Criteria for the Lung Cancer Medications – See Appendix K**
    A. Market News and Updates
    B. Product Summary
    C. College of Pharmacy Recommendations

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

14. **Action Item – Annual Review of Antiviral Medications – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of Antiviral Medications
    C. Prior Authorization of Antiviral Medications
    D. Market News and Updates
    E. Cost Comparison: Prevymis® (Letermovir) Products
    F. College of Pharmacy Recommendations
    G. Utilization Details of Antiviral Medications

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

15. **Action Item – Annual Review of Daybue™ (Trofinetide) – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Daybue™ (Trofinetide)
    C. Prior Authorization of Daybue™ (Trofinetide)
    D. Market News and Updates

E. College of Pharmacy Recommendations
F. Utilization Details of Daybue™ (Trofinetide)

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

16. Action Item – Annual Review of Strensiq® (Asfotase Alfa) – See Appendix N

A. Current Prior Authorization Criteria
B. Utilization of Strensiq® (Asfotase Alfa)
C. Prior Authorization of Strensiq® (Asfotase Alfa)
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Strensiq® (Asfotase Alfa)

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

17. Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) – See Appendix O

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. Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Genitourinary and Gynecologic Cancer Medications

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

18. Annual Review of the SoonerCare Pharmacy Benefit – See Appendix P

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. Fiscal Year Comparison

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

19. Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Cobenfy™ (Xanomeline/Trospium), Erzofri® [Paliperidone Palmitate Extended-Release (ER) Injection], and Opipza™ (Aripiprazole Oral Film) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Atypical Antipsychotic Medications
C. Prior Authorization of Atypical Antipsychotic Medications
D. Oklahoma Resources
E. Market News and Updates
F. Cobenfy™ (Xanomeline/Trospium) Product Summary
G. Cost Comparisons
H. College of Pharmacy Recommendations
I. Utilization Details of Atypical Antipsychotic 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 Carbamazepine 200mg Chewable Tablet, Femlyv™ [Norethindrone Acetate/Ethinyl Estradiol Orally Disintegrating Tablet (ODT)]; Focinvez™ (Fosaprepitant Injection), Imkeldi (Imatinib Oral Solution), IVRA (Melphalan 90mg/mL Injection), Myhibbin™ (Mycophenolate Mofetil Oral Suspension), Ondansetron 16mg ODT, Tezruly™ (Terazosin Oral Solution), Topiramate 50mg Sprinkle Capsule, Veltassa® (Patiromer) 1g Powder Packet, and Vigafyde™ (Vigabatrin Oral Solution) – See 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. Wilson, Dr. Haymore, Chairman:

21. Annual Review of Rezdiffra™ (Resmetirom) – See Appendix S

A. Current Prior Authorization Criteria
B. Utilization of Rezdiffra™ (Resmetirom)
C. Prior Authorization of Rezdiffra™ (Resmetirom)
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Rezdiffra™ (Resmetirom)

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

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

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

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

A. Alzheimer's Disease Medications
B. Colorectal Cancer (CRC) Medications

C. Epidermolysis Bullosa (EB) Medications
D. Testosterone Products
*Future product and class reviews subject to change.

24. 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. SoonerSelect PA data only includes medications billed as pharmacy claims (NDC) and does not include those billed as medical claims (HCPCS), where applicable.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING MAY 14, 2025

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP	X	
Kenneth Foster, MHS, PA-C		X
Bret Haymore, M.D.; Chairman	X	
T. Craig Kupiec II, M.D., MSPH	X	
Lee Muñoz, D.Ph.	X	
James Osborne, Pharm.D.		X
Edna Patatanian, Pharm.D., FASHP; Vice Chairwoman	X	
Beth Walton, Pharm.D.	X	
Jennifer Weakley, M.D., DipABLM		X

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Michaela DeRemer, Pharm.D., MBA, BCPS; Clinical Pharmacist	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	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	
Chinemerem Opara, Pharm.D.; Pharmacy Resident	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	
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director		X
Christina Foss; Chief of Staff, State Medicaid Director		X
Conner Mulvaney, J.D.; Deputy General Counsel	X	
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Chief Medical Officer		X

Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Sharon Smith, Pharm.D.; Clinical Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	

OTHERS PRESENT:	
Jill Milton, Bayer	Taha Khan, Vertex
Michael Faithe, Jazz Pharmaceuticals	David Mendoza, Otsuka
Todd Dickerson, Jazz Pharmaceuticals	Bryan Mauk, Vertex
Mark Kaiser, Otsuka	Rhonda Clark, Indivior
Roberto Pedraza, Vertex	Kristen Winters, Centene
Todd Ness, AbbVie	Matt John, Otsuka
Logan Poole, Novo Nordisk	Melissa Abbott
Bobby White, Eisai	Irene Chung, Aetna
Eardie Curry, Genentech	Lee Stout, Chiesi
Lindsey Walter, Novartis	Phil Lohec, Viatris
Janie Huff, Madrigal Pharmaceuticals	Christine Dube, AstraZeneca
John Bullard, Alexion	Diedra Williams, Humana
Pam Storey, PTC Therapeutics	Kent Douglas, Neurocrine
Ginger Papesh, Novo Nordisk	Brian Denger, Parent Project Muscular Dystrophy
Dana Pipkin, Sarepta	Lindsey Baker, Genentech
Dan Sheehan, Pfizer	Marcia Barbe, NS Pharma
Saurabh Patel, AbbVie	Matt Metcalf, Callidtas
Marc Parker, VS Health Group	Nick Trombold, Alexion
Scott Burns, Johnson & Johnson	Jennifer Lauper, Bristol Myers Squibb
Benjamin Skoog, Acadia	

PRESENT FOR PUBLIC COMMENT:	
Taha Khan, Vertex	Michael Faithe, Jazz Pharmaceuticals

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 TAHA KHAN

2B: AGENDA ITEM NO. 16 MICHAEL FAITHE

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: **APPROVAL OF DUR BOARD MEETING MINUTES**

3A: APRIL 9, 2025 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Haymore

Dr. Patatanian moved to approve; seconded by Dr. Walton

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT**

4A: PHARMACY HELPDESK ACTIVITY FOR APRIL 2025

4B: MEDICATION COVERAGE ACTIVITY FOR APRIL 2025

Non-presentation item; materials included in agenda packet by Dr. Wilson
ACTION: NONE REQUIRED

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

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE ALHEMO® (CONCIZUMAB-MTCI), BEQVEZ™ (FIDANACOGENE ELAPARVOVEC), HYMPAVZI™ (MARSTACIMAB-HNCQ), AND QFITLIA™ (FITUSIRAN) AND UPDATE THE APPROVAL CRITERIA FOR THE HEMOPHILIA MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARIES
6C: OKLAHOMA HEALTH CARE AUTHORITY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Ratterman
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE ADZYNMA (ADAMTS13, RECOMBINANT-KRHN) AND ALVAIZ® (ELTROMBOPAG)
7A: MARKET NEWS AND UPDATES
7B: PRODUCT SUMMARIES
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE JOURNAVX™ (SUZETRIGINE)
8A: MARKET NEWS AND UPDATES
8B: JOURNAVX™ (SUZETRIGINE) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Kupiec moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE XOLREMDI® (MAVORIXAFOR) AND UPDATE THE APPROVAL CRITERIA FOR THE GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AND STEM CELL MOBILIZERS
9A: MARKET NEWS AND UPDATES
9B: XOLREMDI® (MAVORIXAFOR) PRODUCT SUMMARY
9C: 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

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE OCREVUS ZUNOVO™ (OCRELIZUMAB/ HYALURONIDASE-OCSQ) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE SCLEROSIS (MS) MEDICATIONS

10A: MARKET NEWS AND UPDATES

10B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran

Dr. Patatanian moved to approve; seconded by Dr. Walton

ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: VOTE TO PRIOR AUTHORIZE AGAMREE® (VAMOROLONE) AND DUVYZAT™ (GIVINOSTAT) AND UPDATE THE APPROVAL CRITERIA FOR THE MUSCULAR DYSTROPHY MEDICATIONS

11A: MARKET NEWS AND UPDATES

11B: PRODUCT SUMMARIES

11C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

Dr. Muñoz moved to approve; seconded by Dr. Walton

ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS

12A: CURRENT PRIOR AUTHORIZATION CRITERIA

12B: UTILIZATION OF SMA MEDICATIONS

12C: PRIOR AUTHORIZATION OF SMA MEDICATIONS

12D: MARKET NEWS AND UPDATES

12E: COLLEGE OF PHARMACY RECOMMENDATIONS

12F: UTILIZATION DETAILS OF SMA MEDICATIONS

Materials included in agenda packet; presented by Dr. DeRemer

Dr. Patatanian moved to approve; seconded by Dr. Muñoz

ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF LUNG CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AXTLE™ (PEMETREXED), BIZENGRI® (ZENOCUTUZUMAB-ZBCO), IMDELLTRA™ (TARLATAMAB-DLLE), LAZCLUZE™ (LAZERTINIB), AND TECENTRIQ HYBREZA™ (ATEZOLIZUMAB/HYALURONIDASE-TQJS)

13A: CURRENT PRIOR AUTHORIZATION CRITERIA

13B: UTILIZATION OF LUNG CANCER MEDICATIONS

13C: PRIOR AUTHORIZATION OF LUNG CANCER MEDICATIONS

13D: MARKET NEWS AND UPDATES

13E: PRODUCT SUMMARIES

13F: COST COMPARISON: PEMETREXED PRODUCTS

13G: COLLEGE OF PHARMACY RECOMMENDATIONS

13H: 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

AGENDA ITEM NO. 14: ANNUAL REVIEW OF BOTULINUM TOXINS AND 30-DAY NOTICE TO PRIOR AUTHORIZE DAXXIFY® (DAXIBOTULINUMTOXINA-LANM)

14A: CURRENT PRIOR AUTHORIZATION CRITERIA

14B: UTILIZATION OF BOTULINUM TOXINS

14C: PRIOR AUTHORIZATION OF BOTULINUM TOXINS

14D: MARKET NEWS AND UPDATES

14E: DAXXIFY® (DAXIBOTULINUMTOXINA-LANM) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF BOTULINUM TOXINS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 15:</u> ANNUAL REVIEW OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE) AND 30-DAY NOTICE TO PRIOR AUTHORIZE BRYNOVIN™ (SITAGLIPTIN ORAL SOLUTION), GLIMEPIRIDE 3MG TABLET, METFORMIN 750MG TABLET, MERILOG™ (INSULIN ASPART-SZJJ), AND ZITUVIMET™ XR [SITAGLIPTIN/METFORMIN EXTENDED-RELEASE (ER)]
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
15C: PRIOR AUTHORIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
15D: MARKET NEWS AND UPDATES
15E: COST COMPARISONS
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
Materials included in agenda packet; presented by Dr. O'Halloran
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 ONYDA™ XR [CLONIDINE EXTENDED-RELEASE (ER) ORAL SUSPENSION]
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: ONYDA™ XR (CLONIDINE ER SUSPENSION) PRODUCT SUMMARY
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> 30-DAY NOTICE TO PRIOR AUTHORIZE SOFDRA™ (SOFPIRONIUM 12.45% TOPICAL GEL)
17A: INTRODUCTION
17B: SOFDRA™ (SOFPIRONIUM 12.45% TOPICAL GEL) PRODUCT SUMMARY
17C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 18:</u> ANNUAL REVIEW OF AGE-RELATED MACULAR DEGENERATION (AMD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ENZEEVU™ (AFLIBERCEPT-ABZV), OPUVIZ™ (AFLIBERCEPT-YSZY), AND YESAFILI™ (AFLIBERCEPT-JBVF
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF AMD MEDICATIONS
18C: PRIOR AUTHORIZATION OF AMD MEDICATIONS

18D: MARKET NEWS AND UPDATES
18E: COST COMPARISON: AFLIBERCEPT BIOSIMILARS
18F: COLLEGE OF PHARMACY RECOMMENDATIONS
18G: UTILIZATION DETAILS OF AMD MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 19:</u> ANNUAL REVIEW OF PARKINSON'S DISEASE (PD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CREXONT® [CARBIDOPA/LEVODOPA EXTENDED-RELEASE (ER) CAPSULE], ONAPGO™ (APOMORPHINE INJECTION FOR CONTINUOUS INFUSION), AND VYALEV™ (FOSCARBIDOPA/FOSLEVODOPA INJECTION FOR CONTINUOUS INFUSION)
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF PD MEDICATIONS
19C: PRIOR AUTHORIZATION OF PD MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: PRODUCT SUMMARIES
19F: COST COMPARISON: ORAL CARBIDOPA/LEVODOPA PRODUCTS
19G: COLLEGE OF PHARMACY RECOMMENDATIONS
19H: UTILIZATION DETAILS OF PD MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JUNE

<u>AGENDA ITEM NO. 20:</u> ANNUAL REVIEW OF PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE VANRAFIA™ (ATRASENTAN)
20A: CURRENT PRIOR AUTHORIZATION CRITERIA
20B: UTILIZATION OF PRIMARY IGAN MEDICATIONS
20C: PRIOR AUTHORIZATION OF PRIMARY IGAN MEDICATIONS
20D: MARKET NEWS AND UPDATES
20E: VANRAFIA™ (ATRASENTAN) PRODUCT SUMMARY
20F: COLLEGE OF PHARMACY RECOMMENDATIONS
20G: UTILIZATION DETAILS OF PRIMARY 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. 21:</u> U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Non-presentation item; materials included in agenda packet by Dr. Wilson
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 22:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
22A: ANTIVIRAL MEDICATIONS
22B: ATYPICAL ANTIPSYCHOTIC MEDICATIONS
22C: GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
22D: 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

<u>AGENDA ITEM NO. 23:</u> ADJOURNMENT
The meeting was adjourned at 5:45pm.

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

Memorandum

Date: May 16, 2025

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 May 14, 2025

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 Alhemo® (Concizumab-mtci), Beqvez™ (Fidanacogene Elaparvovec-dzkt), Hympavzi™ (Marstacimab-hncq), and Qfitlia™ (Fitusiran) and Update the Approval Criteria for the Hemophilia Medications

MOTION CARRIED by unanimous approval.

The Oklahoma Health Care Authority recommends the prior authorization of Alhemo® (concizumab-mtci), Beqvez™ (fidanacogene elaparvovec-dzkt), Hympavzi™ (marstacimab-hncq), and Qfitlia™ (fitusiran) with the following criteria (shown in red):

Alhemo® (Concizumab-mtci) Approval Criteria:

1. An FDA approved diagnosis of hemophilia A or B with inhibitors; and
2. Member must be 12 years of age or older; and

3. Member's recent weight (taken within the past 3 months) must be provided and must be ≥25kg; and
4. Member must not be undergoing immune tolerance induction (ITI); and
5. Member must not have a history of or be at high risk for thromboembolic events; and
6. Female members of reproductive potential must meet the following:
    a. Must not be pregnant; or
        i. If member is pregnant or becomes pregnant during treatment, the risk to the fetus must be weighed against the benefit to the mother; and
    b. Must agree to use effective birth control during treatment and for at least 7 weeks after the last dose; and
7. Prescriber must agree the member will not be continuing on other prophylactic therapies; and
8. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
9. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of Alhemo®; and
10. Prescriber must verify that the member has been counseled on the potential risk of thrombosis and use of bypassing agents at the lowest possible dose for breakthrough bleeding episodes based on severity and location of bleed; and
11. Requests must be for an FDA approved dosing regimen as outlined in the package labeling; and
12. Initial approvals will be for 3 months for the loading dose of 1mg/kg on day 1 and 0.2mg/kg daily until individualization of the maintenance dose has been achieved. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness.

Beqvez™ (Fidanacogene Elaparvovec-dzkt) Approval Criteria:

1. A diagnosis of severe or moderately severe congenital, X-linked, hemophilia B (FIX ≤2%); and
2. Member must be a male 18 years of age or older; and
3. Member must not have a history of an inhibitor, or a recent positive screening defined as ≥0.6 Bethesda units prior to administration of fidanacogene elaparvovec-dzkt; and
4. Member must not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test; and
5. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and

6. Member must have had >50 previous exposure days of treatment with factor IX; and
7. Member must not have any of the following:
    a. Current liver-related coagulopathy; or
    b. Hypoalbuminemia; or
    c. Persistent jaundice; or
    d. Cirrhosis; or
    e. Portal hypertension; or
    f. Splenomegaly; or
    g. Hepatic encephalopathy; or
    h. Hepatic fibrosis; or
    i. Active viral hepatitis; and
8. Members with human immunodeficiency virus (HIV) must not be uncontrolled with antiviral therapy as shown by CD4+ counts ≤200cells/mm^3 or viral load ≥20 copies/mL; and
9. Member must not have received prior treatment with any gene therapy for hemophilia B; and
10. Provider must perform a liver health assessment including:
    a. Enzyme testing (ALT, AST, ALP); and
    b. Hepatic ultrasound and elastography; and
11. Member's recent weight must be provided (taken within the last month) to ensure appropriate dosing; and
12. Prescriber must counsel member not to donate semen, and if member is of reproductive potential, then their female partners must agree to prevent or postpone pregnancy for 6 months after treatment with fidanacogene elaparvovec-dzkt; and
13. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
14. Fidanacogene elaparvovec-dzkt must be administered in an appropriate clinical setting and member must be monitored for at least 3 hours post infusion; and
15. Prescriber agrees to monitor liver enzymes and the factor IX activity level following administration of fidanacogene elaparvovec-dzkt per the package labeling as follows:
    a. Weeks 1 through 16: once to twice weekly; and
    b. Weeks 17 and 18: weekly; and
    c. Weeks 19 through 52: at weeks 24, 32, 42, and 52; and
    d. Years 2 and 3: quarterly; and
    e. Years 4 through 6: twice yearly; and
    f. Yearly thereafter; and
16. Prescriber agrees to start corticosteroids as indicated in the package labeling based on liver enzyme results and the factor IX activity level; and
17. Approvals will be for 1 treatment per member per lifetime.

Hympavzi™ (Marstacimab-hncq) Approval Criteria:

1. A diagnosis of moderately severe to severe hemophilia A (FVIII <2%) without inhibitors or moderately severe to severe hemophilia B (FIX activity <2%) without inhibitors; and
2. Member must be 12 years of age or older and weigh at least 35kg; and
3. Member must not have a current inhibitor or documented history of an inhibitor; and
4. For females of reproductive potential:
    a. Member must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
    b. Member must be willing to use effective contraception during and after treatment for at least 2 months after the last dose; and
5. Member must not have uncontrolled human immunodeficiency virus (HIV) as shown by CD4+ counts ≤200cells/mm^3; and
6. Prescriber must agree the member will not be continuing other prophylactic therapies; and
7. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
8. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of Hympavzi™; and
9. Prescriber must verify that the member has been counseled on the use of factor replacement therapy at the lowest possible dose for breakthrough bleeding episodes; and
10. Initial approvals will be for 3 months of therapy. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness; and
11. Approvals will be for 300mg loading dose followed by 150mg weekly doses. Approvals may be granted for dose escalation to 300mg weekly when the following are met:
    a. Member weighs ≥50kg; and
    b. There have been ≥2 spontaneous bleeding episodes which were treated with factor replacement therapy in the last 6 months despite compliance; and
    c. Absence of inhibitor development.

Qfitlia™ (Fitusiran) Approval Criteria:

1. A diagnosis of severe hemophilia A or B, with or without factor inhibitors; and
2. Member must be 12 years of age or older; and
3. Member must not have a history of or be at high risk for thromboembolic events; and
4. Member must not have clinically significant liver disease; and

5. Member must not have active hepatitis C; and
6. Member must not have an acute or chronic hepatitis B infection; and
7. Members with human immunodeficiency virus (HIV) must not be uncontrolled with antiviral therapy as shown by CD4+ counts ≤200cells/mm^3 or viral load ≥20 copies/mL; and
8. In a member with a history of symptomatic gallbladder disease, a reason why the member cannot use other available treatments must be provided; and
9. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
10. Prescriber must agree the member will not be continuing other prophylactic therapies for longer than 7 days after initiation of fitusiran; and
11. Prescriber must agree to perform an FDA-cleared test for antithrombin activity at weeks 4, 12, 20, and 24 and adjust the dosing as outlined in the package labeling; and
12. Prescriber must agree to perform baseline liver tests prior to initiation of fitusiran and monthly for at least 6 months and after any dose increase; and
13. Prescriber must verify that the member or caregiver has been trained on the subcutaneous administration and counseled on the storage of fitusiran; and
14. Prescriber must verify that the member has been counseled on the use of factor replacement therapy or bypassing agent as outlined in the prescribing information for breakthrough bleeding episodes; and
15. Initial approvals will be for 3 months of therapy. Subsequent approvals will be the duration of 1 year if there is documentation of clinical effectiveness.

Additionally, the Oklahoma Health Care Authority recommends updating the approval criteria for Feiba® (anti-inhibitor coagulation complex), NovoSeven® RT [coagulation factor VIIa (recombinant)] and Sevenfact® [coagulation factor VIIA (recombinant)-jncw] with the following based on net costs (changes shown in red):

Feiba® (Anti-Inhibitor Coagulation Complex) Approval Criteria:

1. Member must be diagnosed with hemophilia A or B with an inhibitor; and
   a. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci), Hemlibra® (emicizumab-kxwh), or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; ~~and~~ or
   b. For a diagnosis of hemophilia B with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo®

(concizumab-mtci) or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; and

2. Feiba® must be prescribed by a hematologist specializing in rare bleeding disorders practicing in a federally recognized Hemophilia Treatment Center (HTC) or a mid-level practitioner ~~with a supervising~~ under the supervision of a physician ~~that is a hematologist specializing in rare bleeding disorders~~ at an HTC.

NovoSeven® RT [Coagulation Factor VIIa (Recombinant)] Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Hemophilia A or B with inhibitors; or
      i. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci), Hemlibra® (emicizumab-kxwh), or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; or
      ii. For a diagnosis of hemophilia B with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci) or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; or
   b. Congenital factor VII deficiency; or
   c. Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets; or
   d. Acquired hemophilia; and
2. NovoSeven® RT must be prescribed by a hematologist specializing in rare bleeding disorders practicing in a federally recognized Hemophilia Treatment Center (HTC) or a mid-level practitioner ~~with a supervising~~ under the supervision of a physician ~~that is a hematologist specializing in rare bleeding disorders~~ at an HTC.

Sevenfact® [Coagulation Factor VIIA (Recombinant)-jncw] Approval Criteria:

1. An FDA approved diagnosis; and
   a. For a diagnosis of hemophilia A with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci), Hemlibra® (emicizumab-kxwh), or Qfitlia™ (fitusiran) for prophylaxis therapy must be provided; or
   b. For a diagnosis of hemophilia B with an inhibitor, a patient-specific, clinically significant reason why the member cannot use Alhemo® (concizumab-mtci) or Qfitlia™ (Fitusiran) for prophylaxis therapy must be provided; and
2. Sevenfact® must be prescribed by a hematologist specializing in rare bleeding disorders practicing in a federally recognized Hemophilia Treatment Center (HTC) or a mid-level practitioner ~~with a supervising~~ under the supervision of a physician ~~that is a hematologist specializing in rare bleeding disorders~~ at an HTC.

Finally, the Oklahoma Health Care Authority recommends updating the approval criteria for Hemlibra® (emicizumab-kxwh) with the following based on guidelines (changes shown in red):

Hemlibra® (Emicizumab-kxwh) Approval Criteria:

1. Member must have a diagnosis of hemophilia A; and
2. Hemlibra® must be prescribed by a hematologist specializing in rare bleeding disorders practicing in a federally recognized Hemophilia Treatment Center (HTC) or a mid-level practitioner ~~with a supervising~~ under the supervision of a physician ~~that is a hematologist specializing in rare bleeding disorders~~ at an HTC.; and
3. Prescriber must be able to monitor appropriate blood clotting tests and levels utilizing testing which accounts for the interaction of Hemlibra® and blood factors by following the Medical and Scientific Advisory Council (MASAC) guidance; and
4. For members with hemophilia A with an inhibitor to factor VIII:
    a. A treatment plan must be developed to address breakthrough bleeds and procedures. Prescriber must counsel member and/or caregiver on the risks of utilizing Feiba® for breakthrough bleeding while on Hemlibra®, and member should be monitored closely if any bypassing agent is given; or
5. For members without an inhibitor and having severe hemophilia A or those with moderate hemophilia A presenting as severe:
    ~~a. Member's current prophylaxis therapy is not adequate to prevent spontaneous bleeding episodes, or the member is unable to maintain venous access for prophylactic infusions; and~~
    b. Treatment plan must be made to address breakthrough bleeds and procedures; and
    c. Routine lab screenings must occur for factor VIII inhibitor while using Hemlibra® since this would change the treatment plan for bleeds and procedures; and
6. Prescriber must agree the member will not be continuing other prophylactic therapies; and
7. First dose must be given in a health care facility; and
8. In order to calculate appropriate dosing, the member's recent weight must be provided and been taken within the last 3 months; and
9. Initial approvals will be for 3 months of therapy. Subsequent approvals will be for the duration of 1 year, if there has been a decrease in the member's spontaneous bleeding episodes since initiating Hemlibra® treatment.

Recommendation 4: Vote to Prior Authorize Adzynma (ADAMTS13, Recombinant-krhn) and Alvaiz® (Eltrombopag)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Adzynma (ADAMTS13, recombinant-krhn) and Alvaiz® (eltrombopag) with the following criteria (shown in red):

Adzynma (ADAMTS13, Recombinant-krhn) Approval Criteria:

1. An FDA approved diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by:
   a. Molecular genetic testing confirming biallelic pathogenic variants in the *ADAMTS13* gene (results of genetic testing must be submitted); and
   b. ADAMTS13 activity testing showing <10% of normal ADAMTS13 activity (results of activity testing must be submitted); and
2. Member's recent weight (within the last 3 weeks) must be provided in order to ensure appropriate dosing in accordance with the package labeling; and
3. For prophylactic therapy, member has a history of ≥1 documented TTP event or is currently receiving prophylactic therapy; and
4. Must be prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the treatment of cTTP; and
5. For prophylactic enzyme replacement therapy (ERT):
   a. 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 treatment (e.g., improvement in acute and subacute TTP events, TTP manifestations, other clinical symptoms associated with TTP); and
6. For on-demand ERT:
   a. Approvals will be for 1 month; and
   b. If additional days are needed, requests should specify that the acute event has not resolved.

Alvaiz® (Eltrombopag) Approval Criteria [Persistent or Chronic Immune Thrombocytopenia (ITP) Diagnosis]:

1. An FDA approved diagnosis of persistent or chronic ITP; and
2. Member must have a platelet count of <30 x 10^9/L; and
3. Alvaiz® must not be used in an attempt to normalize platelet counts; and
4. Member must be 6 years of age or older; and
5. Member must not have a recent diagnosis of myelodysplastic syndromes; and
6. Previous insufficient response to at least 1 of the following treatments:
   a. Corticosteroids; or
   b. Immunoglobulins; or
   c. Splenectomy; and

7. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
8. Prescriber must attest that all other causes of thrombocytopenia, including malignancy and liver disease, have been ruled out; and
9. Prescriber must verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and
10. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz®; and
11. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of ITP; and
12. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 54mg per day, as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 90 tablets per 30 days; or
    c. 36mg strength: 30 tablets per 30 days; or
    d. 54mg strength: 30 tablets per 30 days.

Alvaiz® (Eltrombopag) Approval Criteria [Chronic Hepatitis C-Associated Thrombocytopenia Diagnosis]:

1. Member must have diagnosis of chronic hepatitis C-associated thrombocytopenia; and
2. Member must have a platelet count of $<75 \times 10^9/L$; and
3. Member must be 18 years of age or older; and
4. Member must not have a recent diagnosis of myelodysplastic syndromes; and
5. Member must be initiating interferon-based therapy (regimen must be provided); and
6. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
7. Prescriber must verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and
8. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz® and concomitant hepatitis C therapy; and
9. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of hepatitis C-associated thrombocytopenia; and
10. Continuation requests will not be approved once antiviral therapy has been discontinued; and
11. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 72mg per day, as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 120 tablets per 30 days; or
    c. 36mg strength: 60 tablets per 30 days; or
    d. 54mg strength: 30 tablets per 30 days.

Alvaiz® (Eltrombopag) Approval Criteria [Refractory Severe Aplastic Anemia Diagnosis]:

1. Member must have diagnosis of refractory severe aplastic anemia; and
2. Member must have a platelet count of ≤30 x 10^9/L; and
3. Member must not have a diagnosis of Fanconi anemia; and
4. Member must be 18 years of age or older; and
5. Member must not have a recent diagnosis of myelodysplastic syndromes; and
6. Member must have a documented trial of immunosuppressive therapy; and
7. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
8. Prescriber must verify that members will receive baseline and follow-up ocular examinations as recommended in the package labeling; and
9. Prescriber must agree to monitor hepatic function prior to and during treatment with Alvaiz®; and
10. Must be prescribed by, or in consultation with, a hematologist or other specialist with expertise in the treatment of aplastic anemia; and
11. Quantity limits will apply based on FDA-approved dosing, up to a maximum of 108mg per day as follows:
    a. 9mg strength: 30 tablets per 30 days; or
    b. 18mg strength: 120 tablets per 30 days; or
    c. 36mg and 54mg strengths: 60 tablets per 30 days.

Recommendation 5: Vote to Prior Authorize Journavx™ (Suzetrigine)

MOTION CARRIED by unanimous approval.

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

Journavx™ (Suzetrigine) Approval Criteria:

1. An FDA approved diagnosis of moderate to severe acute pain; and
2. Member must be 18 years of age or older; and
3. The underlying cause of the acute pain must be provided; and
4. Member must have a current numeric pain rating scale (NPRS) score ≥4 (NPRS score must be provided on the request); and
5. Member must not be taking any strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin); and
6. Member must not have severe hepatic impairment (Child-Pugh class C); and
7. If member is using hormonal contraceptives containing progestins, other than levonorgestrel and norethindrone, prescriber must confirm the member has been counseled to use an additional nonhormonal contraceptive method or an alternative hormonal contraceptive during

treatment with Journavx™ and 28 days after Journavx™ discontinuation; and
8. A patient specific, clinically significant reason why the member cannot use other non-opioid pain relievers, including acetaminophen and a non-steroidal anti-inflammatory drug (NSAID), must be provided; and
9. Journavx™ will not be approved for concurrent use with an opioid; and
10. A quantity limit of 30 tablets for a 14-day supply will apply. The use of Journavx™ for acute pain has not been studied for longer than 14 days. Journavx™ will not be approved for use beyond 14 days or for chronic pain.

Recommendation 6: Vote to Prior Authorize Xolremdi® (Mavorixafor) 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 Xolremdi® (mavorixafor) with the following criteria (shown in red):

Xolremdi® (Mavorixafor) Approval Criteria:
1. An FDA approved diagnosis of warts, hypogammaglobulinemia, infections, and myelokathexis (WHIM) syndrome; and
   a. Diagnosis must be confirmed by the presence of a pathogenic or likely pathogenic genotypic variant of the *CXCR4* gene (results of genetic testing must be submitted); and
2. Member must be 12 years of age or older; and
3. Must be prescribed by, or in consultation with, a hematologist, immunologist, or other specialist with expertise in treatment of WHIM syndrome (or an advanced care practitioner with a supervising physician who is a hematologist, immunologist, or other specialist with expertise in treatment of WHIM syndrome); and
4. The member's recent weight (within the last 3 months) must be provided with the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
5. 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 an effective method of contraception during treatment and for at least 3 weeks after discontinuing treatment; and
6. Female members must not be breastfeeding during treatment and for at least 3 weeks after discontinuation of treatment; and
7. Prescriber must agree to counsel the member on proper administration, including taking Xolremdi® on an empty stomach after an overnight fast and at least 30 minutes before food; and

8. Prescriber must verify the member does not have severe renal impairment [creatinine clearance (CrCl) 15-30mL/min] or end-stage renal disease (CrCl <15mL/min); and
9. Prescriber must verify the member does not have moderate or severe hepatic impairment (Child-Pugh B or C); and
10. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments or increased monitoring of Xolremdi® or the concomitant medication(s), according to package labeling, before initiating and throughout treatment with Xolremdi®; and
11. Prescriber must verify that any modifiable risk factors for QTc prolongation (e.g., hypokalemia, hypomagnesemia) are corrected prior to initiation of therapy; and
12. Prescriber must agree to perform and monitor electrocardiogram (ECG) at baseline and as clinically indicated, thereafter, for patients with risk factors for QTc prolongation (e.g., receiving concomitant medications with known potential to prolong the QTc interval or concomitant medications that increase Xolremdi® exposure); and
13. For members who are using Xolremdi® concomitantly with other medications that are known to increase Xolremdi® exposure and/or prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures) and evaluate the need for a dose reduction based on clinical response; and
14. A quantity limit of 120 capsules per 30 days will apply; and
15. 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 as indicated by 1 of the following:
    a. Documentation of sustained improvement in absolute neutrophil count (ANC) and/or absolute lymphocyte count (ALC) is provided; or
    b. If the member does not show a sustained improvement in ANC and/or ALC, a clinical rationale for continuation of treatment must be provided for reauthorization.

The College of Pharmacy also recommends removing the prior authorization for Nyvepria® (pegfilgrastim-apgf) as a medical benefit only 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® Onpro® (pegfilgrastim), Nyvepria® (pegfilgrastim-apgf), 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 Nyvepria® (pegfilgrastim-apgf) will be covered as a medical only benefit without prior authorization.

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® Onpro® (pegfilgrastim), Nyvepria® (pegfilgrastim-apgf), or Ziextenzo® (pegfilgrastim-bmez) must be provided; and
3. Neulasta® Onpro® (pegfilgrastim) and Nyvepria® (pegfilgrastim-apgf) will be covered as a medical only benefit without prior authorization.

Recommendation 7: Vote to Prior Authorize Ocrevus Zunovo™ (Ocrelizumab/Hyaluronidase-ocsq) and Update the Approval Criteria for the Multiple Sclerosis (MS) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Ocrevus Zunovo™ (ocrelizumab/hyaluronidase-ocsq) with criteria similar to the Ocrevus® (ocrelizumab) approval criteria (changes shown in red):

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 ~~Ocrevus®~~ 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 be trained on the proper storage of the requested product ~~Ocrevus®~~; and
5. Prescriber must confirm that member will be monitored appropriately per package labeling ~~for 1 hour~~ after each infusion or injection; and
6. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating ocrelizumab ~~Ocrevus®~~ therapy and member does not have active HBV; and
7. Verification from the prescriber that member has no active infection(s); and
8. Verification from the prescriber that female members are not currently pregnant and will use contraception while receiving ocrelizumab ~~Ocrevus®~~ therapy and for 6 months after the last dose ~~infusion~~ of ocrelizumab ~~Ocrevus®;~~ and
9. Approvals will be for the duration of 1 year, and compliance will be checked for continued approval.

Additionally, the College of Pharmacy recommends updating the Copaxone® (glatiramer acetate) approval criteria based on the FDA's safety alert and updating the approval criteria for Gilenya® (fingolimod), Mayzent® (siponimod), Ponvory® (ponesimod), Tascenso ODT® [fingolimod orally disintegrating tablet (ODT)], and Zeposia® (ozanimod) based on the FDA safety-related label changes and to be consistent with clinical practice and the other MS medications (changes shown in red):

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 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. Compliance will be checked for continued approval every 6 months.

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
   ~~a. Member has experienced at least 1 relapse in the previous 12 months or is transitioning from existing MS therapy; 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; and
   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. Verification from the prescriber that member has no active infection(s); and
8. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
~~9. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
~~10. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; 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.

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; 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 Mayzent®; 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. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
11. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
12. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~
13. ~~Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate (HR) or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and~~
14. ~~Verification from the prescriber that the member has been assessed for previous confirmed history of chickenpox or vaccination against varicella. Members without history of chickenpox or varicella vaccination should receive a full course of varicella vaccine prior to commencing treatment with Mayzent®; and~~

15. 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
16. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
17. 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
18. 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
19. Compliance will be checked for continued approval every 6 months; and
20. Quantity limits according to package labeling will apply.

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 AV block (Mobitz type I), or a history of HF or 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. 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
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. Member must not have received prior treatment with alemtuzumab; and
~~8. Member must not be concurrently using strong CYP3A4 and UGT1A1 inducers (e.g., rifampin, phenytoin, carbamazepine); and~~
9. Verification from the prescriber that the 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. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
~~12. Verification from the prescriber that the member has undergone an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Ponvory®; and~~
~~13. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
14. Verification from the prescriber that the member's blood pressure will be monitored during treatment with Ponvory®; and
~~15. Verification from the prescriber that the member has undergone an ophthalmic evaluation prior to starting therapy with Ponvory® and the member will be monitored for changes in vision throughout therapy; and~~
~~16. Verification from the prescriber that the 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 per package labeling; and~~
~~17. Verification from the prescriber that the 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~~
18. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and

19. 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
20. 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
21. Compliance will be checked for continued approval every 6 months; and
22. 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. Member must have had at least 1 relapse in the previous 12 months; and~~
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. 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
6. 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; and
    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
7. 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

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. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
~~11. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
12. 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
13. A patient-specific, clinically significant reason why the member cannot use Gilenya® (fingolimod) capsules must be provided; and
14. Compliance will be checked for continued approval every 6 months.

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. Member must not have received prior treatment with alemtuzumab; and
6. Verification from the prescriber that member has no active infection(s); and
7. Verification from the prescriber that member will be monitored for signs and symptoms of progressive multifocal leukoencephalopathy (PML) throughout therapy; and
8. Member must not be concurrently using strong CYP2C8 inhibitors/ inducers ~~or breast cancer resistance protein (BCRP) inhibitors~~; and
9. Verification from the prescriber that member has no active infection(s); and
10. ~~Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and~~
11. ~~Prescriber must conduct an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present before initiating Zeposia®; and~~
12. ~~Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and~~
13. ~~Ophthalmic evaluation and verification that member will be monitored for changes in vision throughout therapy; and~~

~~14. Verification from the prescriber that the member has been assessed for medications and conditions that cause reduction in heart rate or AV conduction delays and that the member will be followed with appropriate monitoring per package labeling; and~~
~~15. Verification from the prescriber that the member has been assessed for 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~~
16. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
17. 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
18. 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
19. 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
20. Compliance will be checked for continued approval every 6 months; and
21. A quantity limit of 30 capsules per 30 days will apply.

Finally, the College of Pharmacy recommends updating the Briumvi® (ublituximab-xiiy), Kesimpta® (ofatumumab), and Mavenclad® (cladribine), approval criteria to be consistent with clinical practice and the other MS medications (changes shown in red):

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. Member must have had at least 1 relapse in the previous 12 months; and~~
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. 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 be trained on the proper storage of Briumvi®; and
6. Prescriber must confirm that member will be monitored for 1 hour following the first 2 infusions and as indicated for subsequent infusions; and
7. Prescriber must verify hepatitis B virus (HBV) testing has been performed prior to initiating Briumvi® therapy and member does not have active HBV; and
8. Verification from the prescriber that member has no active infection(s); and
9. 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
10. Approvals will be for the duration of 1 year, and compliance will be checked 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. Member must have had at least 1 relapse in the previous 12 months; and~~
4. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
5. 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
6. Prescriber must agree to monitor quantitative serum immunoglobulin level before, during, and after discontinuation of treatment with Kesimpta® until B-cell repletion; and
7. Prescriber must verify the member has no active infection(s); and
8. Prescriber must verify the first injection of Kesimpta® will be administered by a health care professional prepared to manage injection-related adverse reactions; and
9. Kesimpta® must be shipped via cold chain supply and the member or member's caregiver must be trained on the proper storage and subcutaneous (sub-Q) administration of Kesimpta®; and
10. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of treatment with Kesimpta®; and

11. Female members of reproductive potential must use an effective method of contraception during treatment and for 6 months after stopping Kesimpta®; and
12. 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
13. Compliance will be checked for continued approval every 6 months.

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. Member must have had at least 1 relapse in the previous 12 months; and~~
5. Approvals will not be granted for concurrent use with other disease-modifying therapies; and
6. Member must have had an inadequate response to 2 or more medications indicated for the treatment of MS; and
7. Prescriber must confirm that the member does not have any contraindications for use of cladribine; and
8. Prescriber must confirm member does not have an active malignancy; and
9. 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
10. 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
11. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber; and
12. Verification from the prescriber that member has no active infection(s); and
13. Liver function tests (LFTs) and verification that levels are acceptable to the prescriber; and
14. 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
15. Quantity limits according to package labeling will apply; and
16. 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.

Recommendation 8: Vote to Prior Authorize Agamree® (Vamorolone) and Duvyzat™ (Givinostat) and Update the Approval Criteria for the Muscular Dystrophy Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Agamree® (vamorolone) and Duvyzat™ (givinostat) with the following criteria (shown in red):

Agamree® (Vamorolone Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 2 years of age or older; and
3. Agamree® must be prescribed by, or in consultation with, a prescriber who specializes in the treatment of DMD; and
4. Member must have a minimum 6-month trial of prednisone that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with Agamree® or a patient specific, clinically significant reason why the member cannot use prednisone must be provided; and
5. A patient specific, clinically significant reason why the member cannot use brand name Emflaza® (deflazacort) must be provided; and
6. Prescriber must verify the member has a baseline eye examination; and
7. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to the package labeling; and
8. For continued authorization, an updated weight must be provided, and the member must have had a repeat eye exam with results that are acceptable to the prescriber; and
9. A quantity limit of 300mL per 40 days will apply.

Duvyzat™ (Givinostat Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 6 years of age or older; and
3. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
4. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and

5. Prescriber must verify platelet counts and triglycerides have been evaluated at baseline, and levels are acceptable to the prescriber; and
6. Prescriber must agree to monitor member for adverse reactions such as a decrease in platelet counts, increase in triglycerides, or moderate to severe diarrhea and agree to modify the dose based on the package labeling recommendations, if needed; and
7. If member has underlying cardiac disease or is taking concomitant medications that cause QT prolongation, prescriber must agree to obtain an electrocardiogram (ECG) before initiating treatment with Duvyzat™, during concomitant use, and as clinically indicated; and
8. Approvals will be for the duration of 1 year. For each subsequent approval, the prescriber must document the member is tolerating and benefiting from treatment, as indicated by improvement, stabilization, or a slower progression of disease compared to the typical DMD progression (i.e., improved functional tests, strength, or pulmonary function test); and
9. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to the package labeling; and
10. A quantity limit of 420mL per 35 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Elevidys (delandistrogene moxeparvovec-rokl) based on the new FDA approved expanded indication (changes shown in red):

Elevidys (Delandistrogene Moxeparvovec-rokl) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be at least 4 years ~~through 5 years~~ of age; and
3. ~~Prescriber must attest the member is ambulatory and the results of 1 of the following tests must be submitted:~~
   - ~~a. North Star Ambulatory Assessment (NSAA); or~~
   - ~~b. 6-minute walk test (6MWT); or~~
   - ~~c. 10-meter walk test (10mWT); or~~
   - ~~d. Ascend 4 Steps; or~~
   - ~~e. Time to Rise (TTR); or~~
   - ~~f. 100-meter timed test; and~~
4. Elevidys must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Member's baseline anti-AAVrh74 total binding antibody titers must be <1:400; and
6. Member must not have any deletion in exon 8 and/or exon 9 in the *DMD* gene; and

7. If the member has a deletion in the *DMD* gene in exon 1 to 17 and/or exons 59 to 71, the prescriber must verify the member will be monitored for a severe immune-mediated myositis reaction; and
8. Member must not have any active infections and if the member does have an active infection, the prescriber must verify Elevidys infusion will be postponed until infection has resolved; and
9. Prescriber must verify the member will initiate a corticosteroid regimen 1 day prior to the infusion of Elevidys and continue for a minimum of 60 days to reduce the risk of an immune response as specified in the package labeling; and
10. Prescriber must verify liver function tests (LFTs) (e.g., GGT, total bilirubin) will be performed prior to Elevidys administration and will be monitored weekly for the first 3 months following Elevidys infusion then as clinically indicated; and
11. Prescriber must verify troponin-I will be monitored before the Elevidys infusion and weekly for the first month following infusion then as clinically indicated; and
12. Prescriber must verify that platelet counts will be monitored before the Elevidys infusion and weekly for the first 2 weeks following infusion then as clinically indicated; and
13. Member will not be approved for concomitant treatment with exon skipping therapy (e.g., Amondys 45, Exondys 51, Viltepso®, Vyondys 53) following Elevidys infusion (current authorizations for exon skipping therapy will be discontinued upon Elevidys approval); and
14. Member's current weight (kg) taken within the past ~~3 weeks~~ 6 months must be provided on the request to ensure accurate weight-based dosing according to package labeling; and
15. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends updating the approval criteria for Emflaza® (deflazacort) to be consistent with clinical practice (changes shown in red):

Emflaza® (Deflazacort) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 2 years of age or older; and
3. Emflaza® must be prescribed by, or in consultation with, a prescriber who specializes in the treatment of DMD; and
4. Member must have a minimum 6-month trial of prednisone that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with Emflaza® or a patient specific, clinically significant reason why the member cannot use prednisone must be provided; and

5. ~~A patient-specific, clinically significant reason why the member cannot use prednisone even when the tablets are crushed must be provided; and~~
6. ~~Patients already established on deflazacort via the ACCESS DMD Program must also document a patient-specific, clinically significant reason why the member cannot use prednisone even when the tablets are crushed; and~~
7. For Emflaza® suspension, a patient-specific, clinically significant reason why the member cannot use the tablet formulation in the place of oral suspension even when the tablets are crushed must be provided; and
8. Emflaza® is brand preferred. Requests for generic deflazacort will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
9. Prescriber must verify the member has had a baseline eye examination; and
10. The member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
11. For continued authorization, an updated weight must be provided, and the member must have had a repeat eye exam with results that are acceptable to the prescriber; and
12. For the tablets, a quantity limit of 30 tablets per 30 days will apply, and for the suspension, a quantity limit of 39mL (3 bottles) per 30 days will apply. Quantity limit override requests will be approved as appropriate based on the member's recent weight taken within the last 30 days.

Recommendation 9: Fiscal Year 2024 Annual Review of Spinal Muscular Atrophy (SMA) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Evrysdi® (risdiplam) approval criteria to include the prior authorization of the Evrysdi® (risdiplam) tablet formulation and to be consistent with other criteria that require genetic testing (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 ~~to an oral solution~~ 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 Evrysdi® *Prescribing Information*; 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 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 Evrysdi® *Prescribing Information*; and
17. For the oral solution, ~~A~~ 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.

The College of Pharmacy also recommends updating the Spinraza® (nusinersen) approval criteria to be consistent with other criteria that require genetic testing (changes shown in red):

Spinraza® (Nusinersen) Approval Criteria:

1. Diagnosis of spinal muscular atrophy (SMA):
   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 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.

Lastly, the College of Pharmacy recommends updating the Zolgensma® (onasemnogene abeparvovec-xioi) approval criteria based on the updates to the package labeling and to be consistent with other criteria that require genetic testing (changes shown in red):

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~~, and troponin I~~ 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) 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.

Recommendation 10: Annual Review of Lung Cancer Medications and 30-Day Notice to Prior Authorize Axtle™ (Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2025.

Recommendation 11: Annual Review of Botulinum Toxins and 30-Day Notice to Prior Authorize Daxxify® (DaxibotulinumtoxinA-lanm)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2025.

Recommendation 12: Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Brynovin™ (Sitagliptin Oral Solution), Glimepiride 3mg Tablet, Merilog™ (Insulin Aspart-szjj), Metformin 750mg Tablet, and Zituvimet™ XR [Sitagliptin/Metformin Extended-Release (ER)]

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2025.

Recommendation 13: Annual Review of Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications and 30-Day Notice to Prior Authorize Onyda™ XR [Clonidine Extended-Release (ER) Suspension]

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2025.

Recommendation 14: 30-Day Notice to Prior Authorize Sofdra™ (Sofpironium 12.45% Topical Gel)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2025.

Recommendation 15: Annual Review of Age-Related Macular Degeneration (AMD) Medications and 30-Day Notice to Prior Authorize Enzeevu™ (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2025.

Recommendation 16: Annual Review of Parkinson's Disease (PD) Medications and 30-Day Notice to Prior Authorize Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsule], Onapgo™ (Apomorphine Injection for Continuous Infusion), and Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2025.

Recommendation 17: Annual Review of Primary Immunoglobulin A Nephropathy (IgAN) Medications and 30-Day Notice to Prior Authorize Vanrafia™ (Atrasentan)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN JUNE 2025.

Recommendation 18: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

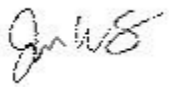
NO ACTION REQUIRED.

Recommendation 19: Future Business

NO ACTION REQUIRED.

Colleagues at Oklahoma Health Care Authority,

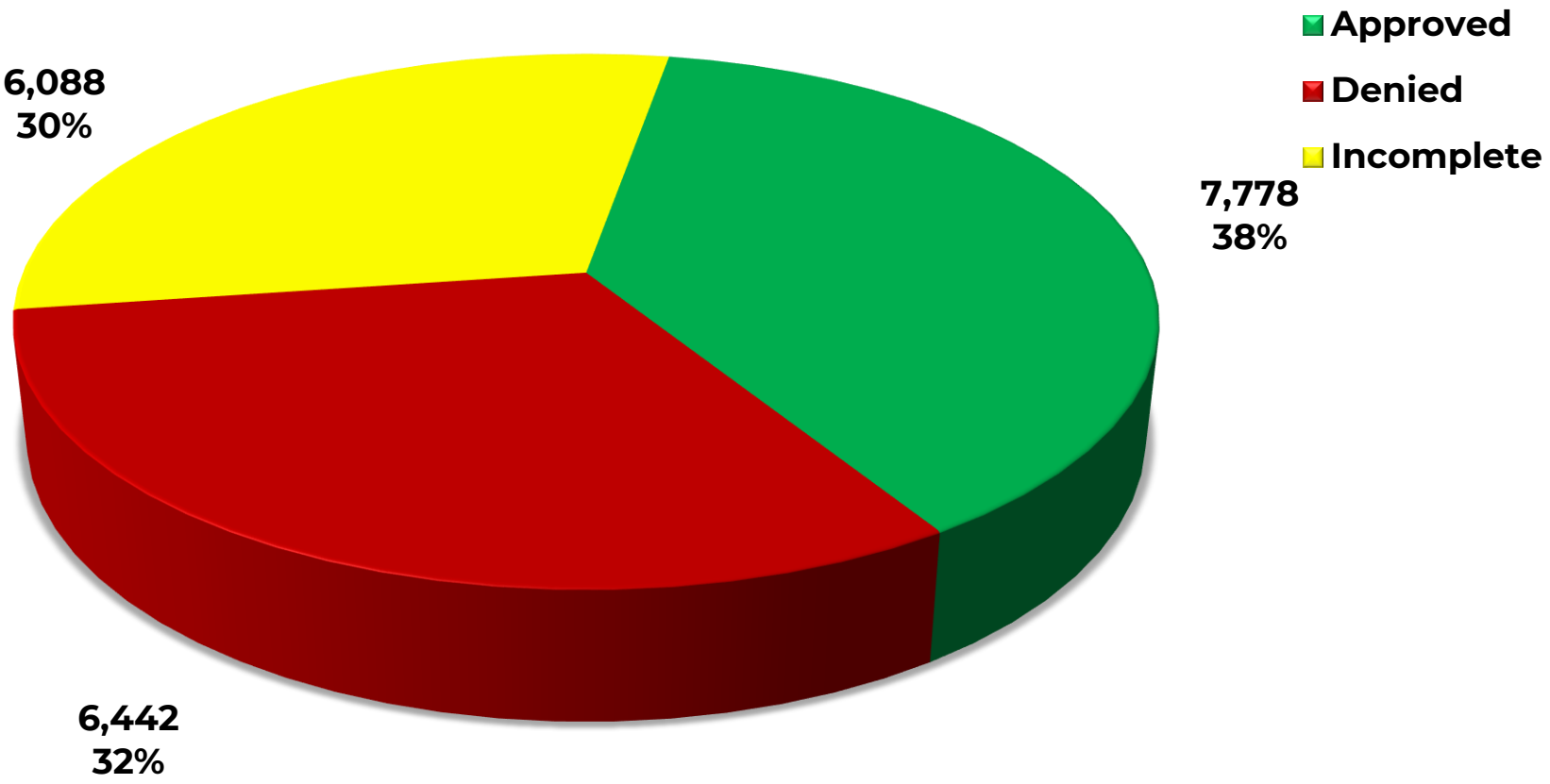
I am a board certified anesthesiologist and pain physician that has been caring for Oklahoma's medicaid population since I started in practice in 2015. I have been prescribing Journavx for acute pain. Patients have reported excellent pain relief and minimal to no side effects. I think this medication would be ideal to add to Oklahoma's Medicaid formulary as it does not appear to be abusable and has no addiction potential. I have used it with excellent efficacy as an additional medication to prescribe to patients that are on chronic opioids but have had surgery or some other acute pain causing event. This is a much safer option vs increasing opioids in the immediate postoperative period. I look forward to being able to offer this medication to my SoonerCare patients in the future.

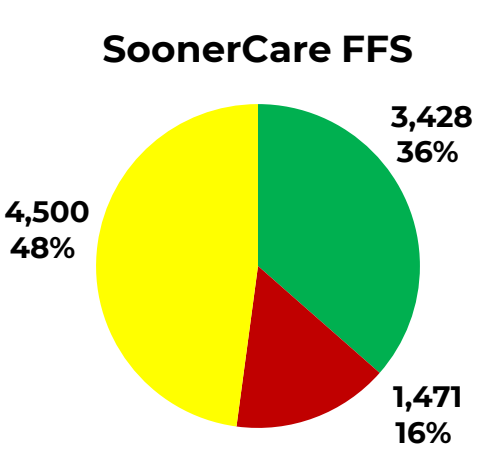


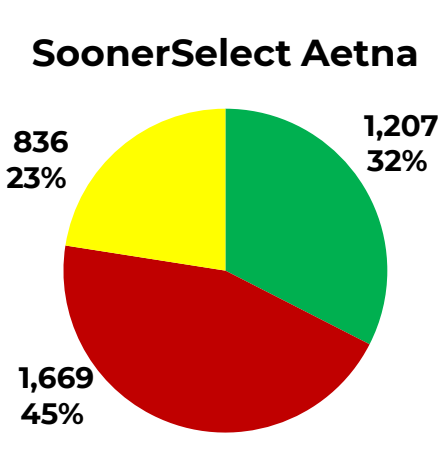
James W. Stephens, DO

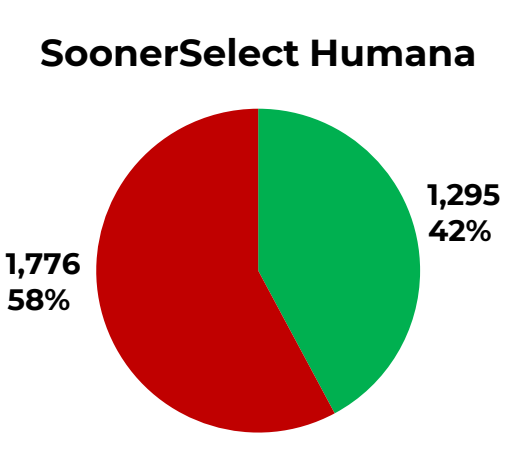
Appendix B

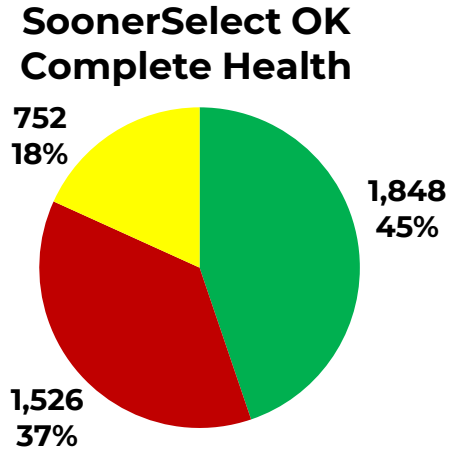
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: MAY 2025





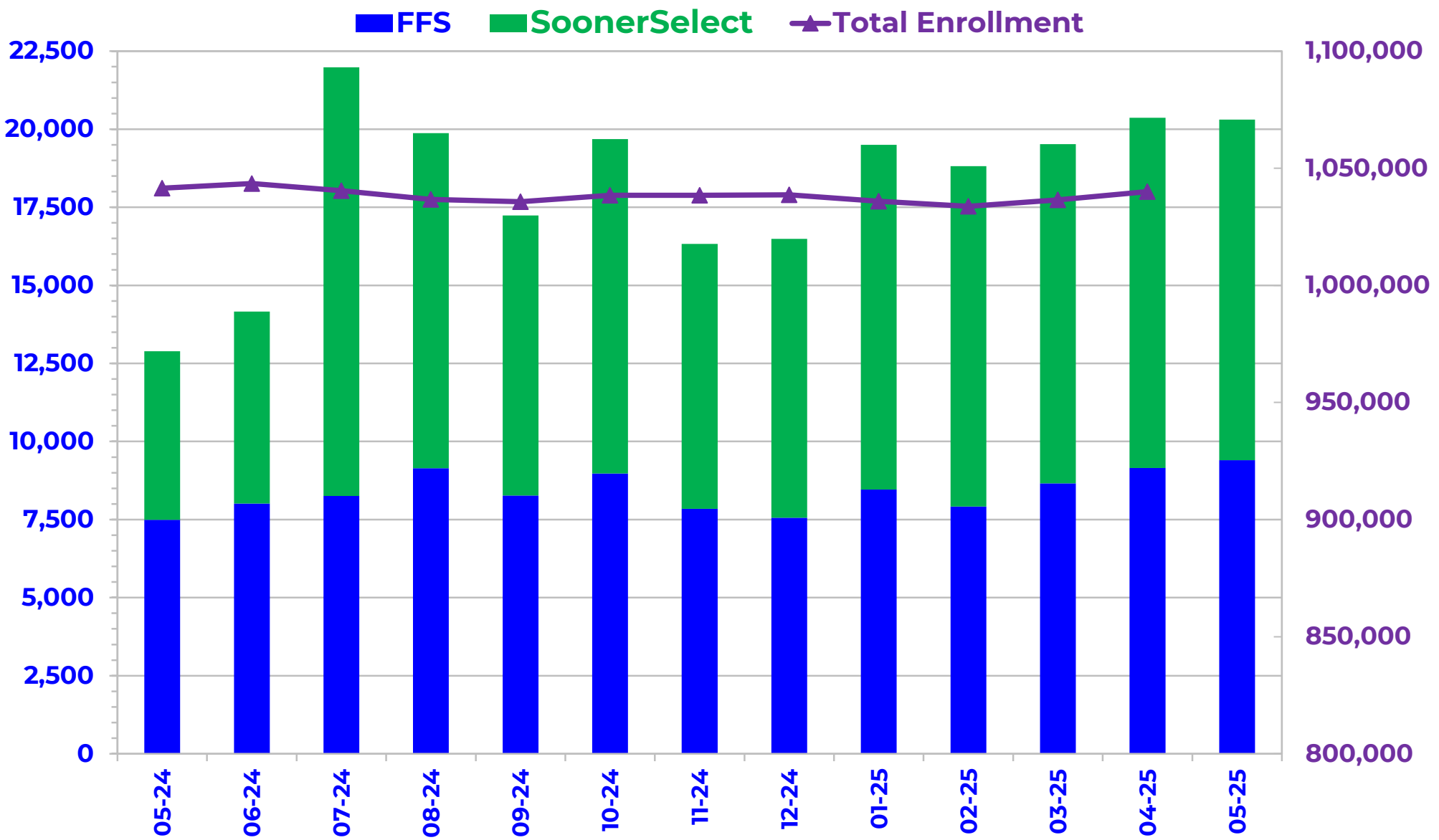






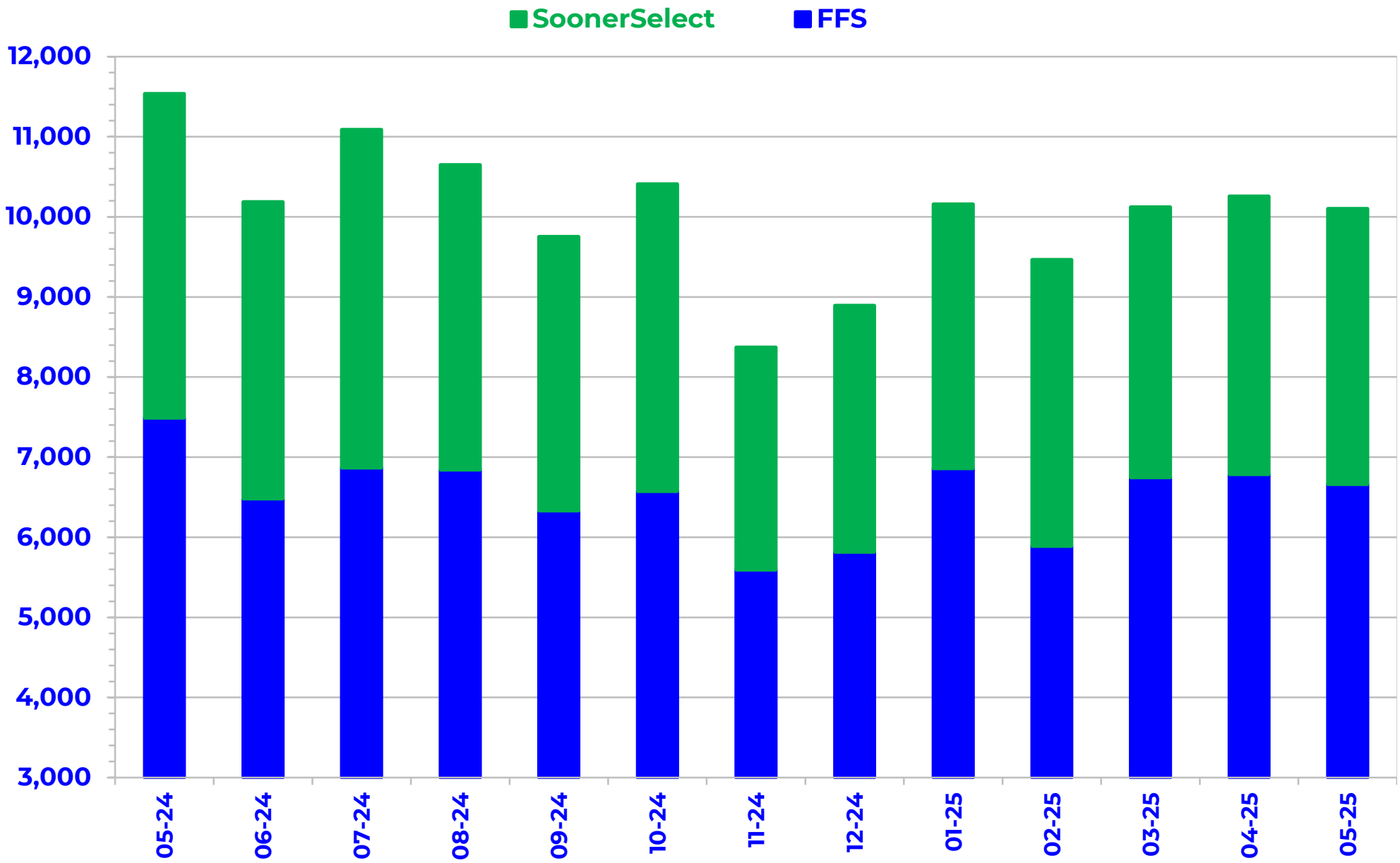
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: MAY 2024 – MAY 2025



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: MAY 2024 – MAY 2025



SoonerCare FFS Prior Authorization Activity

5/1/2025 Through 5/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	6	3	1	2	246
Amphetamines	642	415	6	221	353
Analgesics - Anti-Inflammatory	206	95	22	89	320
Analgesics - Nonnarcotic	19	0	2	17	0
Analgesics - Opioid	300	137	26	137	131
Androgens - Anabolic	81	20	19	42	315
Anorectal and Related Products	1	0	1	0	0
Anorexiants Non-Amphetamine	5	0	2	3	0
Anthelmintics	14	1	1	12	8
Anti-Infective Agents - Misc.	35	14	4	17	210
Anti-Obesity Agents	103	3	93	7	136
Antianxiety Agents	25	1	2	22	360
Antiasthmatic and Bronchodilator Agents	544	88	87	369	326
Antibiotics	35	13	3	19	264
Anticoagulants	10	1	0	9	351
Anticonvulsants	214	101	12	101	336
Antidepressants	227	59	39	129	291
Antidiabetics	1,592	398	358	836	352
Antidiarrheal/Probiotic Agents	1	0	0	1	0
Antidotes and Specific Antagonists	7	0	4	3	0
Antiemetics	32	2	5	25	268
Antifungals	9	1	2	6	360
Antihistamines	28	9	1	18	360
Antihyperlipidemics	85	22	23	40	279
Antihypertensives	20	5	6	9	359
Antimyasthenic/Cholinergic Agents	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	190	121	8	61	170
Antiparkinson and Related Therapy Agents	4	0	1	3	0
Antipsychotics/Antimanic Agents	371	130	28	213	354
Antivirals	24	10	3	11	50
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	257	154	23	80	354
Beta Blockers	11	3	0	8	360
Calcium Channel Blockers	14	3	2	9	246
Cardiovascular Agents - Misc.	86	47	6	33	329
Chemicals	1	0	0	1	0
Contraceptives	29	15	4	10	329
Corticosteroids	13	0	2	11	0
Cough/Cold/Allergy	1	0	1	0	0
Dermatologicals	416	103	125	188	237
Diagnostic Products	85	20	11	54	153

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Digestive Aids	8	3	0	5	258
Diuretics	19	7	1	11	306
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	166	77	25	64	253
Estrogens	9	3	1	5	359
Gastrointestinal Agents - Misc.	377	88	83	206	238
Genitourinary Agents - Misc.	14	2	2	10	360
Gout Agents	7	5	0	2	360
Hematological Agents - Misc.	15	7	0	8	303
Hematopoietic Agents	63	28	12	23	139
Hypnotics/Sedatives/Sleep Disorder Agents	64	8	7	49	292
Laxatives	19	4	3	12	208
Medical Devices and Supplies	281	43	63	175	314
Migraine Products	389	86	79	224	230
Minerals and Electrolytes	9	1	4	4	363
Miscellaneous Therapeutic Classes	57	23	10	24	340
Multivitamins	10	1	1	8	360
Musculoskeletal Therapy Agents	48	4	12	32	21
Nasal Agents - Systemic and Topical	25	3	3	19	360
Neuromuscular Agents	67	30	24	13	344
Ophthalmic Agents	88	24	13	51	227
Other*	65	16	6	43	158
Otic Agents	48	9	8	31	58
Passive Immunizing and Treatment Agents	4	0	0	4	0
Pharmaceutical Adjuvants	2	2	0	0	360
Progestins	7	2	1	4	222
Psychotherapeutic and Neurological Agents - Misc.	223	75	43	105	201
Respiratory Agents - Misc.	28	15	0	13	293
Stimulants - Misc.	229	94	19	116	328
Thyroid Agents	9	2	5	2	357
Ulcer Drugs/Antispasmodics/Anticholinergics	77	20	10	47	279
Urinary Antispasmodics	46	6	6	34	303
Vaginal and Related Products	8	0	2	6	0
Vasopressors	2	0	0	2	0
Vitamins	42	6	28	8	288
Total	**8,269**	**2,688**	**1,404**	**4,177**	
Overrides					
Brand	19	6	1	12	357
Compound	13	9	0	4	25
Diabetic Supplies	3	3	0	0	105
Dosage Change	171	157	0	14	14
High Dose	1	0	0	1	0
IHS-Brand	1	1	0	0	360

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Ingredient Duplication	6	2	0	4	18
Lost/Broken Rx	68	56	5	7	28
MAT Override	15	14	1	0	82
NDC vs Age	207	131	27	49	290
NDC vs Sex	17	12	2	3	286
Nursing Home Issue	31	25	0	6	16
Opioid MME Limit	66	23	2	41	148
Opioid Quantity	19	11	3	5	163
Other	51	30	9	12	18
Quantity vs Days Supply	377	225	15	137	274
STBS/STBSM	18	12	1	5	93
Step Therapy Exception	2	0	0	2	0
Stolen	9	8	0	1	33
Third Brand Request	36	15	1	20	17
Overrides Total	**1,130**	**740**	**67**	**323**	
Total Regular PAs + Overrides	**9,399**	**3,428**	**1,471**	**4,500**	

Denial Reasons	
Unable to verify required trials.	3,994
Does not meet established criteria.	1,514
Lack required information to process request.	548
Other PA Activity	
Duplicate Requests	1,026
Letters	41,328
No Process	4
Helpdesk Initiated Prior Authorizations	370
PAs Missing Information	308
Pharmacotherapy	60
Changes to Existing PAs	536

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

SoonerSelect Aetna Prior Authorization Activity

5/1/2025 Through 5/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	2	1	1	0	365
Amphetamines	275	209	28	38	359
Analgesics - Anti-Inflammatory	117	76	30	11	331
Analgesics - Nonnarcotic	12	3	8	1	245
Analgesics - Opioid	181	81	66	34	197
Androgens - Anabolic	61	12	47	2	365
Anorectal and Related Products	1	0	0	1	0
Anthelmintics	2	1	1	0	30
Antianginal Agents	3	0	0	3	0
Antianxiety Agents	23	5	7	11	281
Antiasthmatic and Bronchodilator Agents	221	39	128	54	306
Antibiotics	24	5	12	7	130
Anticoagulants	7	2	1	4	184
Anticonvulsants	56	10	24	22	260
Antidepressants	195	35	80	80	315
Antidiabetics	553	141	317	95	315
Antiemetics	8	3	0	5	275
Antifungals	6	2	1	3	76
Antihistamines	27	9	17	1	365
Antihyperlipidemics	44	7	17	20	279
Antihypertensives	24	1	3	20	365
Anti-Infective Agents - Misc.	12	5	5	2	91
Antineoplastics and Adjunctive Therapies	47	13	1	33	314
Anti-Obesity Agents	99	0	92	7	0
Antiparkinson and Related Therapy Agents	5	1	0	4	365
Antipsychotics/Antimanic Agents	176	52	73	51	360
Antivirals	4	1	1	2	184
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	84	66	14	4	359
Beta Blockers	21	0	0	21	0
Calcium Channel Blockers	14	4	2	8	365
Cardiovascular Agents - Misc.	20	5	12	3	365
Contraceptives	10	1	8	1	365
Corticosteroids	40	23	8	9	216
Dermatologicals	301	106	148	47	224
Diagnostic Products	57	21	13	23	346
Dietary Products/Dietary Management Products	1	0	1	0	0
Diuretics	12	1	0	11	365
Endocrine and Metabolic Agents - Misc.	23	12	10	1	283
Estrogens	16	7	7	2	365
Gastrointestinal Agents - Misc.	117	40	64	13	215
General Anesthetics	1	1	0	0	0
Genitourinary Agents - Misc.	3	0	3	0	0
Gout Agents	4	0	0	4	0
Hematological Agents - Misc.	3	2	0	1	365
Hematopoietic Agents	12	7	3	2	311
Hypnotics/Sedatives/Sleep Disorder Agents	28	4	13	11	213
Laxatives	13	1	9	3	30

*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
Medical Devices and Supplies	104	29	46	29	338
Migraine Products	205	41	148	16	260
Minerals and Electrolytes	7	2	1	4	274
Miscellaneous Therapeutic Classes	6	2	2	2	365
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	47	3	9	35	162
Nasal Agents - Systemic and Topical	14	0	8	6	0
Neuromuscular Agents	11	7	3	1	337
Nutrients	1	1	0	0	365
Ophthalmic Agents	26	8	12	6	285
Other*	17	3	7	7	267
Otic Agents	25	0	23	2	0
Passive Immunizing and Treatment Agents	16	0	16	0	0
Progestins	8	6	1	1	365
Psychotherapeutic and Neurological Agents - Misc.	31	16	14	1	192
Respiratory Agents - Misc.	3	3	0	0	365
Stimulants - Misc.	102	54	37	11	361
Ulcer Drugs/Antispasmodics/Anticholinergics	74	10	29	35	313
Urinary Antispasmodics	11	0	7	4	0
Vaginal and Related Products	3	0	2	1	0
Vitamins	34	5	29	0	206
****Total**	**3,712**	**1,207**	**1,669**	**836**	

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

Overrides					
Brand	1	1	0	0	365
Other	837	1	0	836	0
Quantity Level Limit	32	32	0	0	314
Step Therapy Met	3	3	0	0	142
Overrides Total	**873**	**37**	**0**	**836**	

Denial Reason	
Benefit	102
Experimental/Investigational	189
Lack Required Infomation to Process Request	108
Medical Necessity	1,267
Other	3
Other PA Activity	
Duplicate Requests	15
Letters	4,530
No Process	333
Changes to existing PAs	0
Helpdesk initiated PA	2
PAs missing info	8

*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

5/1/2025 Through 5/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	4	1	3	0	55
Amphetamines	3	1	2	0	365
Analgesics - Anti-Inflammatory	60	47	13	0	280
Analgesics - Nonnarcotic	5	2	3	0	183
Analgesics - Opioid	75	35	40	0	196
Androgens - Anabolic	64	17	47	0	172
Anthelmintics	3	1	2	0	365
Antiasthmatic and Bronchodilator Agents	145	50	95	0	238
Antibiotics	11	1	10	0	122
Anticonvulsants	13	7	6	0	334
Antidepressants	37	18	19	0	397
Antidiabetics	219	72	147	0	265
Antiemetics	1	0	1	0	0
Antifungals	1	0	1	0	0
Antihistamines	1	0	1	0	0
Antihyperlipidemics	19	3	16	0	287
Anti-Infective Agents - Misc.	3	3	0	0	365
Antimyasthenic/Cholinergic Agents	1	1	0	0	153
Antineoplastics and Adjunctive Therapies	39	35	4	0	259
Anti-Obesity Agents	75	2	73	0	1
Antivirals	3	2	1	0	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	9	4	5	0	319
Cardiovascular Agents - Misc.	20	12	8	0	365
Chemicals	1	0	1	0	0
Contraceptives	15	13	2	0	328
Dermatologicals	137	56	81	0	184
Diagnostic Products	42	40	2	0	339
Digestive Aids	1	0	1	0	0
Diuretics	2	1	1	0	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	4	0	4	0	0
Endocrine and Metabolic Agents - Misc.	44	28	16	0	291
Estrogens	8	1	7	0	122
Gastrointestinal Agents - Misc.	82	39	43	0	207
Gout Agents	2	1	1	0	730
Hematological Agents - Misc.	2	2	0	0	365
Hematopoietic Agents	15	8	7	0	190
Hypnotics/Sedatives/Sleep Disorder Agents	5	2	3	0	365
Laxatives	7	2	5	0	243
Migraine Products	115	63	52	0	184
Minerals and Electrolytes	1	0	1	0	0
Miscellaneous Therapeutic Classes	6	4	2	0	274
Multivitamins	4	0	4	0	0
Musculoskeletal Therapy Agents	22	11	11	0	349
Nasal Agents - Systemic and Topical	5	1	4	0	73
Neuromuscular Agents	32	21	11	0	228
Ophthalmic Agents	26	8	18	0	235
Other*	18	7	11	0	225
Psychotherapeutic and Neurological Agents - Misc.	16	10	6	0	264
Respiratory Agents - Misc.	3	2	1	0	274
Stimulants - Misc.	12	7	5	0	304
Thyroid Agents	1	0	1	0	0
Ulcer Drugs/Antispasmodics/Anticholinergics	19	6	13	0	320

*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
Urinary Antispasmodics	11	1	10	0	456
Vaginal and Related Products	2	1	1	0	183
Vitamins	51	5	46	0	49
Total	**1,522**	**654**	**868**	**0**	
Overrides					
Ingredient Duplication	126	67	59	0	237
NDC vs Age	375	247	128	0	239
Opioid MME Limit	6	4	2	0	284
Opioid Quantity	5	5	0	0	338
Other	144	59	85	0	162
Quantity vs Days Supply	220	141	79	0	241
STBS/STBSM	423	12	411	0	11
Step Therapy Exception	250	106	144	0	158
Overrides Total	**1,549**	**641**	**908**	**0**	
Total Regular PAs + Overrides	**3,071**	**1,295**	**1,776**	**0**	
Denial Reasons					
Benefit					766
Medical Necessity					1,010

*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

5/1/2025 Through 5/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	1	0	1	180
Amphetamines	232	155	23	54	249
Analgesics - Anti-Inflammatory	120	71	31	18	359
Analgesics - Nonnarcotic	8	1	5	2	365
Analgesics - Opioid	367	143	155	69	210
Androgens - Anabolic	58	10	37	11	330
Anorectal and Related Products	2	0	1	1	0
Anorexiants Non-Amphetamine	1	0	0	1	0
Anthelmintics	7	3	4	0	182
Antianxiety Agents	22	8	12	2	273
Antiasthmatic and Bronchodilator Agents	276	86	153	37	301
Antibiotics	20	8	7	5	305
Anticoagulants	3	1	2	0	230
Anticonvulsants	55	29	20	6	358
Antidepressants	127	48	63	16	330
Antidiabetics	647	344	212	91	348
Antidotes and Specific Antagonists	1	0	0	1	0
Antiemetics	6	1	1	4	232
Antifungals	2	0	2	0	0
Antihistamines	22	7	10	5	350
Antihyperlipidemics	18	3	15	0	181
Antihypertensives	4	4	0	0	303
Anti-Infective Agents - Misc.	11	3	6	2	303
Antineoplastics and Adjunctive Therapies	73	43	11	19	234
Anti-Obesity Agents	72	3	38	31	196
Antiparkinson and Related Therapy Agents	3	2	1	0	272
Antipsychotics/Antimanic Agents	140	69	57	14	356
Antivirals	3	2	0	1	196
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	161	104	43	14	340
Beta Blockers	6	3	2	1	271
Calcium Channel Blockers	2	0	2	0	0
Cardiovascular Agents - Misc.	102	58	27	17	363
Chemicals	1	0	0	1	0
Contraceptives	19	6	10	3	274
Corticosteroids	5	1	1	3	92
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	363	155	131	77	256
Diagnostic Products	43	21	15	7	314
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	5	2	2	1	365
Diuretics	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	47	24	19	4	305
Estrogens	6	3	1	2	323
Gastrointestinal Agents - Misc.	104	29	62	13	237
Genitourinary Agents - Misc.	1	1	0	0	365
Gout Agents	8	1	7	0	180
Hematological Agents - Misc.	11	5	2	4	250
Hematopoietic Agents	28	6	13	9	121

*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
Histamine H3-Receptor Antagonist/Inverse Agonists	9	2	1	6	365
Hypnotics/Sedatives/Sleep Disorder Agents	39	13	19	7	234
Laxatives	14	3	8	3	365
Medical Devices and Supplies	133	75	32	26	338
Migraine Products	175	53	92	30	269
Minerals and Electrolytes	1	0	1	0	0
Miscellaneous Therapeutic Classes	36	24	6	6	331
Multivitamins	9	2	4	3	365
Musculoskeletal Therapy Agents	29	8	13	8	211
Nasal Agents - Systemic and Topical	14	0	11	3	0
Neuromuscular Agents	21	13	2	6	334
Ophthalmic Agents	26	5	12	9	284
Other*	62	14	10	38	281
Otic Agents	29	4	21	4	365
Progestins	4	0	3	1	0
Psychotherapeutic and Neurological Agents - Misc.	41	13	20	8	227
Respiratory Agents - Misc.	15	15	0	0	287
Stimulants - Misc.	206	126	40	40	294
Thyroid Agents	4	1	1	2	365
Toxoids	1	0	1	0	0
Ulcer Drugs/Antispasmodics/Anticholinergics	27	8	17	2	319
Urinary Antispasmodics	11	5	5	1	232
Vaccines	2	0	2	0	0
Vaginal and Related Products	1	0	1	0	0
****Total**	**4,126**	**1,848**	**1,526**	**752**	

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

Denial Reasons	
Benefit	1
Medical Necessity	1,525

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

Appendix C

Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Utilization Update

Oklahoma Health Care Authority
June 2025

Introduction[1,2,3]

In the United States, it is estimated that over 38 million people have a diagnosis of diabetes, and 1.2 million Americans are diagnosed every year. In Oklahoma, approximately 405,800 adults have been diagnosed with diabetes, resulting in an estimated cost of $5.2 billion each year.

Type 2 diabetes (T2D) accounts for 90-95% of all diabetes cases, and the 2025 American Diabetes Association (ADA) *Standards of Medical Care in Diabetes* guidelines recommend pharmacologic therapy should be started at the time T2D is diagnosed, without delay, unless there are contraindications. Medication plans should have adequate efficacy to achieve and maintain individualized treatment goals with respect to glucose lowering, reduction of cardiovascular (CV) and kidney disease risks, weight management, and impacts on other health conditions and treatment burden.

DPP-4 inhibitors have been U.S. Food and Drug Administration (FDA) approved for T2D since 2006, and there are currently 4 FDA approved available DPP-4 inhibitors (i.e., sitagliptin, saxagliptin, linagliptin, alogliptin), as well as combination products with metformin and sodium-glucose cotransporter-2 (SGLT-2) inhibitors. The 2025 ADA guidelines have made new recommendations and updates surrounding the use of DPP-4 inhibitors and their place in therapy including:

- Concurrent use of DPP-4 inhibitors with a glucagon-like peptide 1 receptor agonist (GLP-1 RA) or a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 RA is not recommended due to lack of additional glucose lowering beyond that of a GLP-1 RA alone.
- Metformin is more effective than DPP-4 inhibitors in lowering $A1_C$ and weight when used as monotherapy.
- The largest reductions in $A1_C$ levels are achieved by treatment plans that include insulin, select GLP-1 RAs, and tirzepatide, while DPP-4 inhibitors resulted in the smallest reductions in $A1_C$.
- Individuals with T2D and moderate levels of CV disease risk appear to derive CV and mortality benefits with preferential use of GLP-1 RAs and SGLT-2 inhibitors compared with sulfonylureas or DPP-4 inhibitors.
- DPP-4 inhibitors are weight neutral or have a modest beneficial effect on weight.

- When initiating intensification of insulin therapy, metformin, SGLT-2 inhibitors, and GLP-1 RAs (or a dual GIP/GLP-1 RA) should be maintained where appropriate and the use of sulfonylureas, meglitinides, and DPP-4 inhibitors should be limited or discontinued, as these medications do not have additional beneficial effects on CV, kidney, weight, or liver outcomes.
- For individuals with a history of pancreatitis, the use of incretin medications (i.e., GLP-1 RAs, GIP/GLP-1 RAs, DPP-4 inhibitors) should be avoided.
- For individuals with maturity-onset diabetes of the young due to *HNF1A* mutations, addition of a DPP-4 inhibitor to a sulfonylurea may help improve glycemic variability and attainment of glycemic goals.

Based on the 2025 ADA pharmacological treatment flow chart, metformin continues to be a 1st-line recommended option, and GLP-1 and GIP/GLP-1 RAs and SGLT-2 inhibitors are now listed as preferred options based on their efficacy for glucose lowering and additional indications, while DPP-4 inhibitors have become a lower recommended treatment option.

DPP-4 Inhibitor Utilization in the SoonerCare Population

A claims analysis was performed to identify members utilizing a DPP-4 inhibitor and to assess members with concurrent use of a DPP-4 inhibitor and a GLP-1 RA or GIP/GLP-1 RA. Members were included in the claims analysis for DPP-4 utilization if they had a paid claim for a DPP-4 inhibitor during the specified time period (05/01/2024 to 04/30/2025). For concurrent use with a GLP-1 RA or GIP/GLP-1 RA, members were flagged if they had overlapping paid claims with a DPP-4 inhibitor for ≥90 days. The results can be seen in Figure 1 below.

Figure 1: SoonerCare DPP-4 Inhibitor Utilization (05/01/2024 – 04/30/2025)	
Members with DPP-4 inhibitor paid claim(s)	1,961
Members with concurrent DPP-4 inhibitor and GLP-1 RA or GIP/GLP-1 RA utilization for ≥90 days	159

DPP-4 = dipeptidyl peptidase-4; GIP = glucose-dependent insulinotropic polypeptide; GLP-1 RA = glucagon-like peptide 1 receptor agonist

Conclusions

The results showed that 1,961 members were utilizing a DPP-4 inhibitor within the past year. Of those members, 159 were concurrently utilizing DPP-4 inhibitors and GLP-1 RA or GIP/GLP-1 RAs for ≥90 days. There were 545 unique providers in the total analysis, with 163 providers prescribing a DPP-4 inhibitor and/or concurrent use with a GLP-1 RA or GIP/GLP-1 RA. It is important to note that the analysis is based on paid SoonerCare pharmacy claims and does not include whether a member received their medications through a non-

SoonerCare source (i.e., private insurance, free clinics, samples). Additionally, during this time frame there was a substantial shortage of GLP-1 RAs which could have led to an increase in DPP-4 inhibitor utilization due to their similar mechanism of action. These results indicate a need for provider and member education regarding the importance of the utilization of guideline-recommended T2D medications with the best efficacy to ensure the best possible outcomes for SoonerCare members with T2D.

Recommendations

The College of Pharmacy recommends an educational provider mailing with the goal of targeting prescribers for members currently utilizing a DPP-4 inhibitor and for members using concurrent DPP-4 inhibitors and GLP-1 RAs or GIP/GLP-1 RAs. The intent of the educational mailing is to decrease any duplications in therapy without additional benefit and to ensure appropriate utilization of guideline-recommended therapy in order to improve the quality of care for SoonerCare members with T2D.

[1] American Diabetes Association (ADA). The Burden of Diabetes in Oklahoma. Available online at: https://diabetes.org/sites/default/files/2025-05/the-burden-of-diabetes-oklahoma-05-08-25.pdf. Issued 02/2025. Last accessed 05/22/2025.
[2] ADA Professional Practice Committee. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes – 2025. *Diabetes Care* 2025; 48(1): S27–S49. doi: 10.2337/dc25-S002.
[3] ADA Professional Practice Committee. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2025. *Diabetes Care* 2025; 48(1): S181–S206. doi: 10.2337/dc25-S009.

Appendix D

Vote to Prior Authorize Daxxify® (DaxibotulinumtoxinA-lanm) and Update the Approval Criteria for the Botulinum Toxins

Oklahoma Health Care Authority
June 2025

Market News and Updates[1,2,3]

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

- **August 2023:** The FDA approved Daxxify® (daxibotulinumtoxinA-lanm) for the treatment of cervical dystonia. Previously, Daxxify® was only FDA approved to temporarily improve moderate to severe glabellar lines, a cosmetic indication. Daxxify® was not covered by SoonerCare until the manufacturer entered into a federal drug rebate agreement effective October 1, 2024. Daxxify® is the first botulinum toxin type A (BoNTA) to be formulated with a proprietary peptide technology that helps eliminate the need for animal or human components.

Guideline Update(s):

- **American Headache Society (AHS):**
  - In March 2024, the AHS issued a position statement update regarding the use of calcitonin gene-related peptide (CGRP) targeting therapies. The key updates included:
    - CGRP-targeting therapies are considered a first-line option for migraine prevention.
    - All therapies previously recommended by the AHS as first-line preventive options are still considered first-line options, which include onabotulinumtoxinA. Additionally, candesartan was added.
    - CGRP-targeting therapies have additional evidence supporting their use that previous therapies do not, including responder rates, efficacy in patients with multiple prior treatment failures, efficacy in those with acute medication overuse, and those who do and do not have aura.
    - Cost considerations should include not only the direct cost of treatments, but also the indirect costs of health care utilization and acute therapies, as well as socioeconomic costs for those who are disabled by migraines.
- **American Urological Association (AUA):**
  - According to the AUA Neurogenic Lower Urinary Tract Dysfunction (NLUTD) 2021 Guidelines, optional studies in patients with NLUTD

include a voiding/catheterization diary, pad test, and non-invasive uroflow.

Daxxify® (DaxibotulinumtoxinA-lanm) Product Summary[4]

Therapeutic Class: Acetylcholine release inhibitor and neuromuscular-blocking agent

Indication(s): Treatment of cervical dystonia in adult patients

- Please Note: Daxxify® is also FDA approved for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients; however, that indication is considered cosmetic and will not be covered by SoonerCare.

How Supplied: Sterile lyophilized powder in 50-unit or 100-unit single-dose vials (SDVs)

Dosing and Administration:

- The recommended dose for cervical dystonia is 125-250 units given intramuscularly (IM) as a divided dose among affected muscles.
- The potency units for Daxxify® are not interchangeable with other preparations of botulinum toxin products; therefore, units of biological activity of Daxxify® cannot be compared to or converted into units of any other botulinum toxin product.
- Daxxify® should be administered no more frequently than every 3 months for any indication.

Efficacy: The efficacy of Daxxify® was evaluated in a randomized, double-blind, placebo-controlled, multicenter trial.

- Key Inclusion Criteria:
  - Clinical diagnosis of cervical dystonia
  - Baseline Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total score ≥20, TWSTRS severity score ≥15, TWSTRS disability score ≥3, and TWSTRS pain score ≥1
  - For patients who previously received botulinum toxin treatment, ≥14 weeks have passed since the most recent botulinum toxin injection
- Intervention: 301 patients were randomized 3:3:1 to receive a single dose of 2.5mL of either Daxxify® 125 units, Daxxify® 250 units, or placebo divided amongst the affected muscles
- Primary Outcome: Mean change in the TWSTRS total score from baseline averaged over weeks 4 and 6
- Results: The mean change from baseline in the total TWSTRS score was significantly greater for both dosage groups of Daxxify® compared to placebo.

- The least squares mean difference from placebo in the Daxxify® 125 units group was -8.4 [95% confidence interval (CI): -12.2, -4.6; P<0.0001].
- The least squares mean difference from placebo in the Daxxify® 250 units group was -6.6 (95% CI: -10.4, -2.8; P<0.0007).

Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment	Cost Per Year
Daxxify® 100-unit vial	**$2.99**	**$897.00**	**$3,588.00***
Botox® 100-unit vial	$6.48	$1,944.00	$7,776.00⁺
Dysport® 500-unit vial	$1.81	$1,810.00	$7,240.00ᵅ
Myobloc® 10,000-unit vial	$0.13	$1,300.00	$5,200.00ᵝ
Xeomin® 50-unit vial	$5.33	$799.50	$3,198.00ᵘ

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 is based on the max FDA approved dose for cervical dystonia of 250 units every 3 months, assuming the use of (3) 100-unit vials. Daxxify® 50-unit vial is not yet available.
⁺Cost is based on the max FDA approved dose for cervical dystonia of 300 units every 3 months.
ᵅCost is based on the max FDA approved dose for cervical dystonia of 1,000 units every 3 months.
ᵝCost is based on the max FDA approved dose for cervical dystonia of 10,000 units every 3 months.
ᵘCost is based on the max FDA approved dose for cervical dystonia of 120 units every 3 months, assuming the use of 3 full vials.

Recommendations

The College of Pharmacy recommends the prior authorization of Daxxify® (daxibotulinumtoxinA-lanm) with criteria similar to other botulinum toxins and adding the diagnosis of sialorrhea to be consistent with the FDA approved label for botulinum toxins (changes shown in red):

Botulinum Toxins Approval Criteria:

1. For approval of Daxxify®, Myobloc®, or Xeomin®, a patient-specific, clinically significant reason the member cannot use Botox® or Dysport® must be provided; and
2. Cosmetic indications will not be covered; and
3. A diagnosis of chronic migraine (tension headaches are not a covered diagnosis), neurogenic detrusor overactivity, and non-neurogenic overactive bladder will require manual review (see specific criteria below); and
4. The following indications have been determined to be appropriate and are covered:
    a. Spasticity associated with:
        i. Cerebral palsy; or
        ii. Paralysis; or
        iii. Generalized weakness/incomplete paralysis; or

iv. Larynx; or
v. Anal fissure; or
vi. Esophagus (achalasia and cardiospasms); or
vii. Eye and eye movement disorders; or

b. Cervical dystonia.

5. Myobloc® or Xeomin® will be covered for a diagnosis of chronic sialorrhea.

Additionally, the College of Pharmacy recommends updating the approval criteria for Botox® (onabotulinumtoxinA) for a diagnosis of chronic migraine based on net cost and to be consistent with the migraine preventive criteria for the calcitonin gene-related peptide (CGRP) inhibitors and current guidelines (changes shown in red):

Botox® (OnabotulinumtoxinA) Approval Criteria [Chronic Migraine Diagnosis*]:

1. FDA indications are met:
   a. Member is 18 years of age or older; and
   b. Member has documented chronic migraine headaches:
      i. Frequency of ≥15 headache days per month with ≥8 migraine days per month and occurring for >3 months; and
      ii. Headache duration of ≥4 hours per day; and
2. Member has been evaluated for all of the following, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:
   a. Red flags; and
   b. Possible indicators of secondary headache; and
   c. Medication overuse; and
~~3. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:~~
   ~~a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); and~~
   ~~b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and~~
~~4. Migraine headache exacerbation secondary to other medical conditions or medication therapies have been ruled out and/or treated. This includes, but is not limited to:~~
   ~~a. Hormone replacement therapy or hormone-based contraceptives; and~~
   ~~b. Chronic insomnia; and~~
   ~~c. Obstructive sleep apnea; and~~
5. Member has no contraindications to Botox® injections; and
6. The member has failed medical migraine preventative therapy, including ≥2 agents with different mechanisms of action. Trials must be

at least 8 weeks in duration (or documented adverse effects) for oral medications and at least 3 months in duration for injectable medications (or documented adverse effects). ~~within the last 365 days~~. This includes, but is not limited to:

a. Select antihypertensive therapy (e.g., beta blockers); or
b. Select anticonvulsant therapy; or
c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; ~~and~~ or
d. Select calcitonin gene-related peptide (CGRP) inhibitors (e.g., Aimovig®, Ajovy®, Emgality®); and

~~7. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:~~

~~a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and~~
~~b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and~~
~~c. Opioids (≥10 days/month for >3 months); and~~
~~d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and~~
~~e. Ergotamine-containing medications (≥10 days/month for >3 months); and~~
~~f. Triptans (≥10 days/month for >3 months); and~~

~~8. Member is not taking any medications that are likely to be the cause of the headaches; and~~

9. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox® recommended as treatment (not necessarily prescribed or administered by a neurologist); and

~~10. Prescriber must verify that other aggravating factors that are contributing to the development of chronic migraine headaches are being treated when applicable (e.g., smoking); and~~

11. Member will not use the requested medication concurrently with a calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraine headaches.

Finally, the College of Pharmacy recommends updating the approval criteria for Botox® (onabotulinumtoxinA) for the neurogenic detrusor overactivity (NDO) diagnosis to be consistent with current guidelines (changes shown in red):

Botox® (OnabotulinumtoxinA) Approval Criteria [Neurogenic Detrusor Overactivity (NDO) Diagnosis*]:

1. Diagnosis of 1 of the following:
    a. Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury, multiple sclerosis] in adult members; or
    b. NDO in pediatric members; and
2. Underlying pathological dysfunction subtype confirmed by:
    a. Urodynamic studies to determine pathology and serve to provide objective evidence of bladder and external sphincter function; and
    ~~b. A diary of fluid intake, incontinence, voiding, and catheterization times and amounts to provide a record of actual occurrences; and~~
3. Member must have a clinically significant reason why anticholinergic medications are no longer an option for the member; and
4. Member must be 5 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
5. Botox® must be administered by a urologist.

---

[1] Meglio, M. FDA Approves Expanded Indication of DaxibotulinumtoxinA to Treat Cervical Dystonia. Available online: https://www.neurologylive.com/view/fda-approves-expanded-indication-daxibotulinumtoxina-treat-cervical-dystonia. Issued 08/15/2023. Last accessed 05/14/2025.

[2] Charles A, Digre K, Goadsby P, et al. Calcitonin Gene-Related Peptide-Targeting Therapies are a First-Line Option for the Prevention of Migraine: An American Headache Society Position Statement Update. *Headache* 2024; 64:333–341. doi: 10.1111/head.14692.

[3] Ginsberg D, Boone T, Cameron A, et al. The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Diagnosis and Evaluation. *J Urol* 2021; 206: 1097. doi: 10.1097/JU.0000000000002235.

[4] Daxxify® (DaxibotulinumtoxinA-lanm) Prescribing Information. Revance Therapeutics. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761127s002lbl.pdf. Last revised 08/2023. Last accessed 05/14/2025.

Appendix E

Vote to Prior Authorize Brynovin™ (Sitagliptin Oral Solution), Glimepiride 3mg Tablet, Merilog™ (Insulin Aspart-szjj), Metformin 750mg Tablet, and Zituvimet™ XR [Sitagliptin/Metformin Extended-Release (ER)] and Update the Approval Criteria for the Anti-Diabetic Medications

Oklahoma Health Care Authority
June 2025

Market News and Updates[1,2,3,4,5,6,7,8,9]

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

- **July 2024:** Zydus Lifesciences received FDA approval for a New Drug Application (NDA) for Zituvimet™ XR (sitagliptin/metformin). Zituvimet™ XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM). This combination is also available under the brand name Janumet® XR for the same indication.
- **November 2024:** The FDA approved exenatide injection, which is a generic formulation of Byetta®, indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM. This is the first approval of a generic glucagon-like peptide-1 (GLP-1) receptor agonist.
- **December 2024:** The FDA approved liraglutide injection, which is a generic formulation of Victoza®. Liraglutide is indicated to improve glycemic control in adults and pediatric patients 10 years of age and older with T2DM as an adjunct to diet and exercise.
- **January 2025:** The FDA approved Brynovin™ (sitagliptin oral solution) as an adjunct to diet and exercise to improve glycemic control in adults with T2DM. Sitagliptin is also available as an oral tablet formulation. The Wholesale Acquisition Cost (WAC) for Brynovin™ is not available at this time.
- **February 2025:** The FDA approved Merilog™ (insulin aspart-szjj) for the improvement of glycemic control in adults and pediatric patients with diabetes mellitus. Merilog™ is a rapid-acting insulin that is a biosimilar to Novolog® (insulin aspart) and is the first rapid-acting insulin biosimilar to gain FDA approval. Merilog™ will be available in a 3mL prefilled pen and 10mL vial. The WAC for Merilog™ is not available at this time.

News:

- **January 2023:** Sanofi announced that Adlyxin® will no longer be available in the United States. The discontinuation was stated to be due to business decisions and was not due to safety or efficacy issues.
- **August 2024:** A new formulation of glimepiride, available as a 3mg tablet, is being marketed by LifSa Pharma. Glimepiride is also available as 1mg, 2mg, and 4mg tablets.
- **October 2024:** As of October 28, 2024, Bydureon Bcise® (exenatide ER autoinjector) and Byetta® (exenatide) have been discontinued by AstraZeneca. A generic version of Byetta® was recently approved in November 2024.
- **January 2025:** A new formulation of metformin, available as a 750mg immediate-release tablet, is being marketed by LifSa Pharma. Metformin was previously only available as 500mg, 625mg, 850mg, and 1,000mg tablets in the immediate-release formulation.
- **June 2025:** As of June 2025, the FDA Orange Book lists Qternmet® XR (dapagliflozin/saxagliptin/metformin) as a discontinued product. Additionally, there are no generic equivalents for this product.

Cost Comparison: Biguanides

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year
metformin 750mg (generic)	**$33.36**	**$2,001.60**	**$24,019.20**
metformin 625mg (generic)	$32.68⁺	$1,960.80	$23,529.60
metformin 1,000mg (generic)	$0.02	$1.20	$14.40
metformin 500mg (generic)	$0.01	$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).
⁺Cost per tablet varies per NDC
*Cost per month is based on twice daily dosing for each product

Cost Comparison: DPP-4 Inhibitor and Biguanide Combination Products

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
Zituvimet™ XR (sitaglip/met) 50/1,000mg	**$5.06**	**$303.60***	**$3,643.20**
Jentadueto® XR (linaglip/met) 2.5/1,000mg	$8.44	$506.40⁺	$6,076.80
Jentadueto® (linaglip/met) 2.5/1,000mg	$8.43	$505.80⁺	$6,069.60
Janumet XR® (sitaglip/met) 50/1,000mg	$5.28	$316.80*	$3,801.60
Janumet® (sitaglip/met) 50/1,000mg	$5.28	$316.80*	$3,801.60
Zituvimet™ (sitaglip/met) 50/1,000mg	$5.04	$302.40*	$3,628.80
sitagliptin/metformin 50/1,000mg (generic)	$2.67	$160.20*	$1,922.40

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).
DPP-4 = dipeptidyl peptidase-4; linaglip = linagliptin; met = metformin; sitaglip = sitagliptin
*Cost per month based on the maximum FDA approved dosing of 100mg of sitagliptin and 2,000mg of metformin per day.
⁺Cost per month based on the maximum FDA approved dosing of 5mg of linagliptin and 2,000mg of metformin per day.

Cost Comparison: GIP/GLP-1 Agonists

Product	Cost Per Unit	Cost Per Month	Cost Per Year
exenatide 10mcg/0.04mL inj (generic)	**$322.98**	**$775.15***	**$9,301.82**
liraglutide 18mg/3mL inj (generic)	**$64.11**	**$576.99⁺**	**$6,923.88**
Victoza® (liraglutide) 18mg/3mL inj	$87.48	$787.32⁺	$9,447.84
Trulicity® (dulaglutide) 4.5mg/0.5mL inj	$478.18	$956.36ᵅ	$12,432.68
Ozempic® (semaglutide) 8mg/3mL inj	$322.11	$966.33ᵝ	$12,562.29
Rybelsus® (semaglutide) 14mg tablet	$32.18	$965.40¥	$11,584.80
Mounjaro® (tirzepatide) 15mg/0.5mL inj	$522.81	$1,045.62€	$13,593.06

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).
GIP = glucose-dependent insulinotropic polypeptide; GLP-1 = glucagon-like peptide-1; inj = injection; Unit = mL or tablet
*Cost per month based on the maximum FDA approved dosing of 10mcg twice daily
⁺Cost per month based on the maximum FDA approved dosing of 1.8mg once daily
ᵅCost per month based on the maximum FDA approved dosing of 4.5mg once weekly
ᵝCost per month based on the maximum FDA approved dosing of 2mg once weekly
¥Cost per month based on the maximum FDA approved dosing of 14mg once daily
€Cost per month based on the maximum FDA approved dosing of 15mg once weekly

Cost Comparison: Sulfonylureas

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year
glimepiride 3mg (generic)	**$16.89**	**$506.70**	**$6,080.40**
glimepiride 4mg (generic)	$0.04	$1.20	$14.40
glimepiride 2mg (generic)	$0.03	$0.90	$10.80
glimepiride 1mg (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).
*Cost per month based on a dose of 1 tablet once daily for each product

Recommendations

The College of Pharmacy recommends the following changes to the Anti-Diabetic Medications Product Based Prior Authorization (PBPA) category (changes shown in red in the following tier chart):

1. Updating Tier-2, Tier-3, and Special PA Tier approval criteria to specify an FDA approved diagnosis of T2DM is required for approval and to be consistent with current guideline recommendations; and
2. Prior authorization of Brynovin™ (sitagliptin oral solution), glimepiride 3mg tablet, and Zituvimet™ XR (sitagliptin/metformin) and placement into the Special PA Tier with the following additional criteria; and
3. Prior authorization of metformin 750mg tablet and placement into the Special PA Tier; and

4. Moving Byetta® (exenatide) and generic liraglutide to the Special PA Tier based on net costs and the discontinuation of brand name Byetta®; and
5. Creation of Special PA Tier approval criteria for the GLP-1 and glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 agonists based on current guideline recommendations and clinical practice; and
6. Making Victoza® (liraglutide) brand preferred based on net costs; and
7. Moving Invokana® (canagliflozin), Invokamet® (canagliflozin/metformin), and Invokamet® XR (canagliflozin/metformin ER) to Tier-3 based on net costs; and
8. Removing Adlyxin® (lixisenatide) and Qternmet® XR (dapagliflozin/ saxagliptin/metformin ER) based on product discontinuations; and

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Alpha-Glucosidase Inhibitors			
acarbose (Precose®)		miglitol (Glyset®)	
Amylinomimetics			
			pramlintide (Symlin®)
Biguanides			
metformin (Glucophage®)			metformin ER (Fortamet®, Glumetza®)
metformin SR (Glucophage XR®)			metformin soln (Riomet®)
metformin/ glipizide (Metaglip®)			metformin ER susp (Riomet ER™)
metformin/ glyburide (Glucovance®)			metformin 625mg **&** **750mg** tab
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	saxagliptin (Onglyza®)
	linagliptin/ metformin (Jentadueto®)	alogliptin/ metformin (Kazano®)	saxagliptin/ metformin (Kombiglyze®, Kombiglyze XR®)
	linagliptin/metformin ER (Jentadueto® XR)	alogliptin/ pioglitazone (Oseni®)	sitagliptin (Zituvio™)*
	sitagliptin (Januvia®)		sitagliptin/metformin (Zituvimet™)*
	sitagliptin/ metformin (Janumet®)		**sitagliptin/metformin ER (Zituvimet™ XR)***
	sitagliptin/ metformin ER (Janumet XR®)		**sitagliptin oral solution (Brynovin™)***
DPP-4 Inhibitors/SGLT-2 Inhibitors			

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
empagliflozin/ linagliptin (Glyxambi®)			dapagliflozin/ saxagliptin (Qtern®)
			ertugliflozin/ sitagliptin (Steglujan®)
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GLP-1 Agonists and GIP/GLP-1 Agonists*			
	dulaglutide (Trulicity®)	exenatide ER autoinjector (Bydureon BCise®)	**exenatide (Byetta®)***
	~~**exenatide (Byetta®)**~~	semaglutide (Ozempic®)	**liraglutide (generic)***
	liraglutide (Victoza®) – **Brand Preferred**	semaglutide (Rybelsus®)	~~**lixisenatide (Adlyxin®)***~~
			tirzepatide (Mounjaro®)*
GLP-1 Agonists/Insulin			
		insulin degludec/ liraglutide (Xultophy® 100/3.6)*	
		insulin glargine/ lixisenatide (Soliqua® 100/33)*	
SGLT-2 Inhibitors			
dapagliflozin (Farxiga®) – **Brand Preferred**	~~**canagliflozin (Invokana®)**~~	**canagliflozin (Invokana®)**	bexagliflozin (Brenzavvy®)
empagliflozin (Jardiance®)	~~**canagliflozin/ metformin (Invokamet®)**~~	**canagliflozin/ metformin (Invokamet®)**	dapagliflozin (generic)*
	~~**canagliflozin/ metformin ER (Invokamet® XR)**~~	**canagliflozin/ metformin ER (Invokamet® XR)**	dapagliflozin/ metformin ER (generic)*
	dapagliflozin/ metformin ER (Xigduo® XR) – **Brand Preferred**		ertugliflozin (Steglatro®)
	empagliflozin/ metformin (Synjardy®)		ertugliflozin/ metformin (Segluromet®)

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	empagliflozin/ metformin ER (Synjardy® XR)		sotagliflozin (Inpefa®)*
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			~~**dapagliflozin/ saxagliptin/ metformin ER (Qternmet® XR)**~~
Sulfonylureas			
glimepiride (Amaryl®)			**glimepiride 3mg tablet***
glipizide (Glucotrol®)			glipizide 2.5mg immediate-release tablet*
glipizide SR (Glucotrol XL®)			
glyburide (Diabeta®)			
glyburide micronized (Micronase®)			
Thiazolidinediones			
pioglitazone (Actos®)		pioglitazone/ glimepiride (Duetact®)	
		pioglitazone/ metformin (Actoplus Met®, Actoplus Met XR®)	
		rosiglitazone (Avandia®)	

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.
DPP-4 = dipeptidyl peptidase-4; ER = extended-release; GIP = glucose-dependent insulinotropic polypeptide; GLP-1 = glucagon-like peptide-1; PA = prior authorization; SGLT-2 = sodium-glucose cotransporter-2; soln = solution; SR = sustained-release;
susp = suspension

Anti-Diabetic Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A trial at least 3 months in duration (unless intolerable adverse effects) of metformin titrated up to maximum tolerated dose or a patient-specific, clinically significant reason why a 3-month trial of metformin titrated up to maximum tolerated dose is not appropriate must be provided.
3. For initiation with dual or triple therapy, additional Tier-2 medications may be approved based on current American Association of Clinical

Endocrinologists (AACE) or American Diabetes Association (ADA) guidelines.

4. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 medications. Tier structure rules for unique FDA approved indications will apply.

Anti-Diabetic Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. Member must have a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with 1 Tier-2 medication in the same category and have a documented clinical reason why the member cannot continue treatment with the Tier-2 medication.
    a. For members who did not complete a 3 month trial (i.e., due to intolerable adverse effects), the member must have a documented clinical reason why they cannot utilize a different Tier-2 medication in the same category, a Tier-2 medication in a different category, or provide detailed information regarding adverse effects occurring with the Tier-2 medication(s) that are not expected to occur with the requested Tier-3 medication that is in the same category.
    b. For Tier-3 medications that do not have a similar category in Tier-2, a medication from any category in Tier-2 may be used.
3. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications. Tier structure rules for unique FDA approved indications will apply.

Anti-Diabetic Medications Special PA Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. Member must be currently stabilized on the requested product or have attempted at least 3 other categories of Tier-2 or Tier-3 medications, or have a documented clinical reason why the requested product is necessary for the member; and
3. Use of Brynovin™ (sitagliptin oral solution) will require a patient-specific, clinically significant reason why a special formulation is needed and why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors); and
4. ~~Use of Adlyxin® (lixisenatide) or Mounjaro® (tirzepatide) will require a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered glucagon-like peptide-1 receptor agonists (GLP-1 agonists); and~~
5. Use of generic dapagliflozin or dapagliflozin/metformin ER will require a patient-specific, clinically significant reason why they member cannot use brand name Farxiga® (dapagliflozin) or Xigduo® XR (dapagliflozin/

metformin ER) and all available lower-tiered sodium-glucose cotransporter-2 (SGLT-2) inhibitors; and
6. Use of glimepiride 3mg tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including using the lower strengths of glimepiride to achieve the 3mg dose; and
7. Use of glipizide 2.5mg immediate-release tablet will require a patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products including splitting a glipizide 5mg tablet to achieve a 2.5mg dose; and
8. Use of Zituvio™ (sitagliptin), ~~and~~ Zituvimet™ (sitagliptin/metformin), and Zituvimet™ XR (sitagliptin/metformin ER) will require a patient-specific, clinically significant reason why the member cannot use all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors).

Glucagon-Like Peptide-1 (GLP-1) Agonists and Glucose-Dependent Insulinotropic Polypeptide (GIP)/GLP-1 Agonists Special PA Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. Member must be currently stabilized on the requested product (documentation must be provided) or a patient-specific, clinically significant reason (other than convenience) why the member cannot use all available lower-tiered GLP-1 or GIP/GLP-1 agonists must be provided; and
3. Use of generic liraglutide will require a patient-specific, clinically significant reason why the member cannot use brand name Victoza® (liraglutide); and
4. A clinical exception will apply for medications with a unique FDA approved indication not covered by all Tier-2 and Tier-3 GLP-1 or GIP/GLP-1 agonists. Tier structure rules for unique FDA approved indications will apply.

Next, the College of Pharmacy recommends the prior authorization of Merilog™ (insulin aspart-szjj) with the following criteria (shown in red):

Merilog™ (Insulin Aspart-szjj) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Novolog® (insulin aspart) or Fiasp® (insulin aspart) 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.

Additionally, the College of Pharmacy recommends removing the brand preferred status from Humalog® and removing the prior authorization from Fiasp® (insulin aspart) based on net costs (changes shown in red):

Admelog® (Insulin Lispro)~~, Insulin Lispro U-100 (Unbranded Humalog U-100),~~ and Lyumjev® U-100 (Insulin Lispro-aabc 100 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use insulin lispro U-100 (unbranded Humalog® U-100) ~~Humalog® (the brand formulation of Humalog® is preferred)~~.

Humalog® KwikPen® U-200 (Insulin Lispro 200 Units/mL) and Lyumjev® KwikPen U-200 (Insulin Lispro-aabc 200 Units/mL) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. Authorization of the 200 units/mL strength requires a patient-specific, clinically significant reason why the member cannot use the 100 units/mL strength ~~(the brand formulation of Humalog® U-100 is preferred)~~.

~~**Fiasp® (Insulin Aspart) Approval Criteria:**~~

~~1. An FDA approved diagnosis of diabetes mellitus; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use NovoLog® (insulin aspart) must be provided.~~

Finally, the College of Pharmacy recommends updating the Tzield® (teplizumab-mzwv) approval criteria to be consistent with the ADA guidelines and clinical practice (change shown in red):

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
    a. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies; and
        i. Documentation must be submitted with results of autoantibody testing; and
    b. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by ~~an abnormal oral glucose tolerance test (OGTT) meeting~~ 1 of the following (results of lab testing must be submitted):
        i. Fasting plasma glucose ≥100mg/dL and <126mg/dl; or
        ii. 2-hour plasma glucose ≥140 mg/dL and <200mg/dl; or
        iii. Hemoglobin A1c ≥5.7% and <6.5% or ≥10% increase in A1c; or
        iv. 30-, 60-, or 90-minute value ~~on OGTT~~ ≥200mg/dl on 2 separate occasions; and

2. Member must be 8 years of age or older; and
3. Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and
4. Tzield® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. All of the following will be required for initiation of treatment:
    a. Verification that female members of reproductive potential 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 and verification that levels are acceptable to the prescriber; and
    e. Verification that all age-appropriate vaccinations have been administered prior to treatment; and
    f. Prescriber must agree to premedicate the member for the first 5 days of dosing and as needed with a nonsteroidal anti-inflammatory drug (NSAID) or acetaminophen, an antihistamine, and/or an antiemetic; and
6. Tzield® must be administered by a health care professional. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Tzield® will be administered; and
    a. Tzield® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tzield® 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 be trained on the proper storage of Tzield®; and
7. 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
8. A quantity limit of 28mL per 14 days will apply; and
9. Approvals will be for (1) 14-day cycle per member per lifetime.

[1] Zydus Lifesciences. Zydus Receives Final Approval from U.S. FDA for Its NDA Zituvimet™ XR (Sitagliptin and Metformin Hydrochloride) Extended-Release Tablets. Available online at: https://zyduslife.com/investor/admin/uploads/21/83/Zydus-receives-final-approval-from-USFDA-for-its-NDA-ZituvimetTM-XR-(sitagliptin-and-metformin-hydrochloride)-extended-release-tablets.pdf. Issued 07/19/2024. Last accessed 05/21/2025.

[2] Amneal Pharmaceuticals. Amneal Resubmits DHE Autoinjector New Drug Application and Receives U.S. FDA Approval of Exenatide, Its First Generic Injectable GLP-1 Agonist. *Businesswire*. Available online at: https://www.businesswire.com/news/home/20241121053036/en/Amneal-Resubmits-DHE-Autoinjector-New-Drug-Application-and-Receives-U.S.-FDA-Approval-of-Exenatide-its-First-Generic-Injectable-GLP-1-Agonist. Issued 11/21/2024. Last accessed 05/21/2025.

[3] U.S. Food and Drug Administration (FDA). FDA Approves First Generic of Once-Daily GLP-1 Injection to Lower Blood Sugar in Patients with Type 2 Diabetes. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-once-daily-glp-1-injection-lower-blood-sugar-patients-type-2-diabetes. Issued 12/23/2024. Last accessed 05/21/2025.

[4] Brynovin™ (Sitagliptin) – New drug approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_brynovin_2025-0117.pdf. Issued 01/16/2025. Last accessed 05/21/2025.

[5] U.S. FDA. FDA Approves First Rapid-Acting Insulin Biosimilar Product for Treatment of Diabetes. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-rapid-acting-insulin-biosimilar-product-treatment-diabetes. Issued 02/14/2025. Last accessed 05/21/2025.

[6] Sanofi – Discontinuation of Adlyxin® (Lixisenatide). *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-withdrawls/drugwithdrawal_adlyxin_2023-0117.pdf. Issued 01/01/2023. Last accessed 05/21/2025.

[7] U.S. FDA. National Drug Code Directory. Available online at: https://dps.fda.gov/ndc. Last accessed 05/21/2025.

[8] U.S. FDA. FDA Drug Shortages: Discontinuations. Available online at: https://dps.fda.gov/drugshortages/discontinuations/exenatide-synthetic-injectable-suspension-extended-release. Issued 10/28/2024. Last accessed 05/21/2025.

[9] U.S. FDA. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 06/2025. Last accessed 06/03/2025.

Appendix F

Vote to Prior Authorize Onyda™ XR [Clonidine Extended-Release (ER) Suspension] and Update the Approval Criteria for the Attention-Deficit/ Hyperactivity Disorder (ADHD) Medications

Oklahoma Health Care Authority
June 2025

Market News and Updates[1,2,3]

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

- **May 2024:** The FDA approved Onyda™ XR (clonidine ER suspension) for the treatment of ADHD as monotherapy or as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older. Onyda™ XR was approved through the 505(b)(2) pathway based on prior studies utilizing clonidine ER tablets.

News:

- **May 2025:** As of May 2025, the FDA Orange Book lists Adzenys ER™ (amphetamine ER suspension) as a discontinued product. There are currently no generic equivalents for this product.

Onyda™ XR (Clonidine ER Suspension) Product Summary[4]

Therapeutic Class: Centrally acting alpha$_2$-adrenergic agonist

Indication(s): Treatment of ADHD as monotherapy and as adjunctive therapy to CNS stimulant medications in pediatric patients 6 years of age and older

How Supplied: 0.1mg/mL oral suspension in 30mL, 60mL, and 120mL bottles

Dosing and Administration:

- Recommended starting dosage is 0.1mg orally once daily at bedtime with or without food
- Dose may be increased in increments of 0.1mg per day at weekly intervals depending on clinical response up to the maximum recommended dose of 0.4mg once daily at bedtime

Efficacy: The efficacy of Onyda™ XR was based on data from prior studies utilizing clonidine ER tablets.

Cost Comparison:

Product	Cost Per Unit	Cost Per Month*	Cost Per Year
Onyda™ XR (clonidine ER 0.1mg/mL sus) 60mL bottle	**$7.63**	**$915.60**	**$10,987.20**
clonidine ER 0.1mg tablet (generic Kapvay®)	$0.32	$38.40	$460.80

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 month based on the use of 0.4mg per day for each product.
ER = extended-release; sus = suspension; Unit = each mL or tablet

Recommendations

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

1. Prior authorization of Onyda™ XR (clonidine ER suspension) and placement into Tier-3 of the non-stimulants category based on net costs, with the additional criteria shown below; and
2. Moving Daytrana® (methylphenidate ER patch) and Vyvanse® (lisdexamfetamine) capsules from Tier-1 to Tier-2 based on net costs, with the additional criteria shown below; and
3. Moving Vyvanse® (lisdexamfetamine) chewable tablets from Tier-1 to Tier-3 and removing the brand preferred status based on net costs, with the additional criteria shown below; and
4. Moving Dyanavel® XR (amphetamine ER tablet) from Tier-2 to Tier-3 based on net costs; and
5. Moving Adzenys XR-ODT® (amphetamine ER ODT) from the Special PA Tier to Tier-3 based on net costs; and
6. Updating the approval criteria for Kapvay® (clonidine ER tablet) based on clinical practice and net costs; and
7. Removing Adzenys ER™ (amphetamine ER suspension) based on product discontinuation.

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			~~**amphetamine ER susp (Adzenys ER™)**~~ ~~**amphetamine ER ODT (Adzenys XR-ODT®)**~~ 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 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®) ~~**lisdexamfetamine cap and chew tab (Vyvanse®)+ – Brand Preferred**~~	~~**amphetamine ER tab (Dyanavel® XR)**~~ dextroamphetamine ER (Dexedrine Spansules®) **lisdexamfetamine cap (Vyvanse®)+ – Brand Preferred**	**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®) – **Brand Preferred** methylphenidate ER (Concerta®) ~~**methylphenidate ER (Daytrana®) – Brand Preferred**~~ methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin SR®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) **methylphenidate ER (Daytrana®)Δ – Brand Preferred** methylphenidate ER susp (Quillivant XR®)Δ methylphenidate ER (Ritalin LA®)	methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ	**clonidine ER susp (Onyda™ XR)Δ**	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). 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.

+Unique criteria applies for the diagnosis of binge eating disorder (BED). **Other tier trial requirements do not apply for a diagnosis of BED.**

ΔUnique 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
   a. Daytrana® patches are brand preferred. Approval of generic methylphenidate transdermal patches will require a patient-specific, clinically significant reason why brand name Daytrana® cannot be used.
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 trials (within the last 180 days) with a long-acting Tier-1 stimulant~~, Intuniv®, and Strattera®,~~ or non-stimulant unless contraindicated, that did not yield adequate results.~~; and~~

~~c. A patient-specific, clinically significant reason why the member cannot use clonidine immediate-release tablets must be provided.~~

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. Vyvanse® capsules are brand preferred. Approval of generic lisdexamfetamine capsules will require a patient-specific, clinically significant reason why brand name Vyvanse® cannot be used; and
   f. A quantity limit of 30 capsules per 30 days will apply; and
   g. 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. 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.

6. For Vyvanse® chewable tablet, a patient-specific, clinically significant reason why the member cannot use brand Vyvanse® capsules, even when opened and mixed with yogurt, water, or orange juice must be provided; and
   a. 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. ~~Adzenys XR-ODT®, Adzenys ER™,~~ 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.
2. 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.
3. 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.
4. 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.

5. 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. Quantity limits will apply based on FDA-approved dosing.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)- or SoonerSelect health plan-contracted psychiatrist.
3. For ~~Daytrana® patches,~~ Methylin® oral solution, ~~and Vyvanse® chewable tablet,~~ 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~~
   ~~a. Daytrana® patches and Vyvanse® chewable tablets are brand preferred. Approval of generic methylphenidate transdermal patches or lisdexamfetamine chewable tablets will require a patient-specific, clinically significant reason why brand name Daytrana® or Vyvanse® cannot be used.~~

~~4. 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. Vyvanse® capsules are brand preferred. Approval of generic lisdexamfetamine capsules will require a patient-specific, clinically significant reason why brand name Vyvanse® cannot be used; and~~

~~f. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and~~

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

[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/index.cfm. Last revised 04/2025. Last accessed 05/29/2025.

[2] Tris Pharma, Inc. Tris Pharma Receives U.S. FDA Approval for Once-Daily Onyda™ XR (Clonidine Hydrochloride) Extended-Release Oral Suspension, the First-and-Only Liquid Non-Stimulant ADHD Medication. Available online at: https://www.trispharma.com/tris-pharma-receives-u-s-fda-approval-for-once-daily-onyda-xr-clonidine-hydrochloride-extended-release-oral-suspension-the-first-and-only-liquid-non-stimulant-adhd-medication/. Issued 05/29/2024. Last accessed 05/29/2025.

[3] U.S. FDA. Onyda™ XR NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/217645Orig1s000ltr.pdf. Issued 05/24/2024. Last accessed 05/29/2025.

[4] Onyda™ XR (Clonidine Hydrochloride Extended-Release Oral Suspension) Prescribing Information. Tris Pharma, Inc. Available online at: https://www.trispharma.com/generic/ONYDA%20XR%20Full%20Prescribing%20Information.pdf. Last revised 07/2024. Last accessed 05/29/2025.

Appendix G

Vote to Prior Authorize Sofdra™ (Sofpironium 12.45% Topical Gel)

Oklahoma Health Care Authority
June 2025

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

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

- **June 2024:** The FDA approved Sofdra™ (sofpironium 12.45% topical gel), a topical anticholinergic indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older. The International Hyperhidrosis Society, an independent, non-profit organization, and the American Academy of Dermatology (AAD) recommend utilizing conservative topical therapies to treat primary axillary hyperhidrosis. First-line agents include over-the-counter (OTC) or prescription strength topical products containing aluminum salts, such as aluminum chloride hexahydrate. If these treatments fail to provide adequate relief, topical or systemic anticholinergic medications are additional non-invasive therapy options.

Sofdra™ (Sofpironium 12.45% Topical Gel) Product Summary[4,5]

Therapeutic Class: Topical anticholinergic

Indication(s): Treatment of primary axillary hyperhidrosis in adult and pediatric patients 9 years of age and older

How Supplied: Topical gel in a multi-dose metered pump bottle containing 60 pump actuations (0.67mL per actuation) with an applicator

Dosing and Administration:

- 1 pump actuation topically per underarm once daily at bedtime
- Underarms should not be washed for at least 30 minutes before and 8 hours after application
- Underarms should not be shaved at least 8 hours before application
- Use of occlusive dressings should be avoided

Efficacy: The safety and efficacy of Sofdra™ were evaluated in a pooled analysis of 2 randomized, vehicle-controlled multicenter trials, CARDIGAN 1 and CARDIGAN 2, that included a total of 701 patients.

- Key Inclusion Criteria:
  - 9 years of age and older with primary axillary hyperhidrosis
  - Symptoms of axillary hyperhidrosis for ≥6 months

    - Produce ≥50mg of sweat in each underarm with a combined total of ≥150mg over a 5-minute period
    - Hyperhidrosis Disease Severity Measure-Axillary 7-item (HDSM-Ax-7) score ≥3
- Intervention(s):
    - Patients were randomized to receive Sofdra™ or inert vehicle applied once daily a bedtime to each underarm
- Primary Endpoint(s):
    - Proportion of patients having ≥2-point improvement in the HDSM-Ax-7 score from baseline to day 43
    - Change in median gravimetric sweat production (GSP) from baseline to day 43
- Results:
    - 56.3% (N=353) in the Sofdra™ group vs. 37.3% (N=348) in the vehicle group achieved the HDSM-Ax-7 score endpoint (difference: 19%; P<0.0001).
    - The median change in GSP from baseline to day 43 was -138.1mg/5 minutes in the Sofdra™ group vs. -114.5mg/5 minutes in the vehicle group (difference: -23.6mg/5 minutes; P=0.0002).

Cost: The Wholesale Acquisition Cost (WAC) of Sofdra™ is $967.50 per bottle, resulting in a cost of $967.50 per month or $11,640 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Sofdra™ (sofpironium 12.45% topical gel) with the following criteria (shown in red):

Sofdra™ (Sofpironium 12.45% Topical Gel) Approval Criteria:

1. An FDA approved diagnosis of primary axillary hyperhidrosis; and
2. Member must be 9 to 20 years of age; and
3. Documentation of assessment by a licensed behavior specialist or the prescribing physician indicating the member's hyperhidrosis is causing social anxiety, depression, or similar mental health-related issues that impact the member's ability to function in day-to-day living must be provided; and
4. Member must have failed a trial, at least 3 weeks in duration, with the following:
    a. Xerac® AC (aluminum chloride hexahydrate 6.25% topical solution) or at least 1 over-the-counter Certain Dri® antiperspirant; and
    b. Drysol® (aluminum chloride 20% topical solution); and
5. Prescriber must verify that the member has received counseling on the safe and proper use of Sofdra™; and
6. A quantity limit of 40.2mL per 30 days will apply; and

7. Initial approvals will be for the duration of 3 months. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

---

[1] Botanix Pharmaceuticals. FDA Approval of Sofdra™ - The First New Drug for Primary Axillary Hyperhidrosis. Available online at: https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02819259-6A1212299. Issued 06/20/2024. Last accessed 06/03/2025.
[2] International Hyperhidrosis Society. Primary Focal Axillary Hyperhidrosis. Available online at: https://www.sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html. Last revised 2025. Last accessed 05/28/2025.
[3] American Academy of Dermatology Association. Hyperhidrosis: Diagnosis and Treatment. Available online at: https://www.aad.org/public/diseases/a-z/hyperhidrosis-treatment. Last revised 07/16/2024. Last accessed 05/28/2025.
[4] Sofdra™ (Sofpironium) Topical Gel, 12.45% Prescribing Information. Botanix SB Inc. Available online: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217347s000lbl.pdf. Last revised 06/18/2024. Last accessed 05/28/2025.
[5] Pariser D, Glaser DA, Rosso JD, et al. Sofpironium Topical Gel, 12.45%, for the Treatment of Axillary Hyperhidrosis: Pooled Efficacy and Safety Results from 2 Phase 3 Randomized, Controlled, Double-Blind Studies. *J Am Acad Dermatol.* 2025; S0190-9622(25):393-397. doi: 10.1016/j.jaad.2025.02.086.

Appendix H

Vote to Prior Authorize Enzeevu™ (Aflibercept-abzv), Opuviz™ (Aflibercept-yszy), and Yesafili™ (Aflibercept-jbvf) and Update the Approval Criteria for the Age-Related Macular Degeneration (AMD) Medications

Oklahoma Health Care Authority
June 2025

Market News and Updates[1,2,3,4,5,6]

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

- **May 2024:** The FDA approved Opuviz™ (aflibercept-yszy) and Yesafili™ (aflibercept-jbvf) as interchangeable biosimilars to Eylea® (aflibercept).
- **August 2024:** The FDA approved Enzeevu™ (aflibercept-abzv) and Pavblu™ (aflibercept-ayyh) as biosimilars to Eylea® (aflibercept). The Wholesale Acquisition Cost (WAC) of Pavblu™ is $1,665.00 per vial. The cost for the other biosimilars are not available at this time.
- **February 2025:** The FDA approved Susvimo™ (ranibizumab injection), a refillable eye implant that is surgically inserted, for the treatment of diabetic macular edema (DME). Susvimo™ was previously FDA approved for neovascular age-related macular degeneration (nAMD) only. Susvimo™ for a diagnosis of DME was approved based on the results of the Phase 3 Pagoda trial, a randomized, active treatment-controlled, non-inferiority trial comparing Susvimo™ refilled every 6 months to monthly ranibizumab 0.5mg intravitreal injections. The results showed similar improvements in vision for each group.
- **February 2025:** The FDA approved a label expansion for Izervay™ (avacincaptad pegol intravitreal solution) to allow use beyond 12 months. The decision was based on the results of the Phase 3 GATHER2 clinical trial which evaluated the safety and efficacy of Izervay™ through 2 years. The results showed Izervay continued to reduce the rate of geographic atrophy (GA) lesion growth in patients through year 2 versus placebo.
- **May 2025:** The FDA approved Susvimo™ for the treatment of diabetic retinopathy (DR). It was approved based on the results of the Phase 3 Pavilion trial, which showed patients receiving Susvimo™ refilled every 9 months achieved a superior improvement on the Diabetic Retinopathy Severity Scale (DRSS) compared to those under monthly clinical observation who were treated with anti-VEGF injections, as needed, based on disease progression.

Recommendations

The College of Pharmacy recommends the prior authorization of Enzeevu™ (aflibercept-abzv), Opuviz™ (aflibercept-yszy), and Yesafili™ (aflibercept-jbvf) with the following criteria (shown in red):

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.

The College of Pharmacy also recommends updating the approval criteria for Izervay™ (avacincaptad pegol) and Susvimo™ (ranibizumab intravitreal implant) based on the FDA label expansions and net costs (changes shown in red):

Izervay™ (Avacincaptad Pegol) Approval Criteria:

1. An FDA approved indication for the treatment of geographic atrophy (GA) secondary to dry age-related macular degeneration (AMD); and
2. Member must not have ocular or periocular infections or active intraocular inflammation; and
3. Izervay™ must be prescribed and administered by an ophthalmologist, or a physician experienced in intravitreal injections; and
4. Prescribers must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and neovascular (wet) AMD; and
5. ~~A patient specific, clinically significant reason why the member cannot use Syfovre® (pegcetacoplan) must be provided; and~~
6. A quantity limit of (1) 0.1mL single-dose vial per eye once monthly ~~for up to 12 months~~ will apply.

Susvimo™ (Ranibizumab Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Neovascular (wet) age-related macular degeneration (AMD) in adults; or
   b. Diabetic macular edema (DME); or
   c. Diabetic retinopathy (DR); and
2. Member must have previously responded to ≥2 intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and

4. Susvimo™ must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal surgery; and
5. Prescriber must verify the member will be monitored for endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs; and
6. A patient-specific, clinically significant reason why the member cannot use ranibizumab intravitreal injection or other VEGF inhibitor injection products (appropriate to disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea®/Eylea® HD (aflibercept), Lucentis® (ranibizumab)] must be provided; and
7. ~~A quantity limit of one 100mg/0.1mL~~ The following quantity limits will apply per eye:
    a. AMD or DME: (1) 0.1mL single-dose vial (SDV) per ~~180 days~~ 6 months ~~will apply~~; or
    b. DR: (1) 0.1mL SDV per 9 months.

The College of Pharmacy also recommends updating the approval criteria for Vabysmo® (faricimab-svoa intravitreal injection) based on net cost and to be consistent with clinical practice (changes shown in red):

Vabysmo® (Faricimab-svoa Intravitreal Injection) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Neovascular (wet) age-related macular degeneration (AMD); or
    b. Diabetic macular edema (DME); or
    c. Macular edema following retinal vein occlusion (RVO); and
2. Member must be 18 years of age or older; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Vabysmo® must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal injections; and
5. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and arterial thromboembolic events, and
6. Female members 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 3 months after the final dose of Vabysmo®; and
7. Member must have previously tried and failed 1 ~~A patient-specific, clinically significant reason why the member cannot use~~ VEGF inhibitor injection product~~s~~ (appropriate to the disease state) available without

prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli® (ranibizumab-eqrn), Eylea®/Eylea® HD (aflibercept), Lucentis® (ranibizumab), Pavblu™ (aflibercept-ayyh)] or a patient-specific, clinically significant reason why a preferred VEGF inhibitor injection product is not appropriate for the member must be provided; and

8. A quantity limit of 0.05mL per 28 days will apply.

---

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Interchangeable Biosimilars to Eylea® to Treat Macular Degeneration and Other Eye Conditions. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-eylea-treat-macular-degeneration-and-other-eye. Issued 05/20/2024. Last accessed 05/16/2025.

[2] Sandoz. Sandoz Receives FDA Approval for Enzeevu™ (Aflibercept-abzv), Further Strengthening U.S. Biosimilar Position. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2024/08/12/2928076/0/en/Sandoz-receives-FDA-approval-for-Enzeevu-aflibercept-abzv-further-strengthening-US-biosimilar-position.html. Issued 08/12/2024. Last accessed 05/16/2025.

[3] Pavblu™ (aflibercept-ayyh) – New biosimilar approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_pavblu_2024-0829.pdf. Issued 08/23/2024. Last accessed 05/16/2025.

[4] Roche. FDA Approves Roche's Susvimo™ as the First and Only Continuous Delivery Treatment for the Leading Cause of Diabetes-Related Blindness. Available online at: https://www.roche.com/media/releases/med-cor-2025-02-04. Issued 02/03/2025. Last accessed 05/16/2025.

[5] Astellas. U.S. FDA Approves Expanded Label for Astellas Izervay™ (Avacincaptad Pegol Intravitreal Solution) for Geographic Atrophy. Available online at: https://newsroom.astellas.us/2025-02-12-U-S-FDA-Approves-Expanded-Label-for-Astellas-IZERVAY-TM-avacincaptad-pegol-intravitreal-solution-for-Geographic-Atrophy. Issued 02/12/2025. Last accessed 05/16/2025.

[6] Roche. FDA Approves Roche's Susvimo™ for Diabetic Retinopathy. Available online at: https://www.roche.com/media/releases/med-cor-2025-05-22. Issued 05/21/2025. Last accessed 05/28/2025.

Appendix I

Vote to Prior Authorize Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsule], Onapgo™ (Apomorphine Injection for Continuous Infusion), and Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) and Update the Approval Criteria for the Parkinson's Disease Medications

Oklahoma Health Care Authority
June 2025

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

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

- **August 2024:** The FDA approved Crexont® (carbidopa/levodopa ER) for the treatment of Parkinson's disease (PD), post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication in adults. Crexont® is an oral formulation of carbidopa/levodopa that combines both immediate-release (IR) granules and ER pellets. Rytary® (carbidopa/levodopa ER) was FDA approved in 2015 and is another ER formulation of carbidopa/levodopa. Both Crexont® and Rytary® are formulated with IR and ER components that are designed to lengthen the effective time of carbidopa/levodopa; however, Crexont® is formulated with a new mucoadhesive polymer technology that allows longer plasma levels of carbidopa/levodopa in the body. They are available in slightly different strengths and a typical daily dose of Rytary® is 3 capsules, 3 to 4 times per day versus Crexont® which has a typical daily dose of 1 to 2 capsules, 2 to 4 times per day.
- **October 2024:** The FDA approved Vyalev™ (foscarbidopa/foslevodopa injection for continuous infusion) as the first and only subcutaneous (sub-Q) 24-hour infusion of levodopa-based therapy for the treatment of motor fluctuations in adults with advanced PD.
- **February 2025:** The FDA approved Onapgo™ (apomorphine injection for continuous infusion) as the first and only sub-Q apomorphine infusion device for the treatment of motor fluctuations in adults with advanced PD.

News:

- **June 2023:** Sunovion announced that Kynmobi® [apomorphine sublingual (SL) film] will be discontinued in the United States due to limited utilization.

Onapgo™ (Apomorphine Injection for Continuous Infusion) Product Summary[6,7]

Therapeutic Class: Dopaminergic agonist

Indication(s): Treatment of motor fluctuations in adults with advanced PD

How Supplied: One carton containing 5 single-dose, prefilled cartridges with each cartridge containing 98mg/20mL of apomorphine hydrochloride

Dosing and Administration:

- Onapgo™ should be administered by sub-Q infusion via the Onapgo™ pump.
  - Patients selected for treatment with Onapgo™ should be capable of understanding and trained on using the delivery system, either themselves or with the assistance of a caregiver.
- The daily dosage is determined by individualized patient titration and is composed of a continuous dosage and as needed extra dose(s). Initiation and dose titrations should be done under medical supervision.
- The recommended initial continuous dosage is 1mg/hour with a maximum of 6mg/hour for up to 16 hours per day. The maximum recommended total daily dosage, including the continuous dosage and any extra dose(s), is 98mg generally administered over the waking day.
- Onapgo™ is not substitutable for apomorphine products intended for intermittent use.
- See the full *Prescribing Information* for dose calculations, titration recommendations, premedication and concomitant medications, preparation and administration instructions, and recommended dose adjustments.

Efficacy: The safety and efficacy of Onapgo™ were evaluated in a Phase 3 multicenter, parallel-group, double-blind, randomized, placebo-controlled trial in patients with PD who experienced motor fluctuations while receiving carbidopa/levodopa and other concomitant medications to treat PD for 12 weeks, including 1-4 weeks of dose titration and then continued treatment at an individualized, stable dosage. Patients then had the option to receive Onapgo™ in a 52-week, open-label treatment period.

- <u>Key Inclusion Criteria:</u>
  - Diagnosis of PD >3 years without any other known or suspected cause of parkinsonism
  - Levodopa-related motor fluctuations that had not been adequately controlled by optimized medical treatment
  - Mean “off” time >3 hours/day for 2 days (based on diaries at screening and baseline), with no day with <2 hours of “off” time recorded

- Intervention(s): Patients were randomized 1:1 to receive Onapgo™ 5mg/mL solution or placebo for 12 weeks.
- Endpoint(s):
  - Primary Endpoint
    - Change in total daily "off" time assessed from baseline to the end of the 12-week treatment period based on patient diaries
  - Key Secondary Endpoint:
    - Change in daily "on" time without troublesome dyskinesia from baseline to the end of the 12-week treatment period
- Results:
  - Primary Endpoint:
    - Change from baseline in mean total daily "off" time was -2.55 hours in the Onapgo™ group vs. -0.90 hours in the placebo group [treatment difference: -1.65 hours; 95% confidence interval (CI): -2.91, -0.38; P=0.0114]
  - Key Secondary Endpoint:
    - Change from baseline in mean total daily "on" time without troublesome dyskinesia was 2.76 hours in the Onapgo™ group vs. 1.12 hours in the placebo group (treatment difference: 1.64 hours; 95% CI: 0.28, 3.00; P=0.0188).

Cost: The Wholesale Acquisition Cost (WAC) of Onapgo™ is $14.38 per mL or $1,438 per carton. This results in an estimated cost of $8,628 per month or $103,536 per year based on the maximum recommended dose of 98mg (20mL) per day.

Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) Product Summary[8,9]

Therapeutic Class: Aromatic amino acid decarboxylation inhibitor and an aromatic amino acid

Indication(s): Treatment of motor fluctuations in adults with advanced PD

How Supplied: One carton containing 7 single-dose vials with each vial containing 120mg foscarbidopa and 2,400mg foslevodopa per 10mL

Dosing and Administration:
- Vyalev™ should be administered as a sub-Q infusion via the Vyafuser™ pump
  - Patients selected for treatment with Vyalev™ should be capable of understanding and using the delivery system themselves or with assistance from a caregiver. Patients should be trained on the proper use of Vyalev™ and the delivery system prior to initiating.
- The maximum recommended daily dosage of Vyalev™ is 3,525mg of foslevodopa (approximately 2,500mg of levodopa).

- Prescribing a backup oral carbidopa/levodopa product should be recommended in the event that delivery of Vyalev™ is interrupted, which may result in underdosing. Sudden discontinuation or rapid dose reduction of Vyalev™, without administration of alternative dopaminergic therapy, should be generally avoided.
- See the full *Prescribing Information* for calculation of the base continuous dosage, hourly infusion rate, optional loading dose, extra dose, and preparation and administration instructions.

Efficacy: The efficacy of Vyalev™ was studied in a 12-week, randomized, double-blind, double-dummy, active-controlled, multicenter trial in patients with advanced PD. The study included a screening period, an oral carbidopa/levodopa stabilization period, and a double-blind treatment period.

- Key Inclusion Criteria:
  - Diagnosis of idiopathic PD responsive to levodopa
  - On a minimum of 400mg/day of levodopa equivalents and having inadequately controlled motor fluctuations
  - Average "off" time of ≥2.5 hours/day over 3 consecutive diary days with ≥2 hours each day
- Intervention(s): Patients were randomized 1:1 to receive continuous sub-Q infusion of Vyalev™ plus oral placebo capsules or placebo continuous sub-Q infusion plus oral carbidopa/levodopa IR tablets for 12 weeks.
- Endpoint(s):
  - Primary Endpoint:
    - Mean change from baseline to week 12 in the total daily mean "on" time without troublesome dyskinesia based on PD diary
  - Key Secondary Endpoint:
    - Mean change from baseline to week 12 in the total daily mean "off" time
- Results:
  - Primary Endpoint:
    - The change from baseline in total daily mean "on" time without troublesome dyskinesia was 2.72 hours in the Vyalev™ group vs. 0.97 hours in the oral carbidopa/levodopa group (treatment difference: 1.75 hours; 95% CI: 0.46, 3.05; P=0.0083).
  - Key Secondary Endpoint:
    - The change from baseline in mean total daily "off" time was -2.75 hours in the Vyalev™ group vs. -0.96 hours in the oral carbidopa/levodopa group (treatment difference: -1.79 hours; 95% CI: -3.03, -0.54; P=0.0054).

Cost: The WAC of Vyalev™ is $32.75 per mL or $2,292.50 per carton. This results in an estimated cost of $19,650 per month or $235,800 per year based on the use of 2 vials (20mL) per day.

Cost Comparison: Oral Carbidopa/Levodopa Products

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Crexont® (carbidopa/levodopa ER) 87.5-350mg cap	**$4.14**	**$745.20***	**$8,942.40**
Rytary® (carbidopa/levodopa ER) 48.75-195mg cap	$3.99	$1,077.30⁺	$12,927.60
carbidopa/levodopa CR 50-200mg tab (generic)	$0.21	$31.50ᵝ	$378.00
carbidopa/levodopa IR 25-250mg tab (generic)	$0.14	$16.80ᵅ	$201.60

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).
Cap = capsule; tab = tablet; Unit = capsule or tablet
*Cost per month based on FDA recommended dosing of 700mg of levodopa 3 times daily for a patient converting from 1,000mg of IR levodopa per day.
⁺Cost per month based on FDA recommended dosing of 1,755mg of levodopa per day for a patient converting from 1,000mg of IR levodopa per day.
ᵝCost per month based on FDA recommended dosing of 1,000mg of levodopa per day for a patient converting from 1,000mg of IR levodopa per day.
ᵅCost per month based on an average dose of 1,000mg of levodopa per day using four 25-250mg tablets.

Recommendations

The College of Pharmacy recommends the prior authorization of Crexont® (carbidopa/levodopa ER capsules) with criteria similar to the Rytary® (carbidopa/levodopa ER capsules) approval criteria (changes shown in red):

Crexont® [Carbidopa/Levodopa Extended-Release (ER) Capsules] and Rytary® (Carbidopa/Levodopa ER Capsules) Approval Criteria

1. An FDA approved diagnosis of Parkinson's disease, post-encephalitic parkinsonism, or parkinsonism that may follow carbon monoxide intoxication or manganese intoxication; and
2. A patient-specific, clinically significant reason why the member cannot use other generic carbidopa/levodopa combinations including Sinemet® CR (carbidopa/levodopa ER tablets); and
3. For Crexont® (carbidopa/levodopa ER capsules), a patient-specific, clinically significant reason why the member cannot use Rytary® (carbidopa/levodopa ER capsules) must be provided.

Additionally, the College of Pharmacy recommends the prior authorization of Onapgo™ (apomorphine injection for continuous infusion) and Vyalev™ (foscarbidopa/foslevodopa injection for continuous infusion) with the following criteria (shown in red):

Onapgo™ (Apomorphine Injection for Continuous Infusion) Approval Criteria:

1. An FDA approved indication for the treatment of motor fluctuations in patients with advanced Parkinson's disease; and
2. Member must be 18 years of age or older; and
3. Onapgo™ must be prescribed by, or in consultation with, a neurologist; and
4. Prescriber must verify that member has demonstrated a clear responsiveness to treatment with levodopa and is experiencing persistent motor fluctuations with 3 hours or more of "off" time per day despite optimized carbidopa/levodopa therapy; and
5. Member has documented trials that resulted in an inadequate response despite optimized treatment (or documented intolerance or contraindication) with oral carbidopa/levodopa and 1 of the following:
    a. Dopamine agonist (e.g., pramipexole, ropinirole); or
    b. Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline); or
    c. Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone); or
    d. Amantadine; and
6. Member must not be taking 5-HT_3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron) concomitantly with Onapgo™; and
7. Onapgo™ must be used with the Onapgo™ pump and prescriber must verify that the patient or caregiver has been trained on the proper administration of Onapgo™ with the Onapgo™ pump prior to starting treatment; and
8. Onapgo™ will not be approved for concomitant use with Vyalev™ (foscarbidopa/foslevodopa injection for continuous infusion) or Apokyn® (apomorphine injection); and
9. Initial approvals will be for 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Onapgo™. Subsequent approvals will be for 1 year.

Vyalev™ (Foscarbidopa/Foslevodopa Injection for Continuous Infusion) Approval Criteria:

1. An FDA approved indication for the treatment of motor fluctuations with advanced Parkinson's disease; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a neurologist; and
4. Prescriber must verify that member has demonstrated a clear responsiveness to treatment with levodopa and is experiencing persistent motor fluctuations with 2 and one-half hours or more of "off" time per day despite optimized carbidopa/levodopa therapy; and

5. Member has documented trials that resulted in an inadequate response despite optimized treatment (or documented intolerance or contraindication) with oral carbidopa/levodopa and 1 of the following:
    a. Dopamine agonist (e.g., pramipexole, ropinirole); or
    b. Monoamine oxidase-B (MAO-B) inhibitor (e.g., selegiline, rasagiline); or
    c. Catechol-O-methyltransferase (COMT) inhibitor (e.g., entacapone, tolcapone); or
    d. Amantadine; and
6. Member must not be taking nonselective monoamine oxidase inhibitors (MAOIs) concomitantly with Vyalev™ or within 2 weeks prior to initiating treatment with Vyalev™; and
7. Vyalev™ must be used with the Vyafuser™ pump and prescriber must verify that the patient or caregiver has been trained on the proper administration of Vyalev™ with the Vyafuser™ pump prior to starting treatment; and
8. Vyalev™ will not be approved for concomitant use with Onapgo™ (apomorphine subcutaneous injection); and
9. Initial approvals will be for 6 months. For continued authorization, prescriber must verify member demonstrated a positive clinical response to Vyalev™. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends removal of SoonerCare coverage and of the approval criteria for Kynmobi® (apomorphine SL film) based on product discontinuation (changes shown in red):

~~**Kynmobi® [Apomorphine Sublingual (SL) Film] Approval Criteria:**~~

~~1. An FDA approved diagnosis of acute, intermittent treatment of "off" episodes in patients with Parkinson's disease (PD); and~~
~~2. Member must be taking carbidopa/levodopa in combination with Kynmobi®; and~~
~~3. Member should be experiencing at least 1 well defined "off" episode per day with a total daily "off" time duration of ≥2 hours during the waking day; and~~
~~4. Initial dose titration should occur in an "off" state and in a setting supervised by a health care provider to monitor blood pressure and heart rate; and~~
~~5. Member should not use apomorphine concomitantly with 5-HT_3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron); and~~
~~6. Prescriber must verify the member has been counseled on separating doses by at least 2 hours; and~~
~~7. The maximum single dose approvable is 30mg; and~~
~~8. A quantity limit of 5 doses per day will apply.~~

[1] Amneal Pharmaceuticals. Amneal Receives U.S. FDA Approval for IPX203 for Treatment of Parkinson's Disease to Be Launched as Crexont® (Carbidopa and Levodopa) Extended-Release Capsules. Available online at: https://investors.amneal.com/news/press-releases/press-release-details/2024/Amneal-Receives-U.S.-FDA-Approval-for-IPX203-for-Treatment-of-Parkinsons-Disease-to-Be-Launched-as-CREXONT-Carbidopa-and-Levodopa-Extended-Release-Capsules/default.aspx. Issued 08/07/2024. Last accessed 05/21/2025.

[2] American Parkinson Disease Association. Exploring the Variations of Carbidopa/Levodopa: The Mainstay of Parkinson's Disease Treatment. Available online at: https://www.apdaparkinson.org/article/carbidopa-levodopa-formulations-and-parkinsons-disease/. Issued 10/08/2024. Last accessed 05/21/2025.

[3] AbbVie. U.S. FDA Approves Vyalev™ (Foscarbidopa and Foslevodopa) for Adults Living with Advanced Parkinson's Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/us-fda-approves-vyalev-foscarbidopa-and-foslevodopa-for-adults-living-with-advanced-parkinsons-disease-302278666.html. Issued 10/17/2024. Last accessed 05/21/2025.

[4] Supernus Pharmaceuticals. Supernus Announces FDA Approval of Onapgo™ (Apomorphine Hydrochloride) for Parkinson's Disease. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2025/02/04/3020423/19871/en/Supernus-Announces-FDA-Approval-of-ONAPGO-apomorphine-hydrochloride-for-Parkinson-s-Disease.html. Issued 02/04/2025. Last accessed 05/21/2025.

[5] Wexler M. Kynmobi to be Discontinued in US and Canada Due to Limited Use. *Parkinson's News Today*. Available online at: https://parkinsonsnewstoday.com/news/kynmobi-discontinued-us-canada-limited-use-sunovion/. Issued 06/12/2023. Last accessed 05/21/2025.

[6] Onapgo™ (Apomorphine) Prescribing Information. Supernus Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/214056s000lbl.pdf. Last revised 02/2025. Last accessed 05/21/2025.

[7] Katzenschlager R, Poewe W, et al. Apomorphine Subcutaneous Infusion in Patients with Parkinson's Disease with Persistent Motor Fluctuations (TOLEDO): A Multicentre, Double-Blind, Randomised, Placebo-Controlled Trial. *Lancet Neurol* 2018; 17: 749–759. doi: 10.1016/S1474-4422(18)30239-4.

[8] Vyalev™ (Foscarbidopa/Foslevodopa) Prescribing Information. AbbVie. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216962s000lbl.pdf. Last revised 10/2024. Last accessed 05/21/2025.

[9] Soileau M, Aldred J, et al. Safety and efficacy of Continuous Subcutaneous Foslevodopa-Foscarbidopa in Patients with Advanced Parkinson's Disease: A Randomised, Double-Blind, Active-Controlled, Phase 3 Trial. *Lancet Neurol* 2022; 21: 1099–1109. doi: 10.1016/S1474-4422(22)00400-8.

Appendix J

Vote to Prior Authorize Vanrafia™ (Atrasentan) and Update the Approval Criteria for the Primary Immunoglobulin A Nephropathy (IgAN) Medications

Oklahoma Health Care Authority
June 2025

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

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

- **December 2023:** The FDA granted full approval to Tarpeyo® [budesonide delayed release (DR) capsule] to reduce the loss of kidney function in adults with primary IgAN at risk for disease progression. It was previously approved under accelerated approval, based on the surrogate marker of proteinuria. The confirmatory trial showed a statistically significant benefit over placebo in estimated glomerular filtration rate (eGFR) over the 2-year trial period. At 2 years, there was a 6.11mL/min/1.73m^2 decline in eGFR in the Tarpeyo® group compared with a 12.0mL/min/1.73m^2 decline in the placebo group (P<0.0001).
- **September 2024:** The FDA granted full approval to Filspari® (sparsentan) to slow kidney function decline in adults with primary IgAN who are at risk of disease progression. Filspari® was previously approved under accelerated approval based on the surrogate marker of proteinuria. The full FDA approval was based on the results of the PROTECT confirmatory trial which showed the mean eGFR slope from baseline to week 110 was -3.0mL/min/1.73m^2/year for Filspari® and -4.2mL/min/1.73m^2/year for irbesartan, corresponding to a statistically significant treatment effect of 1.2mL/min/1.73m^2/year (P=0.0168).
- **April 2025:** The FDA approved Vanrafia™ (atrasentan) for the reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression.

Guideline Update(s):

- **August 2024:** Updated draft guidelines for the management of IgAN and immunoglobulin A vasculitis (IgAV) were published by Kidney Disease Improving Global Outcomes (KDIGO) for public draft review. Some of the key updates included:
  - The definition of a patient at risk of progressive loss of kidney function was changed from the prior definition of proteinuria >0.75-1g/day despite ≥90 days of optimized supportive care. The update 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 <0.5g/day and multiple therapies may be needed to achieve this goal.
- The focus of management for most patients should be simultaneous to prevent or reduce IgA immune complex formation and immune complex-mediated glomerular injury [i.e., treatment with Tarpeyo® (budesonide DR 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].
- Tarpeyo® is the only treatment to date proven to reduce the levels of pathogenic forms of IgA and IgA immune complexes. These effects have not been shown with other oral formulations of budesonide. Healthcare providers should also advise that it is possible that repeated 9-month cycles of Tarpeyo® or a reduced-dose maintenance regimen may be required to maintain disease remission, as an increase in proteinuria and decline in eGFR was observed on stopping Tarpeyo® treatment.

Vanrafia™ (Atrasentan) Product Summary[5]

Therapeutic Class: Endothelin receptor antagonist (ERA)

Indication(s): To reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5g/g

- This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Vanrafia™ slows kidney function decline 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: 0.75mg tablet

Dosing and Administration:

- The recommended dose of Vanrafia™ is 0.75mg orally once daily with or without food.
- Tablets should be swallowed whole and should not be cut, crushed, or chewed.

Efficacy: The safety and efficacy of Vanrafia™ were studied in a randomized, double-blind, placebo-controlled, multicenter Phase 3 ALIGN clinical trial.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Biopsy proven primary IgAN
  - eGFR ≥30mL/min/1.73m^2
  - Urine protein ≥1g/day
  - Stable dose of maximally tolerated RASi which was continued throughout the trial
  - 64 patients were also on an SGLT-2 inhibitor
- Intervention: Randomized 1:1 to receive either Vanrafia™ 0.75mg or placebo once daily
- Primary Outcome: The primary endpoint was the percent reduction in UPCR at week 36 relative to baseline.
- Results: Vanrafia™ showed a 36% reduction in UPCR compared to placebo [95% confidence interval (CI): 26%, 45%; P<0.0001] at week 36. The treatment effect on UPCR at week 36 was also consistent in the 64 patients who were also on an SGLT-2 inhibitor.

Cost Comparison:

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
Vanrafia™ (atrasentan) 0.75mg tablet	**$445.21**	**$13,356.30**	**$160,275.60***
Filspari® (sparsentan) 400mg tablet	$414.41	$12,432.30	$ 149,187.60*

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).
*Cost is based on the FDA approved dosing of 1 tablet daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Vanrafia™ (atrasentan) with the following criteria (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; 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. 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
8. 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 recommends updating the Filspari® (sparsentan) and Tarpeyo® (budesonide DR capsule) approval criteria based on the FDA full approvals and the KDIGO guidelines (changes shown in red):

Filspari® (Sparsentan) Approval Criteria:

1. An FDA approved indication to ~~reduce proteinuria~~ slow kidney function decline 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; 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 rapid disease progression as demonstrated by ≥1 of the following, despite 3 months of maximal supportive care:~~
   ~~a. Urine protein-to-creatinine (UPCR) ratio ≥1.5g/g; or~~
   ~~b. Proteinuria >0.75g/day; and~~
6. 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
7. 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

8. Prescriber must verify the member will discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) prior to initiating treatment 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, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
13. A quantity limit of 30 tablets per 30 days will apply.

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

1. An FDA approved indication to reduce ~~proteinuria~~ the loss of kidney function 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; 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 rapid disease progression as demonstrated by ≥1 of the following, despite maximal supportive care:~~
   ~~a. Urine protein-to-creatinine ratio (UPCR) ≥1.5g/g; or~~
   ~~b. Proteinuria >0.75g/day; and~~
6. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent); and
7. 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
~~8. A patient-specific, clinically significant reason why a 6-month trial of an alternative formulation of budesonide DR oral capsules (e.g., Entocort® EC) or alternative oral corticosteroids is not appropriate for the member must be provided; and~~
9. 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

10. A quantity limit of 120 capsules per 30 days will apply.

---

[1] Calliditas Therapeutics. Calliditas Therapeutics Announces Full FDA Approval of Tarpeyo®, the Only FDA-Approved Treatment for IgA Nephropathy to Significantly Reduce the Loss of Kidney Function. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/calliditas-therapeutics-announces-full-fda-approval-of-tarpeyo-the-only-fda-approved-treatment-for-iga-nephropathy-to-significantly-reduce-the-loss-of-kidney-function-302020478.html. Issued 12/20/2023. Last accessed 05/16/2025.

[2] Travere® Therapeutics. Travere® Therapeutics Announces Full FDA Approval of Filspari® (Sparsentan), the Only Non-Immunosuppressive Treatment that Significantly Slows Kidney Function Decline in IgA Nephropathy. Available online at: https://ir.travere.com/press-releases/news-details/2024/Travere-Therapeutics-Announces-Full-FDA-Approval-of-FILSPARI-sparsentan-the-Only-Non-Immunosuppressive-Treatment-that-Significantly-Slows-Kidney-Function-Decline-in-IgA-Nephropathy-09-05-2024/default.aspx. Issued 09/05/2024. Last accessed 05/16/2025.

[3] Novartis. Novartis Receives FDA Accelerated Approval for Vanrafia™ (Atrasentan), the First and Only Selective Endothelin A Receptor Antagonist for Proteinuria Reduction in Primary IgA nephropathy (IgAN). *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2025/04/03/3054782/0/en/Novartis-receives-FDA-accelerated-approval-for-Vanrafia-atrasentan-the-first-and-only-selective-endothelin-A-receptor-antagonist-for-proteinuria-reduction-in-primary-IgA-nephropath.html. Issued 04/02/2025. Last accessed 05/16/2025.

[4] Kidney Diseases: Improving Global Outcomes (KDIGO). KDIGO 2024 Clinical Practice Guidelines for the Management of Immunoglobin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Available at: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2024-IgAN-IgAV-Guideline-Public-Review-Draft.pdf. Issued 08/2024. Last accessed 05/16/2025.

[5] Vanrafia™ (Atrasentan) Prescribing Information. Novartis Pharmaceuticals Corporation. Available online at: https://www.novartis.com/us-en/sites/novartis_us/files/vanrafia.pdf. Issued 04/2025. Last accessed 05/16/2025.

Appendix K

Vote to Prior Authorize Axtle™ (Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) and Update the Approval Criteria for the Lung Cancer Medications

Oklahoma Health Care Authority
June 2025

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20]

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

- **May 2024:** The FDA granted accelerated approval to Imdelltra™ (tarlatamab-dlle) for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.
- **June 2024:** The FDA granted accelerated approval to Augtyro™ (repotrectinib) for a new indication for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and that have progressed following treatment or have no satisfactory alternative therapy.
- **June 2024:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with carboplatin and paclitaxel followed by durvalumab as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).
- **June 2024:** The FDA granted accelerated approval to Krazati® (adagrasib) for a new indication, in combination with cetuximab, for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC), as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
- **June 2024:** The FDA approved pemetrexed for injection, 100mg and 500mg, through the 505(b)(2) pathway based on prior studies utilizing Alimta® (pemetrexed). In December 2024, a supplemental New Drug Application (sNDA) was approved allowing the addition of the proprietary name, Axtle™, to the package labeling. Axtle™ is supplied as a lyophilized powder for reconstitution in 100mg or 500mg single-dose vials (SDVs).

- **August 2024:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by single-agent durvalumab as adjuvant treatment after surgery for adults with resectable (tumors ≥4cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
- **August 2024:** The FDA approved Lazcluze™ (lazertinib), in combination with Rybrevant® (amivantamab-vmjw), for the first-line treatment of locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test. The FDA also approved this as a new indication for Rybrevant®.
- **September 2024:** The FDA approved Tecentriq Hybreza™ (atezolizumab/hyaluronidase-tqjs) for subcutaneous (sub-Q) injection for all of the adult indications as the intravenous (IV) formulation of Tecentriq® (atezolizumab), including for NSCLC, small cell lung cancer (SCLC), hepatocellular carcinoma (HCC), melanoma, and alveolar soft part sarcoma (ASPS).
- **September 2024:** The FDA approved Rybrevant® (amivantamab-vmjw) for a new indication, in combination with carboplatin and pemetrexed, the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor.
- **September 2024:** The FDA approved Tagrisso® (osimertinib) for a new indication for the treatment of adult patients with locally advanced, unresectable (stage III) NSCLC whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- **December 2024:** The FDA granted accelerated approval to Bizengri® (zenocutuzumab-zbco) for the treatment of adults with advanced, unresectable or metastatic NSCLC or pancreatic adenocarcinoma harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy.
- **December 2024:** The FDA approved Imfinzi® (durvalumab) for a new indication, as a single agent, for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- **January 2025:** The FDA approved Lumakras® (sotorasib) for a new indication, in combination with panitumumab, for the treatment of adult patients with KRAS G12C-mutated metastatic CRC, as determined

by an FDA approved-test, who have received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.
- **March 2025:** The FDA approved Imfinzi® (durvalumab) for a new indication, in combination with gemcitabine and cisplatin, as neoadjuvant treatment, followed by single agent durvalumab as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer.

News:
- **July 2024:** The FDA's previous accelerated approval for Exkivity® (mobocertinib) has been withdrawn. Takeda, the former manufacturer of Exkivity®, requested the voluntary withdrawal of the accelerated approval because the required post-marketing trial did not verify a clinical benefit of the medication.

Guideline Update(s):
- The National Comprehensive Cancer Network (NCCN) guidelines for colon cancer and rectal cancer recommend the use of sotorasib or adagrasib in combination with cetuximab or panitumumab for patients with KRAS G12C mutation positive disease. Additionally, sotorasib or adagrasib may be used as a single agent for patients who are unable to tolerate an epidermal growth factor receptor (EGFR) inhibitor due to toxicity.
- The NCCN guidelines for kidney cancer recommend erlotinib, when used in combination with bevacizumab, for patients with advanced papillary renal cell carcinoma with non-clear cell histology that is relapsed or surgically unresectable stage IV disease.

Bizengri® (Zenocutuzumab-zbco) Product Summary[21]

Therapeutic Class: Bispecific human epidermal growth factor receptor 2 (HER2)- and human epidermal growth factor receptor 3 (HER3)-directed antibody

Indication(s):
- Treatment of adults with advanced, unresectable or metastatic NSCLC harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy; or
- Treatment of adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a *NRG1* gene fusion with disease progression on or after prior systemic therapy.
- These indications are approved under accelerated approval based on overall 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(s).

How Supplied: 375mg/18.75mL (20mg/mL) solution in an SDV

Dosing and Administration:
- Recommended dose is 750mg as an IV infusion every 2 weeks
- Should be continued until disease progression or unacceptable toxicity

Cost: The Wholesale Acquisition Cost (WAC) is $633.33 per mL, resulting in a cost of $47,499.75 per 28 days or $617,496.75 per year based on the recommended dosing.

Imdelltra™ (Tarlatamab-dlle) Product Summary[22]

Therapeutic Class: Bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy
- This indication is approved under accelerated approval based on overall 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(s).

How Supplied: Lyophilized powder in a 1mg or 10mg SDV

Dosing and Administration: Administered as a 1-hour IV infusion according to the following schedule:
- Cycle 1 (Step-Up Dosing): 1mg on day 1, 10mg on day 8, 10mg on day 15
- Cycle 2 (and Subsequent Cycles): 10mg on day 1 and day 15
- Patients should be observed following Imdelltra™ infusion due to the risk of cytokine release syndrome (CRS) and neurologic toxicity, including immune effector cell-associated neurotoxicity (ICANS). See the full *Prescribing Information* for the recommended monitoring time for each cycle. Additionally, patients should remain within 1 hour of an appropriate health care setting for a total of 48 hours from the start of the infusion and be accompanied by a caregiver following the first 2 doses of cycle 1.
- Following step-up dosing, biweekly dosing should continue until disease progression or unacceptable toxicity.

Cost: The WAC is $1,500 for the 1mg SDV and $15,000 for the 10mg SDV. The cost of cycle 1 would be $31,500. Subsequent cycles would result in a cost of $30,000 per 28 days or $390,000 per year based on the recommended dosing.

Lazcluze™ (Lazertinib) Product Summary[23]

Therapeutic Class: Kinase inhibitor

Indication(s): First-line-treatment, in combination with amivantamab, of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test

How Supplied: 80mg and 240mg oral tablets

Dosing and Administration: Recommended dose is 240mg once daily with or without food, given in combination with amivantamab, until disease progression or unacceptable toxicity

Cost: The WAC is $606.60 per 240mg tablet, resulting in a cost of $18,198.00 per 30 days or $218,376.00 per year based on the recommended dosing.

Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) Product Summary[24]

Therapeutic Class: Combination of atezolizumab, a programmed death-ligand 1 (PD-L1) blocking antibody, and hyaluronidase, an endoglycosidase

Indication(s): Indicated for all of the same adult indications as the IV formulation of atezolizumab, including indications for NSCLC, SCLC, HCC, melanoma, and ASPS

How Supplied: 1,875mg atezolizumab/30,000 units hyaluronidase per 15mL (125mg/2,000 units per mL) solution in a SDV

Dosing and Administration:

- The recommended dose is 15mL (1,875mg atezolizumab and 30,000 units hyaluronidase) administered sub-Q into the thigh over approximately 7 minutes every 3 weeks.
- Tecentriq Hybreza™ must be administered by a health care professional.
- Please refer to the full *Prescribing Information* for indication-specific recommendations, including the duration of treatment, timing of administration relative to other medications, and other administration details.

Cost: The WAC is $750.12 per mL, resulting in a cost of $11,251.80 per 21 days or $191,280.60 per year based on the recommended dosing.

Cost Comparison: Pemetrexed Products

Product	Cost Per 10mg	Cost Per 21 Days*	Cost Per Year
Axtle™ (pemetrexed) (J9292)	**$79.00**	**$7,110.00**	**$120,870.00**
Pemrydi RTU® (pemetrexed) (J9324)	$81.06	$7,295.40	$124,021.80
Pemfexy® (pemetrexed) (J9304)	$46.35	$4,171.50	$70,915.50
pemetrexed (Hospira) (J9294)	$3.86	$347.40	$5,905.80
pemetrexed (Alimta® generic) (J9305)	$3.77	$339.30	$5,768.10
pemetrexed (Sandoz) (J9297)	$1.74	$156.60	$2,662.20

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 500mg/m^2 every 3 weeks for a member with a body surface area (BSA) of 1.73m^2 (using a total of 900mg per dose)

Recommendations

The College of Pharmacy recommends the prior authorization of Bizengri® (zenocutuzumab-zbco), Imdelltra™ (tarlatamab-dlle), and Lazcluze™ (lazertinib) based on recent FDA approval with the following criteria (shown in red):

Bizengri® (Zenocutuzumab-zbco) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced, unresectable or metastatic NSCLC; and
2. Neuregulin 1 (*NRG1*) gene fusion-positive; and
3. Disease progression on or after prior systemic therapy; and
4. Used as single agent.

Bizengri® (Zenocutuzumab-zbco) Approval Criteria [Pancreatic Cancer Diagnosis]:

1. Diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma; and
2. Neuregulin 1 (*NRG1*) gene fusion-positive; and
3. Disease progression on or after prior systemic therapy; and
4. Used as single agent.

Imdelltra™ (Tarlatamab-dlle) Approval Criteria [Extensive Stage Small Cell Lung Cancer (ES-SCLC) Diagnosis]:

1. Diagnosis of ES-SCLC; and
2. Member has disease progression on or after platinum-based chemotherapy; and
3. Healthcare facilities must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities.

Lazcluze™ (Lazertinib) 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 19 deletions or exon 21 L858R substitution mutations; and
3. Used as first-line treatment in combination with amivantamab.

Next, the College of Pharmacy also recommends the prior authorization of Tecentriq Hybreza™ (atezolizumab/hyaluronidase-tqjs) with criteria similar to Tecentriq® (atezolizumab) with the following changes (shown in red):

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 years of age or older for Tecentriq Hybreza™.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of advanced unresectable or metastatic HCC disease; and
2. Used in combination with bevacizumab; and
3. Member has not received prior systemic therapy; and
4. Member must be 18 years of age or older.

Tecentriq® (Atezolizumab) and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) Approval Criteria [Melanoma Diagnosis]:

1. Unresectable or metastatic disease; and
2. BRAF V600 mutation-positive; and
3. In combination with cobimetinib and vemurafenib; and
4. Member must be 18 years of age or older.

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

1. Diagnosis of non-squamous NSCLC; and
    a. First-line therapy for metastatic disease; and
    b. The member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), ROS1, BRAF, MET exon 14 skipping mutation, or RET mutations; and
    c. Used in combination with bevacizumab, paclitaxel, and carboplatin (maximum of 6 cycles) or in combination with paclitaxel (protein bound) and carboplatin; and

d. Atezolizumab and bevacizumab may be continued after the above combination in members without disease progression (applies to the bevacizumab/paclitaxel/carboplatin regimen); or

2. Diagnosis of NSCLC; and
   a. For first-line therapy for metastatic disease:
      i. Used as a single-agent; and
      ii. Member does not have epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), ROS1, BRAF, MET exon 14 skipping, or RET mutations; and
      iii. High programmed death ligand-1 (PD-L1) expression determined by 1 of the following:
         1. PD-L1 stained ≥50% of tumor cells (TC≥50%); or
         2. PD-L1 stained tumor-infiltrating immune cells (IC) covering ≥10% of the tumor area (IC≥10%); or
   b. For subsequent therapy for metastatic disease, meets the following:
      i. Used as a single-agent only; or
3. Diagnosis of stage II or IIIA NSCLC; and
   a. Member has undergone resection and completed platinum-based chemotherapy; and
   b. PD-L1 expression of ≥1% of tumor cells; and
4. Member must be 18 years of age or older.

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

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

The College of Pharmacy also recommends the prior authorization of Axtle™ (pemetrexed) with criteria similar to Pemfexy® (pemetrexed) and Pemrydi RTU® (pemetrexed) based on net costs (changes shown in red):

Axtle™ (Pemetrexed; J9292), Pemfexy® (Pemetrexed; J9304), and Pemrydi RTU® (Pemetrexed; J9324) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use Alimta® (pemetrexed; J9305), pemetrexed ditromethamine (J9323), and other preferred pemetrexed 25mg/mL solution products (J9294 - Hospira, J9296 - Accord, J9297 – Sandoz, J9314 - Teva, J9322 - Bluepoint) that do not require prior authorization must be provided.

Next, the College of Pharmacy recommends updating the Augtyro™ (repotrectinib), Imfinzi® (durvalumab), Rybrevant® (amivantamab-vmjw), and Tagrisso® (osimertinib) approval criteria based on new FDA approvals (changes shown in red):

Augtyro™ (Repotrectinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of solid tumor(s) that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion; and
2. Locally advanced or metastatic or where surgical resection is likely to result in severe morbidity; and
3. Member must be 12 years of age or older; and
4. Progressed following treatment or have no satisfactory alternative therapy; and
5. Used 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.

Imfinzi® (Durvalumab) Approval Criteria [Limited-Stage Small Cell Lung Cancer (LS-SCLC) Diagnosis]:

1. Diagnosis of LS-SCLC; and
2. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; and
3. Used as single agent.

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

1. Diagnosis of resectable (tumors ≥4cm and/or node positive) NSCLC; and
    a. Used in combination with platinum-containing chemotherapy as neoadjuvant treatment before surgery, followed by single agent durvalumab as adjuvant treatment after surgery; and
    b. No epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements; or

2. Diagnosis of unresectable stage II or III non-small cell lung cancer (NSCLC); and
    a. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; or
3. Diagnosis of metastatic NSCLC; and
    a. No EGFR mutation or ALK genomic tumor aberrations; and
    b. Used in combination with tremelimumab-actl and platinum-based chemotherapy.

Rybrevant® (Amivantamab-vmjw) 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 ~~osimertinib~~ an EGFR tyrosine kinase inhibitor.

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

1. Diagnosis of NSCLC; and
    a. As adjuvant therapy following tumor resection in members with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations; and
    b. As a single agent; or
2. Diagnosis of locally advanced, unresectable (stage III) NSCLC; and
    a. EGFR exon 19 deletions or exon 21 L858R mutations; and
    b. As single agent; and
    c. Disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy; or
3. Diagnosis of metastatic NSCLC; and
    a. EGFR T790M mutation-positive disease; or
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and
    c. As a single agent; or
4. Diagnosis of locally advanced or metastatic non-squamous NSCLC; and
    a. Used as first-line treatment; and
    b. EGFR exon 19 deletions or exon 21 L858R mutations; and

c. Used in combination with pemetrexed and platinum-based (cisplatin or carboplatin) chemotherapy.

Next, the College of Pharmacy recommends updating the Krazati® (adagrasib) and Lumakras® (sotorasib) approval criteria based on new FDA approvals and NCCN guideline recommendations (changes shown in red):

Krazati® (Adagrasib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic CRC; and
2. Presence of KRAS G12C mutation; and
3. Member has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
4. Used in combination with cetuximab or panitumumab; or
   a. Used as a single agent if unable to tolerate epidermal growth factor receptor (EGFR) inhibitor due to toxicity.

Lumakras® (Sotorasib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic CRC; and
2. Presence of KRAS G12C mutation; and
3. Member has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
4. Used in combination with cetuximab or panitumumab; or
   a. Used as a single agent if unable to tolerate epidermal growth factor receptor (EGFR) inhibitor due to toxicity.

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

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

1. Diagnosis of ~~kidney cancer~~ advanced papillary renal cell carcinoma; and
2. Non-clear cell histology; and
3. Relapsed disease or surgically unresectable stage IV disease; and
~~4. As a single agent only.~~
5. Used in combination with bevacizumab.

Lastly, the College of Pharmacy recommends removing the approval criteria and SoonerCare coverage for Exkivity® (mobocertinib) based on the withdrawal of its accelerated approval (changes shown in red):

~~**Exkivity® (Mobocertinib) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:**~~

~~1. Diagnosis of advanced or metastatic NSCLC; and~~
~~2. Tumor exhibits an epidermal growth factor receptor (EGFR) exon 20 insertion mutation; and~~

~~3. Disease has progressed on or after platinum-based chemotherapy; and~~
~~4. As a single agent; and~~
~~5. Members who are new to treatment with Exkivity® will generally not be approved.~~

[1] U.S. Food and Drug Administration (FDA). FDA Grants Accelerated Approval to Tarlatamab-dlle for Extensive Stage Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tarlatamab-dlle-extensive-stage-small-cell-lung-cancer. Issued 05/16/2024. Last accessed 05/29/2025.
[2] U.S. FDA. FDA Grants Accelerated Approval to Repotrectinib for Adult and Pediatric Patients with NTRK Gene Fusion-Positive Solid Tumors. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-repotrectinib-adult-and-pediatric-patients-ntrk-gene-fusion-positive. Issued 06/13/2024. Last accessed 05/29/2025.
[3] U.S. FDA. FDA Approves Durvalumab with Chemotherapy for Mismatch Repair Deficient Primary Advanced or Recurrent Endometrial Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-chemotherapy-mismatch-repair-deficient-primary-advanced-or-recurrent. Issued 06/14/2024. Last accessed 05/29/2025.
[4] U.S. FDA. FDA Grants Accelerated Approval to Adagrasib with Cetuximab for KRAS G12C-Mutated Colorectal Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-adagrasib-cetuximab-kras-g12c-mutated-colorectal-cancer. Issued 06/21/2024. Last accessed 05/29/2025.
[5] U.S. FDA. NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/210661Orig1s000ltr.pdf. Issued 06/28/2024. Last accessed 05/29/2025.
[6] U.S. FDA. Supplemental Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/210661Orig1s001ltr.pdf. Issued 12/02/2024. Last accessed 05/29/2025.
[7] Axtle™ (Pemetrexed) Prescribing Information. Avyxa Pharma, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/210661s001lbl.pdf. Last revised 12/2024. Last accessed 05/29/2025.
[8] U.S. FDA. FDA Approves Neoadjuvant/Adjuvant Durvalumab for Resectable Non-Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-

approves-neoadjuvantadjuvant-durvalumab-resectable-non-small-cell-lung-cancer. Issued 08/15/2024. Last accessed 05/29/2025.

[9] U.S. FDA. FDA Approves Lazertinib with Amivantamab-vmjw for Non-Small Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-lazertinib-amivantamab-vmjw-non-small-lung-cancer. Issued 08/19/2024. Last accessed 05/29/2025.

[10] U.S. FDA. FDA Approves Atezolizumab and Hyaluronidase-tqjs for Subcutaneous Injection. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-and-hyaluronidase-tqjs-subcutaneous-injection. Issued 09/12/2024. Last accessed 05/29/2025.

[11] U.S. FDA. FDA Approves Amivantamab-vmjw with Carboplatin and Pemetrexed for Non-Small Cell Lung Cancer with EGFR Exon 19 Deletions or L858R Mutations. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-amivantamab-vmjw-carboplatin-and-pemetrexed-non-small-cell-lung-cancer-egfr-exon-19. Issued 09/19/2024. Last accessed 05/29/2025.

[12] U.S. FDA. FDA Approves Osimertinib for Locally Advanced, Unresectable (Stage III) Non-Small Cell Lung Cancer Following Chemoradiation Therapy. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-osimertinib-locally-advanced-unresectable-stage-iii-non-small-cell-lung-cancer. Issued 09/25/2024. Last accessed 05/29/2025.

[13] U.S. FDA. FDA Grants Accelerated Approval to Zenocutuzumab-zbco for Non-Small Cell Lung Cancer and Pancreatic Adenocarcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-zenocutuzumab-zbco-non-small-cell-lung-cancer-and-pancreatic. Issued 12/04/2024. Last accessed 05/29/2025.

[14] U.S. FDA. FDA Approves Durvalumab for Limited-Stage Small Cell Lung Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-limited-stage-small-cell-lung-cancer. Issued 12/04/2024. Last accessed 05/29/2025.

[15] U.S. FDA. FDA Approves Sotorasib with Panitumumab for KRAS G12C-Mutated Colorectal Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-sotorasib-panitumumab-kras-g12c-mutated-colorectal-cancer. Issued 01/16/2025. Last accessed 05/29/2025.

[16] U.S. FDA. FDA Approves Durvalumab for Muscle Invasive Bladder Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-muscle-invasive-bladder-cancer. Issued 03/28/2025. Last accessed 05/29/2025.

[17] U.S. FDA. Takeda Pharmaceuticals U.S.A., Inc.; Withdrawal of Approval of New Drug Application for Exkivity® (Mobocertinib Succinate) Capsule, Equivalent to 40 Milligrams Base. *Federal Register*. Available online at: https://www.federalregister.gov/documents/2024/07/15/2024-15371/takeda-pharmaceuticals-usa-inc-withdrawal-of-approval-of-new-drug-application-for-exkivity. Issued 07/15/2024. Last accessed 05/29/2025.

[18] National Comprehensive Cancer Network (NCCN). Colon Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Last revised 04/24/2025. Last accessed 05/29/2025.

[19] NCCN. Rectal Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Last revised 03/31/2025. Last accessed 05/29/2025.

[20] NCCN. Kidney Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Last revised 01/09/2025. Last accessed 05/29/2025.

[21] Bizengri® (Zenocutuzumab-zbco) Prescribing Information. Merus US, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761352s001lbl.pdf. Last revised 12/2024. Last accessed 05/29/2025.

[22] Imdelltra™ (Tarlatamab-dlle) Prescribing Information. Amgen, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761344s000lbl.pdf. Last revised 05/2024. Last accessed 05/29/2025.

[23] Lazcluze™ (Lazertinib) Prescribing Information. Janssen Biotech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219008s000lbledt.pdf. Last revised 08/2024. Last accessed 05/29/2025.

[24] Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) Prescribing Information. Genentech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761347s000lbl.pdf. Last revised 09/2024. Last accessed 05/29/2025.

Appendix L

Fiscal Year 2024 Annual Review of Antiviral Medications

Oklahoma Health Care Authority
June 2025

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), Sitavig® (Acyclovir Buccal Tablets), and Xerese® (Acyclovir/Hydrocortisone 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.

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 and Injection) Approval Criteria [Hematopoietic Stem Cell Transplant (HSCT) Diagnosis]:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogenic HSCT; and
2. Member must be CMV R+; and
3. Member must have received a HSCT within the last 28 days; and
4. Members taking concomitant cyclosporine will only be approved for the 240mg dose; and
5. 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
6. 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
7. Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and
8. 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
9. 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
10. A quantity limit of 1 tablet or vial per day will apply.

Prevymis® (Letermovir Tablets and Injection) Approval Criteria [Kidney Transplant Diagnosis]:

1. An FDA approved indication of prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients; and
2. Member must be at high risk [i.e., donor CMV-seropositive/recipient CMV-seronegative (D+/R-)]; and
3. Member must have received a kidney transplant within the last 7 days; and
4. Members taking concomitant cyclosporine will only be approved for the 240mg dose; and
5. 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
6. 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
7. Prescriber must verify the member will be monitored for CMV reactivation while on therapy; and
8. 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
9. A quantity limit of 1 tablet or vial per day will apply.

Zovirax® (Acyclovir Ointment) Approval Criteria:

1. An FDA approved indication of management of initial genital herpes or in limited non-life-threatening mucocutaneous herpes simplex virus (HSV) infections in immunocompromised patients; and
2. A patient-specific clinically significant reason why the member cannot use oral acyclovir, famciclovir, or valacyclovir tablets.

Zovirax® (Acyclovir Suspension) Approval Criteria:

1. An age restriction of 7 years and younger will apply. Members older than 7 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

Utilization of Antiviral Medications: Fiscal Year 2024

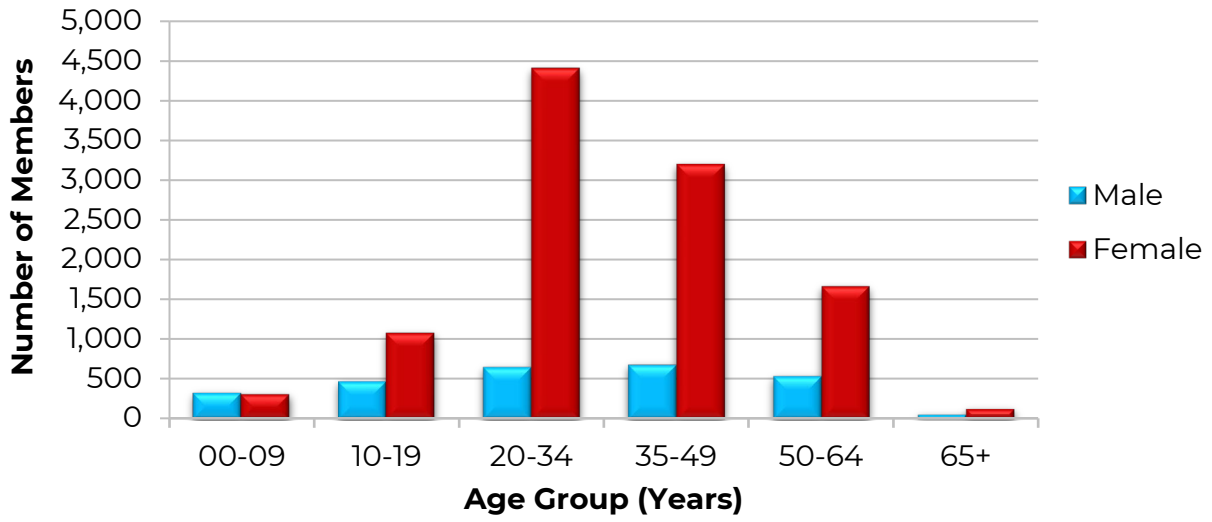
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	14,353	28,290	$1,062,332.29	$37.55	$1.62	1,219,513	656,514
2023 Total	**14,353**	**28,290**	**$1,062,332.29**	**$37.55**	**$1.62**	**1,219,513**	**656,514**
Fiscal Year 2024							
FFS	11,949	21,790	$975,618.87	$44.77	$1.91	941,595	511,799
Aetna	944	1,282	$62,580.89	$48.82	$2.65	46,583	23,572
Humana	1,130	1,588	$61,161.83	$38.52	$2.10	55,991	29,120
OCH	1,008	1,341	$31,805.90	$23.72	$1.41	48,426	22,530
2024 Total	**13,509**	**26,001**	**$1,131,167.49**	**$43.50**	**$1.93**	**1,092,595**	**587,021**
% Change	**-5.90%**	**-8.10%**	**6.50%**	**15.80%**	**19.10%**	**-10.40%**	**-10.60%**
Change	**-844**	**-2,289**	**$68,835.20**	**$5.95**	**$0.31**	**-126,918**	**-69,493**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

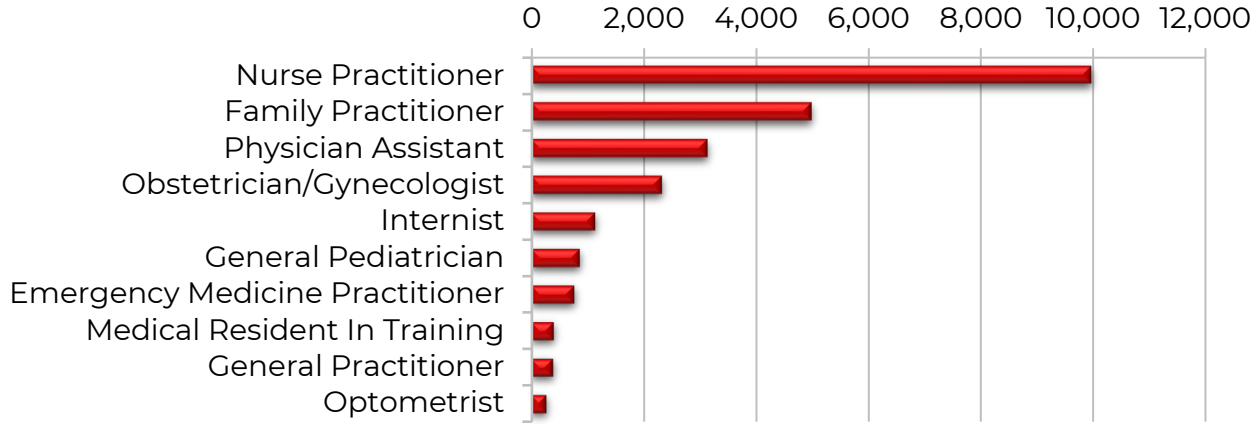
- Aggregate drug rebates collected during fiscal year 2024 for antiviral medications totaled $195,663.36.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Antiviral 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.

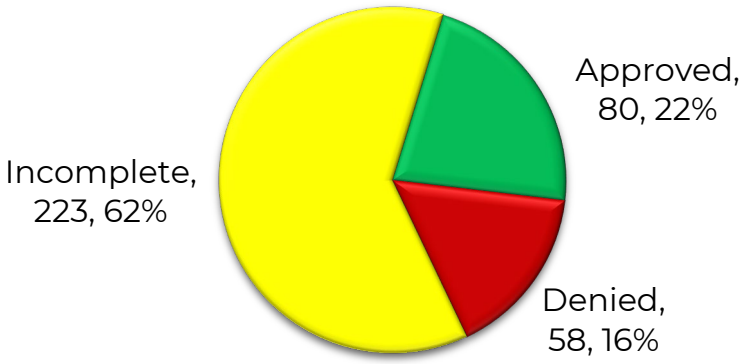
Top Prescriber Specialties of Antiviral Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Antiviral Medications

There were 361 prior authorization requests submitted for antiviral medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	76	22%	219	64%	47	14%	**342**
Aetna	3	23%	4	31%	6	46%	**13**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	1	17%	0	0%	5	83%	**6**
Total	**80**	**22%**	**223**	**62%**	**58**	**16%**	**361**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

Market News and Updates[1,2,3,4,5,6]

Anticipated Patent Expiration(s):

- Prevymis® (letermovir oral pellets): January 2029
- Prevymis® (letermovir oral tablets): January 2029
- Sitavig® (acyclovir buccal tablets): June 2030
- Livtencity® (maribavir tablets): January 2032
- Prevymis® (letermovir injection): February 2033

U.S. Food and Drug Administration (FDA) Label Update(s):

- **August 2024:** The FDA approved a new dosing formulation and age expansions for Prevymis® (letermovir). Prevymis® is now approved for the prevention of cytomegalovirus (CMV) infection and disease for pediatric hematopoietic stem cell transplant (HSCT) recipients 6 months of age and older who weigh at least 6kg and for pediatric kidney transplant recipients 12 years of age and older who weigh at least 40kg. Prevymis® was previously only FDA approved for adults for these indications. Additionally, Prevymis® was approved as an oral pellet formulation available as 20mg or 120mg packets; the oral tablet and injection for intravenous use remain available.

Guideline Update(s):

- **April 2025:** The *International Consensus Guidelines on the Management of Cytomegalovirus in Solid Organ Transplantation* have been updated to include recent advances in CMV management. The updated recommendations for diagnostic techniques emphasize the need for CMV quantitative nucleic acid testing (QNAT) testing to be calibrated to the World Health Organization (WHO) standard. The guidelines now include the data supporting the option of letermovir for prophylaxis in high risk [e.g., donor positive (D+)/recipient negative (R-)] kidney transplant recipients and a recommendation for maribavir for resistance to first-line therapy, except when foscarnet is preferred for patients who are clinically unwell and have a high viral load. Lastly, the update includes recommendations for the use of preemptive therapy in D+/R- liver transplants and new CMV cell-mediated immunity (CMI) testing in R+ kidney transplant recipients to guide prophylaxis.

Pipeline:

- **mRNA-1647:** The Phase 3 randomized, controlled CMVictory trial is evaluating the safety and efficacy of mRNA-1647, an investigational vaccine for the prevention of CMV infection. As CMV is a leading cause of birth defects, the trial includes healthy, non-pregnant, CMV seronegative females 16 to 40 years of age. Preliminary analyses suggest favorable immune responses with mRNA-1647. The trial is

expected to be completed in April 2026. If approved, mRNA-1647 would be the first vaccine for prevention of CMV infection.

- **Potravitug:** An investigational monoclonal antibody product, potravitug, is being evaluated for treatment of BK viremia in kidney transplant recipients. The reactivation of BK polyomavirus doubles the risk of kidney transplant failure. Currently, there are no antiviral therapies for BK viremia, and reduction of immunosuppression is the standard of care. Potravitug is designed to block the attachment of the virus to cells by binding to VP1 proteins in the BK polyomavirus capsid. The safety and efficacy of potravitug are being evaluated in the Phase 2 double-blind, randomized, placebo-controlled trial, SAFE KIDNEY II. The FDA has granted Fast Track designation to potravitug due to the unmet medical need for therapeutics for BK viremia in the transplant setting.

Cost Comparison: Prevymis® (Letermovir) Products

Product	Cost Per Unit	Cost Per Day*	Cost Per 200 Days†
Prevymis® (letermovir) 120mg oral pellets	**$68.60**	**$274.40**	**$54,880**
Prevymis® (letermovir) 240mg tablet	$274.39	$274.39	$54,878
Prevymis® (letermovir) 480mg tablet	$274.39	$274.39	$54,878
Prevymis® (letermovir) 480mg/24mL injection	$15.81	$379.44	$75,888

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, packet, or tablet
*Cost per day based on the maximum FDA recommended dosing of 240mg once daily.
†Per FDA labeling, Prevymis® may be continued for up to 200 days.

Recommendations[7]

The College of Pharmacy recommends the prior authorization of Prevymis® (letermovir) oral pellets with similar criteria as Prevymis® tablets and injection and recommends the following changes to the Prevymis® (letermovir) approval criteria for clarity and based on the FDA approved age expansions (changes shown in red):

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 ~~adult~~ 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. A quantity limit of 1 tablet or vial per day will apply.~~
13. 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 ~~adult~~ 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. A quantity limit of 1 tablet or vial per day will apply.~~
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.

Additionally, the College of Pharmacy recommends removing the prior authorization for Zovirax® (acyclovir ointment) based on net costs (changes shown in red):

~~**Zovirax® (Acyclovir Ointment) Approval Criteria:**~~

~~1. An FDA approved indication of management of initial genital herpes or in limited non-life-threatening mucocutaneous herpes simplex virus (HSV) infections in immunocompromised patients; and~~
~~2. A patient-specific clinically significant reason why the member cannot use oral acyclovir, famciclovir, or valacyclovir tablets.~~

The College of Pharmacy also recommends the removal of brand preferred status for Zovirax® (acyclovir 5% cream) and to update the acyclovir 5% cream (generic Zovirax®) approval criteria based on net costs (changes shown in red):

Zovirax® (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.~~
2. 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.

Lastly, the College of Pharmacy recommends designating Denavir® (penciclovir cream) as brand preferred based on net costs (changes shown in red):

Denavir® (Penciclovir Cream), Sitavig® (Acyclovir Buccal Tablets), and Xerese® (Acyclovir/Hydrocortisone 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.

Utilization Details of Antiviral Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VALACYCLOVIR PRODUCTS						
VALACYCLOVIR TAB 1GM	8,953	5,682	$203,055.82	$22.68	1.58	17.95%
VALACYCLOVIR TAB 500MG	6,588	3,266	$134,652.31	$20.44	2.02	11.90%
SUBTOTAL	**15,541**	**8,948**	**$337,708.13**	**$21.73**	**1.74**	**29.85%**
ACYCLOVIR PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ACYCLOVIR TAB 400MG	5,630	2,800	$77,599.33	$13.78	2.01	6.86%
ACYCLOVIR TAB 800MG	2,141	1,387	$33,168.84	$15.49	1.54	2.93%
ACYCLOVIR CAP 200MG	761	429	$11,041.10	$14.51	1.77	0.98%
ACYCLOVIR SUS 200MG/5ML	707	490	$24,144.62	$3.03	1.44	2.14%
ZOVIRAX 5% CREAM	247	165	$50,768.18	$205.54	1.5	4.49%
ACYCLOVIR 5% OINTMENT	68	60	$1,482.71	$21.80	1.13	0.13%
ACYCLOVIR 5% CREAM	26	25	$4,000.49	$153.87	1.04	0.35%
ACYCLOVIR INJ 50MG/ML	18	3	$4,220.27	$234.46	6	0.37%
SUBTOTAL	**9,598**	**5,359**	**$206,425.54**	**$21.51**	**1.79**	**18.25%**
FAMCICLOVIR PRODUCTS						
FAMCICLOVIR TAB 500MG	284	188	$7,906.43	$27.84	1.51	0.70%
FAMCICLOVIR TAB 250MG	96	39	$2,705.09	$28.18	2.46	0.24%
FAMCICLOVIR TAB 125MG	7	5	$106.62	$15.23	1.4	0.01%
SUBTOTAL	**387**	**232**	**$10,718.14**	**$27.70**	**1.67**	**0.95%**
VALGANCICLOVIR PRODUCTS						
VALGANCICLOVIR TAB 450MG	287	108	$49,115.64	$171.13	2.66	4.34%
VALGANCICLOVIR SOL 50MG/ML	99	27	$88,616.75	$895.12	3.67	7.83%
SUBTOTAL	**386**	**135**	**$137,732.39**	**$356.82**	**2.86**	**12.18%**
LETERMOVIR PRODUCTS						
PREVYMIS TAB 480MG	45	18	$318,816.24	$7,084.81	2.5	28.18%
PREVYMIS TAB 2400MG	4	2	$28,616.28	$7,154.07	2	2.53%
SUBTOTAL	**49**	**20**	**$347,432.52**	**$7,090.46**	**2.45**	**30.71%**
RIBAVIRIN PRODUCTS						
RIBAVIRIN TAB 200MG	23	9	$1,941.61	$84.42	2.56	0.17%
RIBAVIRIN CAP 200MG	9	3	$1,480.89	$164.54	3	0.13%
SUBTOTAL	**32**	**12**	**$3,422.50**	**$106.95**	**2.67**	**0.30%**
MARIBAVIR PRODUCTS						
LIVTENCITY TAB 200MG	4	2	$80,970.12	$20,242.53	2	7.16%
SUBTOTAL	**4**	**2**	**$80,970.12**	**$20,242.53**	**2**	**7.16%**
FOSCARNET PRODUCTS						
FOSCARNET INJ 6,000MG/250ML	2	1	$4,277.75	$2,138.88	2	0.38%
SUBTOTAL	**2**	**1**	**$4,277.75**	**$2,138.88**	**2**	**0.38%**
ACYCLOVIR-HYDROCORITSONE PRODUCTS						
XERESE 5-1% CREAM	2	2	$2,480.40	$1,240.20	1	0.22%
SUBTOTAL	**2**	**2**	**$2,480.40**	**$1,240.20**	**1**	**0.22%**
TOTAL	**26,001**	**13,509***	**$1,131,167.49**	**$43.50**	**1.92**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[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/index.cfm. Last revised 05/2025. Last accessed 05/28/2025.
[2] Prevymis® (Letermovir) Prescribing Information. Merck. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/209939s015,209940s015,219104s001lbl.pdf. Last revised 01/2025. Last accessed 05/28/2025.
[3] Kotton CN, Kumar D, Manuel O, et al. The Fourth International Consensus Guidelines on the Management of Cytomegalovirus in Solid Organ Transplantation. Available online at: https://journals.lww.com/transplantjournal/fulltext/9900/the_fourth_international_consensus_guidelines_on.1056.aspx. Issued 04/09/2025. Last accessed 05/28/2025.
[4] Moderna Clinical Trials. A Clinical Trial of a Cytomegalovirus (CMV) Vaccine in Healthy Women 16 to 40 Years of Age. Available online: https://trials.modernatx.com/study/?id=mRNA-1647-P301. Last accessed 05/28/2025.
[5] Akingbola A, Adegbesan A, Adewole O, et al. The mRNA-1647 Vaccine: A Promising Step Toward the Prevention of Cytomegalovirus Infection (CMV). *Hum Vaccin Immunother*. 2025; 21(1): 2450045. doi: 10.1080/21645515.2025.2450045.
[6] Memo Therapeutics. BKV. Available online at https://memo-therapeutics.com/bkv/. Last accessed 05/28/2025.
[7] Zovirax® (Acyclovir Cream) Prescribing Information. Bausch. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021478s010lbl.pdf. Last revised 12/23/2020. Last accessed 05/28/2025.

Appendix M

Fiscal Year 2024 Annual Review of Daybue® (Trofinetide)

Oklahoma Health Care Authority
June 2025

Current Prior Authorization Criteria

Daybue® (Trofinetide) Approval Criteria:

1. 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 (results of genetic testing must be submitted); 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 and weight loss associated with Daybue® and agree to 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 moderate or severe renal impairment; 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. 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
9. A quantity limit of 3,600mL per 30 days will apply.

Utilization of Daybue® (Trofinetide): Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

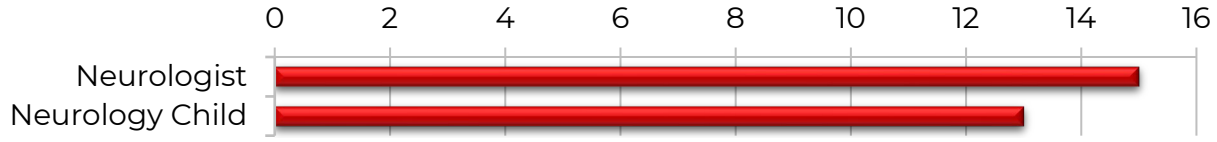
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	4	5	$256,418.55	$51,283.71	$1,805.76	12,150	142
2023 Total	**4**	**5**	**$256,418.55**	**$51,283.71**	**$1,805.76**	**12,150**	**142**
Fiscal Year 2024							
FFS	8	28	$871,997.22	$31,142.76	$1,133.94	54,900	769
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**8**	**28**	**$871,997.22**	**$31,142.76**	**$1,133.94**	**54,900**	**769**
% Change	**100.00%**	**460.00%**	**240.10%**	**-39.30%**	**-37.20%**	**351.90%**	**441.50%**
Change	**4**	**23**	**$615,578.67**	**-$20,140.95**	**-$671.82**	**42,750**	**627**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Demographics of Members Utilizing Daybue® (Trofinetide) (All Plans)

- Due to the limited number of members utilizing Daybue® during fiscal year 2024, detailed demographic information could not be provided.

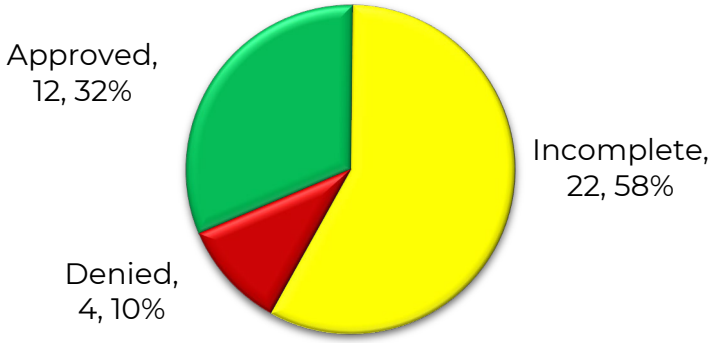
Top Prescriber Specialties of Daybue® (Trofinetide) by Number of Claims (All Plans)



Prior Authorization of Daybue® (Trofinetide)

There were 38 prior authorization requests submitted for Daybue® during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	12	32%	22	58%	4	11%	**38**
Aetna	0	N/A	0	N/A	0	N/A	**0**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**12**	**32%**	**22**	**58%**	**4**	**10%**	**38**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Daybue® (trofinetide): July 2042

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

- **September 2024:** The FDA approved an updated label for Daybue® to add additional information regarding dosage adjustments in patients with moderate renal impairment. Previously, administration of Daybue® was not recommended in patients with moderate renal impairment. Additionally, a new warning was added regarding the risk of vomiting, including aspiration and aspiration pneumonia, in patients treated with Daybue®.

Recommendations

The College of Pharmacy recommends updating the Daybue® (trofinetide) approval criteria based on the recent FDA approved label updates with the following changes (shown in red):

Daybue® (Trofinetide) 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, ~~and~~ 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 ~~moderate or~~ 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. 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
9. A quantity limit of 3,600mL per 30 days will apply.

Utilization Details of Daybue® (Trofinetide): Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DAYBUE SOL 200MG/ML	28	8	$871,997.22	$31,142.76	3.5	100%
TOTAL	**28**	**8***	**$871,997.22**	**$31,142.76**	**3.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
SOL = solution
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[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/index.cfm. Last revised 05/2025. Last Accessed 05/16/2025.
[2] U.S. FDA. Daybue® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/217026Orig1s001;%20s003ltr.pdf. Issued 09/30/2024. Last accessed 05/21/2025.
[3] Daybue® (Trofinetide) Prescribing Information. Acadia Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217026s001s003lbl.pdf. Last revised 09/2024. Last accessed 05/21/2025.

Appendix N

Fiscal Year 2024 Annual Review of Strensiq® (Asfotase Alfa)

Oklahoma Health Care Authority
June 2025

Current Prior Authorization Criteria

Strensiq® (Asfotase Alfa) Approval Criteria:

1. An FDA approved indication for the treatment of members with perinatal/infantile-onset and juvenile-onset hypophosphatasia (HPP); and
2. Confirmed diagnosis by laboratory testing of:
   a. Low age-adjusted alkaline phosphatase (ALP) activity; and
   b. Elevated pyridoxal 5'-phosphate (PLP) levels; and
3. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing per package labeling; and
4. The 80mg/0.8mL vial should not be used in pediatric members weighing <40kg.

Utilization of Strensiq® (Asfotase Alfa): Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

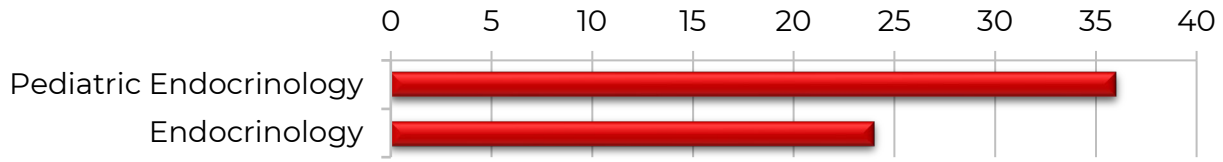
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	9	66	$5,079,938.74	$76,968.77	$2,748.88	1,037	1,848
2023 Total	**9**	**66**	**$5,079,938.74**	**$76,968.77**	**$2,748.88**	**1,037**	**1,848**
Fiscal Year 2024							
FFS	6	54	$4,760,736.14	$88,161.78	$3,223.25	858	1,477
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	2	6	$205,988.46	$34,331.41	$1,226.12	72	168
2024 Total	**6**	**60**	**$4,966,724.60**	**$82,778.74**	**$3,019.29**	**930**	**1,645**
% Change	**-33.30%**	**-9.10%**	**-2.20%**	**7.50%**	**9.80%**	**-10.30%**	**-11.00%**
Change	**-3**	**-6**	**-$113,214.14**	**$5,809.97**	**$270.41**	**-107**	**-203**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Demographics of Members Utilizing Strensiq® (Asfotase Alfa): Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing Strensiq® (asfotase alfa), detailed demographic information could not be provided.

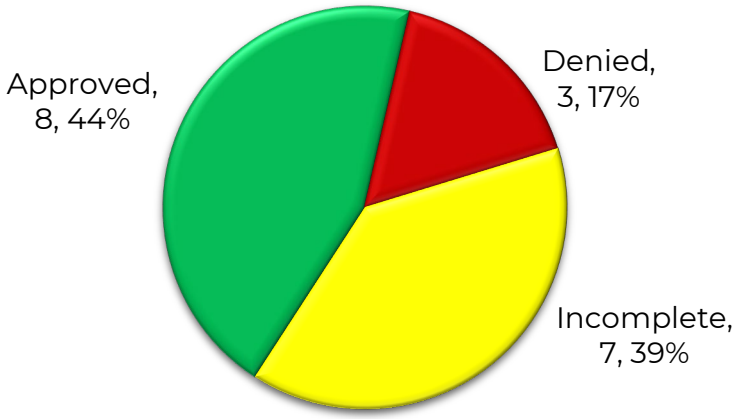
Top Prescriber Specialties of Strensiq® (Asfotase Alfa) by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Strensiq® (Asfotase Alfa)

There were 18 prior authorization requests submitted for Strensiq® (asfotase alfa) during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	8	53%	7	47%	0	0%	**15**
Aetna	0	N/A	0	N/A	0	N/A	**0**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	0	0%	0	0%	3	100%	**3**
Total	**8**	**44%**	**7**	**39%**	**3**	**17%**	**18**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

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

News:

- **Hypophosphatasia (HPP) Diagnosis:** The utilization of molecular genetic testing for confirming the diagnosis of HPP is increasing in clinical practice due to rapidly improving technology, increasing accessibility, and expanding clinical literature. Proposed diagnostic criteria for HPP in children and adults include the presence of a pathogenic or likely pathogenic variant in the *ALPL* gene, which encodes tissue non-specific alkaline phosphatase (TNSALP), as a major diagnostic criterion. However, pathogenic or likely pathogenic variants in the *ALPL* gene are not present in all patients with HPP; therefore, molecular genetic testing should be evaluated in the context of clinical features and laboratory testing of age- and sex- adjusted alkaline phosphatase (ALP) activity along with TNSALP substrate levels, as needed, to confirm the diagnosis of HPP.

Pipeline:

- **ALXN1850:** An ongoing Phase 3, randomized, double-blind, placebo-controlled trial, HICKORY, is evaluating the safety and efficacy of a recombinant ALP, ALXN1850, in adolescent and adult participants with HPP who have never received treatment with Strensiq® (asfotase alfa). The investigational dosing of ALXN1850 is dependent upon body weight and is administered subcutaneously every 2 weeks. Primary completion of HICKORY is estimated to be in July 2025.

Recommendations

The College of Pharmacy recommends updating the approval criteria for Strensiq® (asfotase alfa) based on clinical practice and recent updates in relevant literature (changes shown in red):

Strensiq® (Asfotase Alfa) Approval Criteria:

1. An FDA approved indication for the treatment of members with perinatal/infantile-onset and juvenile-onset hypophosphatasia (HPP); and
2. Confirmed diagnosis by the following ~~laboratory testing of~~ (results of selected tests must be submitted with the request):
    a. Low age- and sex-adjusted alkaline phosphatase (ALP) activity; and
    b. At least 1 of the following:
        i. Elevated level of a tissue non-specific alkaline phosphatase (TNSALP) substrate [e.g., inorganic pyrophosphate (PPi), phosphoethanolamine (PEA), pyridoxal 5'-phosphate (PLP)] ~~levels~~; ~~and~~ or
        ii. Molecular genetic testing documenting pathogenic or likely pathogenic variants in the *ALPL* gene; and

3. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing per package labeling; and
4. The 80mg/0.8mL vial should not be used in pediatric members weighing <40kg.

Utilization Details of Strensiq® (Asfotase Alfa): Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
STRENSIQ INJ 40MG/ML	30	3	$1,029,942.30	$34,331.41	10	20.47%
STRENSIQ INJ 80MG/0.8ML	24	3	$3,844,049.84	$160,168.74	8	77.40%
STRENSIQ INJ 18MG/0.45ML	6	1	$92,732.46	$15,455.41	6	1.87%
TOTAL	**60**	**6***	**$4,966,724.60**	**$82,778.74**	**10**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

---

[1] Bianchi ML, Bishop NJ, Guañabens N, et al. Hypophosphatasia in Adolescents and Adults: Overview of Diagnosis and Treatment. *Osteoporos Int* 2020; 31(8):1445-1460. doi: 10.1007/s00198-020-05345-9.
[2] Khan AA, Brandi ML, Rush ET, et al. Hypophosphatasia Diagnosis: Current State of the Art and Proposed Diagnostic Criteria for Children and Adults. *Osteoporos Int* 2024; 35(3):431-438. doi: 10.1007/s00198-023-06844-1.
[3] Michigami T, Ohata Y, Fujiwara M, et al. Clinical Practice Guidelines for Hypophosphatasia. *Clin Pediatr Endocrinol* 2020; 29(1):9-24. doi: 10.1297/cpe.29.9.
[4] Phase 3 Study of ALXN1850 Versus Placebo in Adolescent and Adult Participants with HPP Who Have Not Previously Been Treated with Asfotase Alfa (HICKORY). *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT06079281. Last revised 04/25/2025. Last accessed 05/29/2025.

Appendix O

Fiscal Year 2024 Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib)

Oklahoma Health Care Authority
June 2025

Current Prior Authorization Criteria

Utilization data for Bavencio® (avelumab), Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), Opdivo® (nivolumab), and Yervoy® (ipilimumab) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the December 2024 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), Talzenna® (talazoparib) and Trodelvy® (sacituzumab govitecan-hziy) and approval criteria for indications other than genitourinary and gynecologic cancers can be found in the September 2024 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 May 2025 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.

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; and
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
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.

*The above criteria for Imfinzi® for bladder cancer and endometrial cancer is currently pending a vote by the DUR Board at the June 2025 DUR Board meeting; please refer to the vote report [Vote to Prior Authorize Axtle™

(Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/Hyaluronidase-tqjs) and Update the Approval Criteria for the Lung Cancer Medications] in the June 2025 DUR Board packet for additional information.

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; and
    b. Mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease.

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) 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 Stage III-IV cervical cancer; and
    a. Used in combination with concomitant chemotherapy and radiation.

Keytruda® (Pembrolizumab) 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) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of high-risk, NMIBC; and
2. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
3. Member must be ineligible for or has elected not to undergo cystectomy.

Keytruda® (Pembrolizumab) 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) 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. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
    b. Progression on primary, maintenance, or recurrence therapy; or
    c. Stable or persistent disease (if not on maintenance therapy); or
    d. Complete remission and relapse after receiving prior chemotherapy.

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 Hormone-Sensitive Prostate Cancer (mHSPC) Diagnosis]:

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

Opdivo® (Nivolumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member has not previously failed other 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 IV 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 IV 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 IV 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. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. In combination with ipilimumab: 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 thereafter; or
    c. In combination with cabozantinib: cabozantinib 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks; nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

Opdivo® (Nivolumab) 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.

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 inhibition and 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.

*The above updated criteria for Tarceva® for kidney cancer is currently pending a vote by the DUR Board at the June 2025 DUR Board meeting; please refer to the vote report [Vote to Prior Authorize Axtle™ (Pemetrexed), Bizengri® (Zenocutuzumab-zbco), Imdelltra™ (Tarlatamab-dlle), Lazcluze™ (Lazertinib), and Tecentriq Hybreza™ (Atezolizumab/ Hyaluronidase-tqjs) and Update the Approval Criteria for the Lung Cancer Medications] in the June 2025 DUR Board packet for additional information.

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.

Trodelvy® (Sacituzumab Govitecan-hziy) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic disease; and
2. Member must have previously received platinum-containing chemotherapy; and
3. Member must have previously received either a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

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

1. Diagnosis of advanced RCC; 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. 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 2024

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 2023							
FFS	154	840	$12,981,757.59	$15,454.47	$519.33	65,635	24,997
2023 Total	**154**	**840**	**$12,981,757.59**	**$15,454.47**	**$519.33**	**65,635**	**24,997**
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	52	$628,001.62	$12,076.95	$411.53	4,582	1,526
OCH	13	32	$368,461.90	$11,514.43	$393.24	2,512	937
2024 Total	**152**	**876**	**$10,297,635.63**	**$11,755.29**	**$399.29**	**70,215**	**25,790**
% Change	**-1.30%**	**4.30%**	**-20.70%**	**-23.90%**	**-23.10%**	**7.00%**	**3.20%**
Change	**-2**	**36**	**-$2,684,121.96**	**-$3,699.18**	**-$120.04**	**4,580**	**793**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	14	70	$810,230.74	$11,574.72	5
2023 Total	**14**	**70**	**$810,230.74**	**$11,574.72**	**5**
Fiscal Year 2024					
FFS	17	150	$1,350,403.93	$9,002.69	8.82
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	1	5	$47,784.00	$9,556.80	5
2024 Total	**17**	**155**	**$1,398,187.93**	**$9,020.57**	**9.12**
% Change	**21.43%**	**121.43%**	**72.57%**	**-22.07%**	**82.40%**
Change	**3**	**85**	**$587,957.19**	**-$2,554.15**	**4.12**

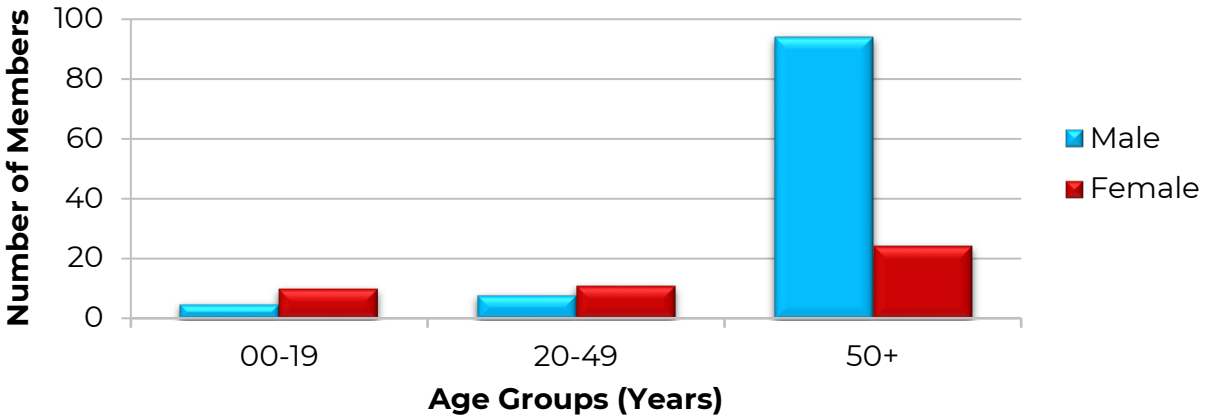
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2024 for genotourinary and gynecologic cancer medications totaled $4,810,155.45.[Δ] Rebates are collected after reimbursement for the

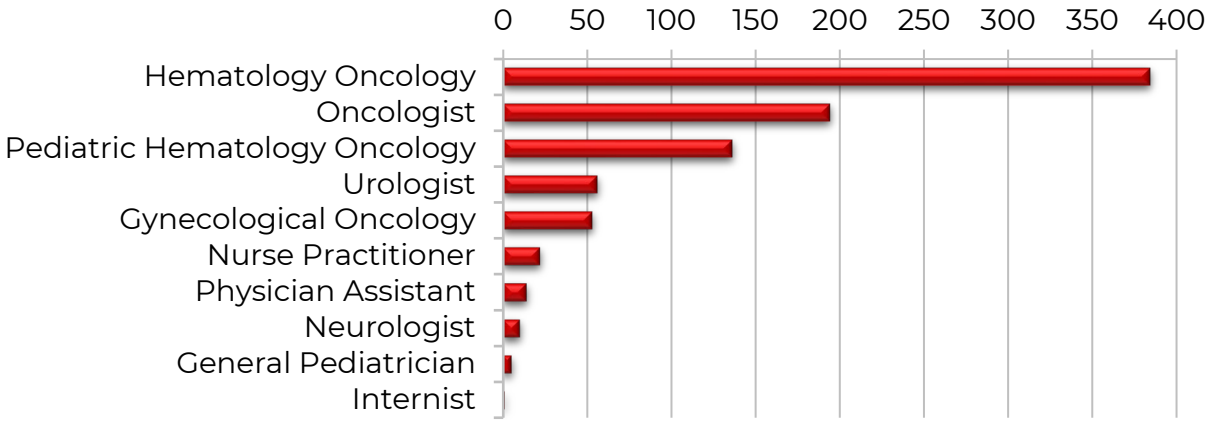
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

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)



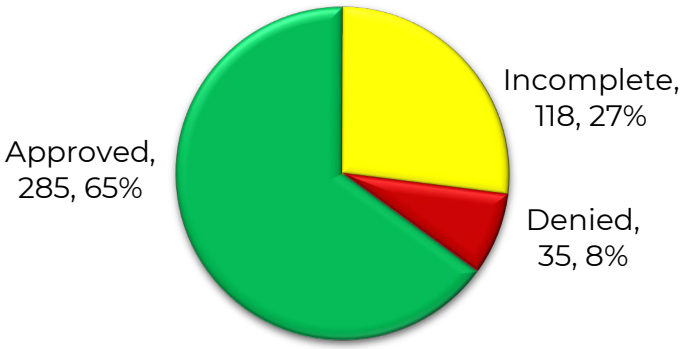
Top Prescriber Specialties of Genitourinary and Gynecologic Cancer Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Genitourinary and Gynecologic Cancer Medications

There were 438 prior authorization requests submitted for genitourinary and gynecologic cancer medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	258	64%	115	29%	29	7%	**402**
Aetna	6	67%	3	33%	0	0%	**9**
Humana	8	89%	0	0%	1	11%	**9**
OCH	13	72%	0	0%	5	28%	**18**
Total	**285**	**65%**	**118**	**27%**	**35**	**8%**	**438**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

Market News and Updates[1,2,3,4,5,6,7,8]

Anticipated Patent Expiration(s):

- Afinitor® (everolimus): July 2028
- Jelmyto® (mitomycin): January 2031
- Jevtana® (cabazitaxel): April 2031
- Cabometyx® (cabozantinib): July 2033
- Yonsa® (abiraterone acetate): May 2034
- Welireg® (belzutifan): September 2034
- Rubraca® (rucaparib): August 2035
- Xtandi® (enzalutamide): February 2037
- Orgovyx® (relugolix): September 2037
- Balversa® (erdafitinib): February 2038
- Nubeqa® (darolutamide): 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 2040
- Pluvicto® (lutetium lu-177 vipivotide tetraxetan): September 2041
- Lynparza® (olaparib): October 2041

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

- **August 2024:** The FDA approved Jemperli (dostarlimab-gxly) for a new indication, in combination with carboplatin and paclitaxel, followed by single-agent dostarlimab-gxly, for adult patients with primary advanced or recurrent endometrial cancer. This approval removes the previous restriction for mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) disease for this indication.
- **March 2025:** The FDA approved Cabometyx® (cabozantinib) for new indications in adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET) or extra-pancreatic neuroendocrine tumors (epNET).
- **March 2025:** The FDA approved Pluvicto® (lutetium Lu 177 vipivotide tetraxetan) for a new indication for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy and are considered appropriate to delay taxane-based chemotherapy.
- **April 2025:** The FDA approved Welireg® (belzutifan) for a label update for the renal cell carcinoma (RCC) indication to clarify that Welireg® is intended for use in patients with advanced RCC with a clear cell component.
- **May 2025:** The FDA approved Avmapki™ Fakzynja™ Co-Pack (avutometinib and defactinib) for the treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer who have received prior systemic therapy.
- **May 2025:** The FDA approved Welireg® (belzutifan) for a new indication for the treatment of adult and pediatric patients 12 years of age and older with locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL).
- **June 2025:** The FDA approved Nubeqa® (darolutamide) for a new indication for the treatment of adult patients with metastatic castration-sensitive prostate cancer (mCSPC).

Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) Product Summary[9]

Therapeutic Class: Kinase inhibitors

Indication(s): Treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer who have received prior systemic therapy

- This indication is approved under accelerated approval based on tumor 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: Supplied as a carton containing the following:

- Avmapki™ (avutometinib) 0.8mg capsules in a 24-count bottle
- Fakzynja™ (defactinib) 200mg tablets in a 42-count bottle

Dosing and Administration:

- Avmapki™: The recommended dosage is 3.2mg [using (4) 0.8mg capsules] orally with food twice weekly (on day 1 and day 4) for the first 3 weeks of each 4-week cycle until disease progression or unacceptable toxicity.
- Fakzynja™: The recommended dosage is 200mg orally with food twice daily for the first 3 weeks of each 4-week cycle until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) of Avmapki™ Fakzynja™ Co-Pack is $734.85 per capsule or tablet. This would result in an estimated cost of $48,500.10 per 28 days or $630,501.30 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Avmapki™ Fakzynja™ Co-Pack (avutometinib and defactinib) with the following criteria (shown in red):

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.

Next, the College of Pharmacy recommends updating the approval criteria for Cabometyx® (cabozantinib), Jemperli (dostarlimab-gxly), Nubeqa® (darolutamide), Pluvicto® (lutetium Lu 177 vipivotide tetraxetan), and Welireg® (belzutifan) based on recent FDA approvals (changes and new criteria noted in red):

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.

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.~~; and~~
b. ~~Mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease.~~

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

1. Diagnosis of ~~mHSPC~~ 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.

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 taxane-based chemotherapy~~; 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.

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.

Lastly, the College of Pharmacy recommends updating the approval criteria for Zytiga® (abiraterone) to be more consistent with the package labeling (changes shown in red):

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.

Utilization Details of Genitourinary and Gynecologic Cancer Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ENZALUTAMIDE PRODUCTS						
XTANDI TAB 80MG	73	11	$1,015,299.01	$13,908.21	6.64	9.86%
XTANDI CAP 40MG	70	15	$950,703.41	$13,581.48	4.67	9.23%
XTANDI TAB 40MG	47	13	$636,892.56	$13,550.91	3.62	6.18%
SUBTOTAL	**190**	**39**	**$2,602,894.98**	**$13,699.45**	**4.87**	**25.28%**
ABIRATERONE PRODUCTS						
ABIRATERONE TAB 250MG	147	23	$20,145.34	$137.04	6.39	0.20%
ABIRATERONE TAB 500MG	27	6	$59,855.32	$2,216.86	4.5	0.58%
SUBTOTAL	**174**	**29**	**$80,000.66**	**$459.77**	**6**	**0.78%**
EVEROLIMUS PRODUCTS						
EVEROLIMUS DIS TAB 5MG	37	6	$732,396.25	$19,794.49	6.17	7.11%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
EVEROLIMUS TAB 5MG	31	8	$109,557.52	$3,534.11	3.88	1.06%
EVEROLIMUS TAB 7.5MG	28	6	$123,082.68	$4,395.81	4.67	1.20%
EVEROLIMUS TAB 10MG	25	8	$116,330.93	$4,653.24	3.13	1.13%
EVEROLIMUS DIS TAB 2MG	15	2	$193,595.85	$12,906.39	7.5	1.88%
AFINITOR DIS TAB 3MG	12	2	$210,153.02	$17,512.75	6	2.04%
AFINITOR DIS TAB 5MG	12	3	$326,926.34	$27,243.86	4	3.17%
AFINITOR DIS TAB 2MG	6	1	$173,001.31	$28,833.55	6	1.68%
EVEROLIMUS DIS TAB 3MG	1	1	$13,035.55	$13,035.55	1	0.13%
SUBTOTAL	**167**	**37**	**$1,998,079.45**	**$11,964.55**	**4.51**	**19.40%**
APALUTAMIDE PRODUCTS						
ERLEADA TAB 60MG	74	11	$1,010,863.20	$13,660.31	6.73	9.82%
SUBTOTAL	**74**	**11**	**$1,010,863.20**	**$13,660.31**	**6.73**	**9.82%**
OLAPARIB PRODUCTS						
LYNPARZA TAB 150MG	44	13	$676,979.00	$15,385.89	3.38	6.57%
LYNPARZA TAB 100MG	19	4	$306,812.58	$16,148.03	4.75	2.98%
SUBTOTAL	**63**	**17**	**$983,791.58**	**$15,615.74**	**3.71**	**9.55%**
DAROLUTAMIDE PRODUCTS						
NUBEQA TAB 300MG	53	13	$676,837.28	$12,770.51	4.08	6.57%
SUBTOTAL	**53**	**13**	**$676,837.28**	**$12,770.51**	**4.08**	**6.57%**
LENVATINIB PRODUCTS						
LENVIMA CAP 10 MG	13	5	$305,932.33	$23,533.26	2.6	2.97%
LENVIMA CAP 20 MG	12	3	$287,948.92	$23,995.74	4	2.80%
LENVIMA CAP 4MG	8	2	$193,300.83	$24,162.60	4	1.88%
LENVIMA CAP 8 MG	4	2	$96,238.64	$24,059.66	2	0.93%
LENVIMA CAP 18 MG	4	2	$93,805.64	$23,451.41	2	0.91%
LENVIMA CAP 14 MG	4	1	$92,419.64	$23,104.91	4	0.90%
LENVIMA CAP 12MG	1	1	$23,451.41	$23,451.41	1	0.23%
SUBTOTAL	**46**	**16**	**$1,093,097.41**	**$23,762.99**	**2.88**	**10.62%**
CABOZANTINIB PRODUCTS						
CABOMETYX TAB 40MG	35	10	$884,219.80	$25,263.42	3.5	8.59%
CABOMETYX TAB 20MG	7	3	$177,497.36	$25,356.77	2.33	1.72%
CABOMETYX TAB 60MG	3	3	$67,342.50	$22,447.50	1	0.65%
SUBTOTAL	**45**	**16**	**$1,129,059.66**	**$25,090.21**	**2.81**	**10.96%**
RELUGOLIX PRODUCTS						
ORGOVYX TAB 120MG	35	4	$93,054.55	$2,658.70	8.75	0.90%
SUBTOTAL	**35**	**4**	**$93,054.55**	**$2,658.70**	**8.75**	**0.90%**
NIRAPARIB PRODUCTS						
ZEJULA TAB 100MG	7	3	$140,458.04	$20,065.43	2.33	1.36%
ZEJULA TAB 200MG	5	2	$86,495.55	$17,299.11	2.5	0.84%
ZEJULA CAP 100MG	2	1	$17,304.12	$8,652.06	2	0.17%
ZEJULA TAB 300MG	2	1	$34,593.42	$17,296.71	2	0.34%
SUBTOTAL	**16**	**7**	**$278,851.13**	**$17,428.20**	**2.29**	**2.71%**
BELZUTIFAN PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
WELIREG TAB 40MG	12	3	$323,098.32	$26,924.86	4	3.14%
SUBTOTAL	**12**	**3**	**$323,098.32**	**$26,924.86**	**4**	**3.14%**
TIVOZANIB PRODUCTS						
FOTIVDA CAP 0.89MG	1	1	$28,007.41	$28,007.41	1	0.27%
SUBTOTAL	**1**	**1**	**$28,007.41**	**$28,007.41**	**1**	**0.27%**
TOTAL	**876**	**152***	**$10,297,635.63**	**$11,755.29**	**5.76**	**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 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PADCEV J9177	65	5	$398,190.80	$6,126.01	13
TIVDAK J9273	46	6	$614,985.60	$13,369.25	7.67
JEVTANA J9043	23	3	$139,634.76	$6,071.08	7.67
ELAHERE J9063	18	1	$206,842.75	$11,491.26	18
JELMYTO J9281	2	1	$24,060.00	$12,030.00	2
XOFIGO A9606	1	1	$14,474.02	$14,474.02	1
TOTAL	**155**	**17**	**$1,398,187.93**	**$9,020.57**	**9.12**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[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/index.cfm. Last revised 05/2025. Last accessed 05/15/2025.
[2] U.S. FDA. FDA Expands Endometrial Cancer Indication for Dostarlimab-gxly with Chemotherapy. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-expands-endometrial-cancer-indication-dostarlimab-gxly-chemotherapy. Issued 08/01/2024. Last accessed 05/16/2025.
[3] U.S. FDA. FDA Approves Cabozantinib for Adults and Pediatric Patients 12 Years of Age and Older with pNET and epNET. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-cabozantinib-adults-and-pediatric-patients-12-years-age-and-older-pnet-and-epnet. Issued 03/26/2025. Last accessed 05/16/2025.
[4] U.S. FDA. FDA Expands Pluvicto's Metastatic Castration-Resistant Prostate Cancer Indication. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-expands-pluvictos-metastatic-castration-resistant-prostate-cancer-indication. Issued 03/28/2025. Last accessed 05/16/2025.
[5] U.S. FDA. Welireg® (Belzutifan) Supplemental Approval/Fulfillment of Postmarketing Commitment Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/215383Orig1s010;%20s011ltr.pdf. Issued 04/15/2025. Last accessed 05/16/2025.
[6] U.S. FDA. FDA Grants Accelerated Approval to the Combination of Avutometinib and Defactinib for KRAS-Mutated Recurrent Low-Grade Serous Ovarian Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-combination-avutometinib-and-defactinib-kras-mutated-recurrent-low. Issued 05/08/2025. Last accessed 05/16/2025.
[7] U.S. FDA. FDA Approves Belzutifan for Pheochromocytoma or Paraganglioma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-belzutifan-pheochromocytoma-or-paraganglioma. Issued 05/14/2025. Last accessed 05/16/2025.
[8] U.S. FDA. FDA Approves Darolutamide for Metastatic Castration-Sensitive Prostate Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-darolutamide-metastatic-castration-sensitive-prostate-cancer. Issued 06/03/2025. Last accessed 06/04/2025.
[9] Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) Prescribing Information. Verastem, Inc. Available online at: https://www.verastem.com/pdf/avmapki-fakzynja-co-pack-full-prescribing-information.pdf. Last revised 05/2025. Last accessed 05/16/2025.

Appendix P

Fiscal Year 2024 Annual Review of the SoonerCare Pharmacy Benefit

Oklahoma Health Care Authority
June 2025

Summary[1]

During fiscal year (FY) 2024 (07/01/2023 to 06/30/2024), prescription drugs accounted for $1.03 billion of the approximately $8.97 billion in total SoonerCare spending. The FY 2022, FY 2023, and FY 2024 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 2022, FY 2023, and FY 2024 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.

The average monthly enrollment increased from FY 2022 to FY 2023 (13.3%) as a result of Oklahoma Medicaid expansion and the federal PHE; however, average monthly enrollment then decreased from FY 2023 to FY 2024 (16.5%) as a result of the unwinding process that followed the end of the PHE.

Similar to the decrease in enrollment in FY 2024, the number of utilizers (SoonerCare members utilizing the pharmacy benefit) and total claims decreased by approximately 5.6% and 6.9%, respectively, from FY 2023 to FY 2024. Likewise, the total pharmacy reimbursement and the annual pharmacy cost per utilizer decreased approximately 9.9% and 4.6%, respectively, from FY 2023 to FY 2024.

While a net decrease was seen in FY 2024 compared to FY 2023 across enrollment, utilizers, claims, and reimbursement, the decrease in reimbursement is likely transient. Multiple confounding variables impacted FY 2024, including the ending of the COVID-19 PHE, the continued impact of the Medicaid expansion, and the transition to a managed care model. In previous years, the high costs associated with the increasing volume of specialty pharmaceutical products, orphan drugs for rare diseases, oncology medications, and cellular and gene therapy products have consistently led to an increase in pharmacy benefit costs; therefore, now that the influences from the PHE are abating, pharmacy reimbursement and costs per utilizer are

expected to resume annual increases in the upcoming fiscal years consistent with past trends.

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 2024 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
2022	7,064,405	1,184,711	659,386	$849,426,322.82	$120.24	$1,288.21
2023	8,357,303	1,342,622	756,019	$1,143,505,997.16	$136.83	$1,512.54
2024	7,778,141	1,120,883	713,376	$1,029,783,782.72	$132.39	$1,443.54

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 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

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 2022	FY 2023	FY 2024
Overall PMPY Value⁺	$907.70	$1,071.93	$1,177.88

⁺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 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

During FY 2022, 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 2024 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 2024, OHCA collected over $729 million in federal and state supplemental rebates, resulting in a total increase from FY 2023 of approximately $2.6 million ($726.4 million in federal and state supplemental rebates collected in FY 2023). 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 4 APM contracts being active in FY 2024. 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 2024 Established APM Contracts

Manufacturer	Details
AbbVie	▪ Treatment patterns in hepatitis C – utilization, treatment duration, and non-responder/re-treatment/ treatment failures (2022-2025)
AveXis	▪ Spinal muscular atrophy (SMA) medication – utilization (2021-2025)
Pear Therapeutics	▪ Adherence and persistence with prescription digital therapeutics – resource utilization (2022-2023)
Supernus	▪ Adherence and persistence in ADHD – medication possession ratios (2022-2025)

ADHD = attention-deficit/hyperactivity disorder; APM = alternative payment model; FY = fiscal year
FY 2024 = 07/01/2023 to 06/30/2024

Drug Approval Trends[10,11,12,13,14,15,16,17,18,19,20]

During FY 2024, 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 2024 included dabigatran (generic Pradaxa®), lisdexamfetamine (generic Vyvanse®), sacubitril/valsartan (generic Entresto®), and azelastine nasal spray (generic Astepro®). A total of 60 novel drugs, including cellular and gene therapies, were approved by the FDA during FY 2024. Select novel drugs approved during FY 2024 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 2024

Drug Name	Date Approved	FDA-Approved Indication	Estimated Annual Cost Per Member*
zuranolone (Zurzuvae®)	08/04/2023	postpartum depression	$16,376.92†
zilucoplan (Zilbrysq®)	10/17/2023	gMG	$399,158.22±
resmetirom (Rezdiffra™)	03/14/2024	NASH with moderate to advanced liver fibrosis	$49,392.00α
givinostat (Duvyzat®)	03/21/2024	DMD	$689,320.80Δ

sotatercept-csrk (Winrevair™)	03/26/2024	PAH	$245,140.00[¥]
ensifentrine (Ohtuvayre™)	06/26/2024	COPD	$35,406.00[Ω]

COPD = chronic obstructive pulmonary disease; DMD = Duchenne muscular dystrophy; gMG = generalized myasthenia gravis; NASH = noncirrhotic nonalcoholic steatohepatitis; PAH = pulmonary arterial hypertension
*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 an FDA approved dose of 50mg orally once daily for 14 days
[‡]Based on an FDA approved dose of 23mg subcutaneously once daily for a member weighing 56kg to <77kg
[α]Based on an FDA approved dose of 100mg orally once daily for a member weighing ≥100kg
[Δ]Based on an FDA approved dose of 31mg orally twice daily for a member weighing 20kg to <40kg
[¥]Based on an FDA approved target dose of 0.7mg/kg subcutaneously every 3 weeks for a member weighing 80kg (assumes the use of one 60mg vial)
[Ω]Based on an FDA approved dose of 3mg via nebulizer twice daily

Traditional Versus Specialty Pharmacy Products[21]

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 64% of the total pharmacy reimbursement and more than 99% of the total claims, in FY 2024.

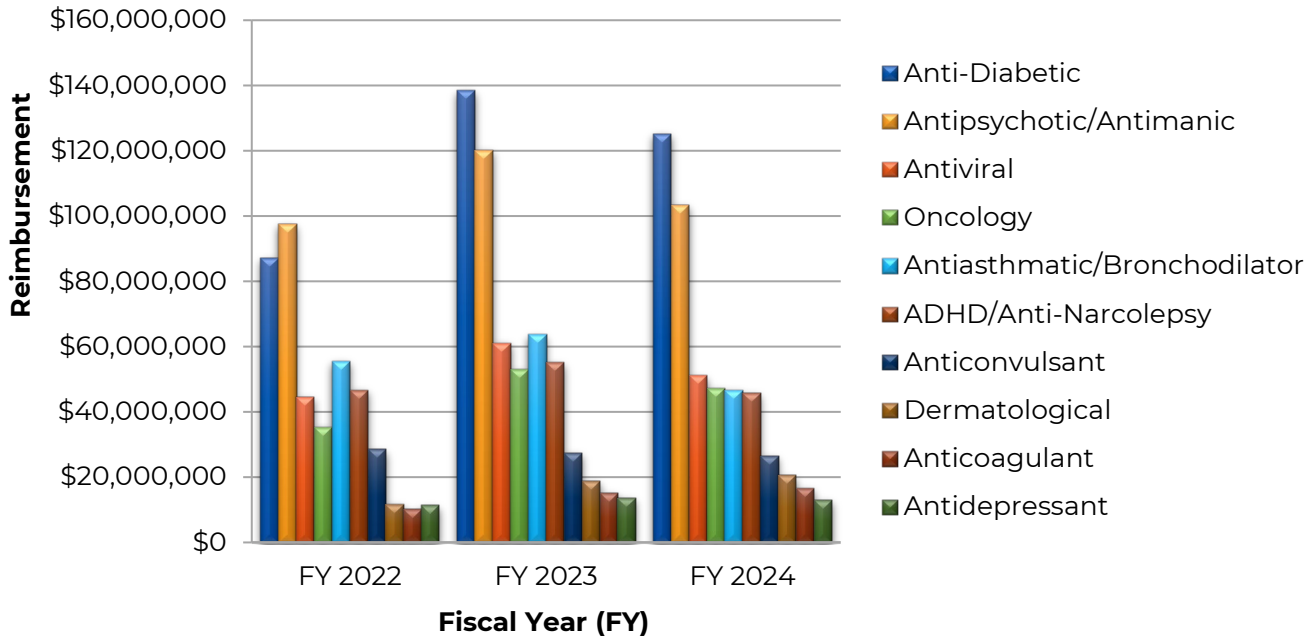
Specialty products, in contrast, are typically injectable, require special handling such as refrigerated transport and special administration techniques, or are indicated for rare diseases requiring unique management. These products include treatments for cystic fibrosis (CF), hemophilia, rheumatoid arthritis, and genetic deficiencies. Specialty pharmaceuticals have become a larger part of reimbursement over the last 10 years, and a recent Reuters analysis noted that prices for newly-launched drugs more than doubled over 4 years largely due to more therapies for rare diseases. Specifically, specialty pharmaceuticals accounted for 36% of the total pharmacy reimbursement in FY 2024 and approximately 1% of the total claims.

Top 10 Traditional Therapeutic Categories by Reimbursement: FY 2024[22]

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 2024 Top 10 Traditional Therapeutic Categories			
FY 2022	**FY 2023**	**FY 2024**	**Therapeutic Category**
$87,110,215.14	$138,411,888.40	**$125,168,660.32**	**Anti-Diabetic**
$97,509,863.45	$120,137,995.42	**$103,399,717.30**	**Antipsychotic/Antimanic**
$44,515,462.21	$61,178,386.05	**$51,093,200.02**	**Antiviral**
$35,277,738.77	$52,883,199.03	**$47,186,131.24**	**Oncology**
$55,401,683.22	$63,682,493.66	**$46,608,166.62**	**Anti-Asthmatic/Bronchodilator**
$46,647,595.82	$55,077,145.69	**$45,718,680.51**	**ADHD/Anti-Narcolepsy**
$28,508,633.98	$27,315,223.28	**$26,476,135.71**	**Anticonvulsant**
$11,689,452.45	$18,875,408.68	**$20,446,417.48**	**Dermatological**
$10,080,041.65	$15,127,560.73	**$16,591,164.53**	**Anticoagulant**
$11,202,533.94	$13,617,946.43	**$12,952,013.83**	**Antidepressant**

Reimbursement does not reflect rebated prices or net costs.
Therapeutic Category based on Medi-Span® Generic Product Identifier (GPI) classification.
ADHD = attention-deficit/hyperactivity disorder; FY = fiscal year
FY 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024



The top 10 traditional therapeutic categories that showed the most significant change from FY 2023 to FY 2024 were the anticoagulant and dermatological categories. Other traditional classes saw minor fluctuations.

- Anticoagulant medications' reimbursement increased by almost 10% ($1.5 million) in FY 2024. 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), 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

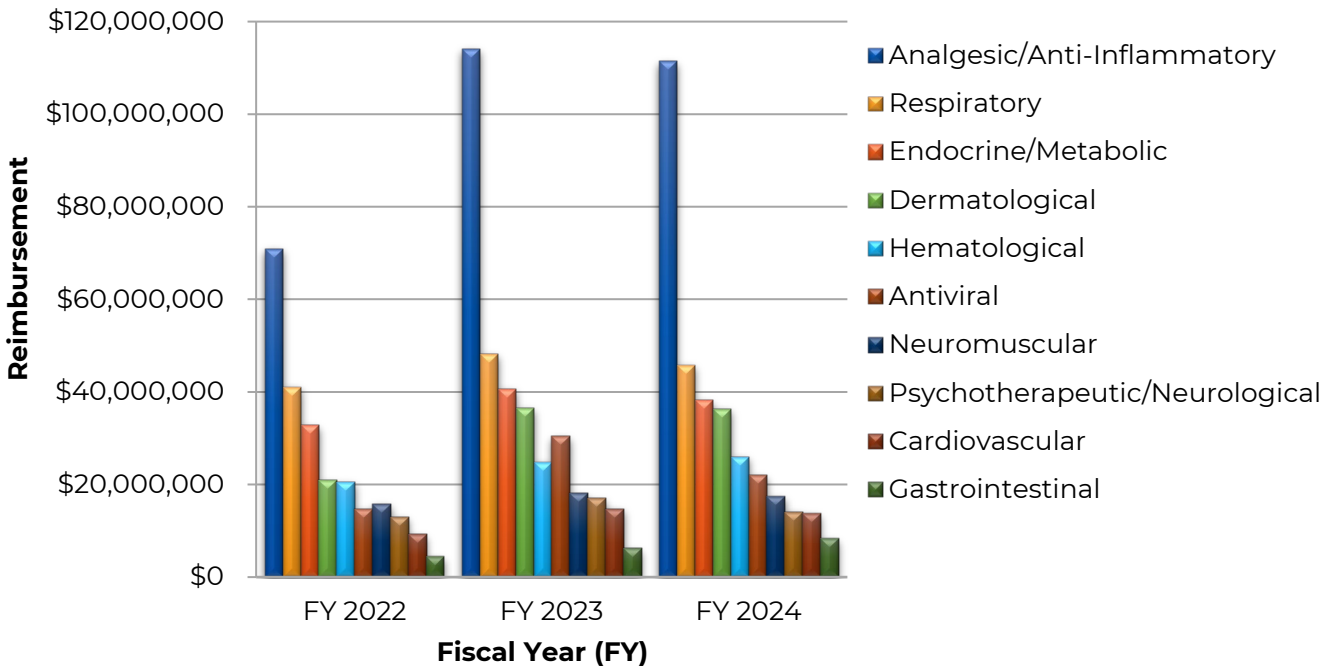
emergency department (ED) or other hospital resources for immediate anticoagulation. Although there was an increase in pharmacy reimbursement, anticoagulant medications have supplemental rebate agreements with SoonerCare, and there was a decrease in inpatient and ED costs related to VTE after the PA removal. Net cost increases are not reflected in this analysis.

- Dermatological medications' reimbursement increased by roughly 8% ($1.6 million) in FY 2024. This increase in reimbursement can be accounted for by increased utilization of Dupixent® (dupilumab), which is in the FY 2024 top 10 medications by reimbursement and currently has multiple FDA approved indications for dermatological conditions (i.e., atopic dermatitis, prurigo, nodularis, chronic spontaneous urticaria), as well as other indications (i.e., asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, COPD).

Top 10 Specialty Therapeutic Categories by Reimbursement: FY 2024[23,24,25]

Table 6: FY 2024 Top 10 Specialty Therapeutic Categories			
FY 2022	**FY 2023**	**FY 2024**	**Therapeutic Categories**
$70,857,678.61	$113,980,864.63	**$111,384,604.36**	**Analgesic/Anti-Inflammatory**
$41,070,103.12	$48,167,938.93	**$45,726,769.37**	**Respiratory**
$32,699,438.32	$40,546,655.97	**$38,102,139.57**	**Endocrine/Metabolic**
$20,783,224.74	$36,563,596.52	**$36,316,544.33**	**Dermatological**
$20,516,839.08	$24,865,590.96	**$25,938,542.02**	**Hematological**
$14,701,587.78	$30,365,950.28	**$21,928,568.11**	**Antiviral**
$15,686,912.08	$18,042,438.99	**$17,431,616.68**	**Neuromuscular**
$12,939,490.05	$16,919,754.46	**$14,062,264.80**	**Psychotherapeutic/Neurological**
$9,166,892.95	$14,732,435.84	**$13,689,600.27**	**Cardiovascular**
$4,447,151.05	$6,138,642.47	**$8,295,300.69**	**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 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024



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.

- Gastrointestinal (GI) medication reimbursement increased by 35% ($2.2 million), moving that category to the top 10 specialty therapeutic categories for FY 2024. The increase in reimbursement can be attributed to increased utilization of various GI specialty medications, including Skyrizi® (risankizumab-rzaa), which is FDA approved for Crohn's disease and ulcerative colitis (UC), Gattex® (teduglutide), which is FDA approved for short bowel syndrome (SBS), and Cimzia® (certolizumab pegol), which is FDA approved for Crohn's disease. Both Skyrizi® and Cimzia® have multiple other non-GI FDA approved indications.
- Hematological medications' reimbursement increased by approximately 4% ($1.1 million) in FY 2024. This increase in reimbursement can be accounted for by increased utilization of hemophilia medications, including increases in Hemlibra® (emicizumab-kxwh), Advate® [antihemophilic factor (recombinant)], and Alprolix® [coagulation factor IX (recombinant), Fc fusion protein].

Top 10 Medications by Reimbursement: FY 2024

Many of the top 10 medications by reimbursement are still branded at this time and not available in a generic formulation. The top products typically come from highly utilized classes such as targeted immunomodulator agents, atypical antipsychotics, anti-diabetic medications, and ADHD medications. 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, as well as antiviral medications for hepatitis C virus and human immunodeficiency virus (HIV). Dupilumab was included in the FY 2024 top 10 after utilization increased due to several new FDA approved indications, and empagliflozin, a sodium-glucose cotransporter-2 (SGLT-2) inhibitor, is new to the top 10 in FY 2024 due to new indications in addition to its use for type 2 diabetes mellitus (T2DM).

Table 7: Top 10 Medications by Reimbursement

Rank	FY 2022	FY 2023	FY 2024
1	adalimumab inj	adalimumab inj	adalimumab inj
2	paliperidone inj	paliperidone inj	paliperidone inj
3	elexacaftor/tezacaftor/ ivacaftor	dulaglutide inj	dulaglutide inj
4	lisdexamfetamine	elexacaftor/tezacaftor/ ivacaftor	elexacaftor/tezacaftor/ ivacaftor
5	lurasidone	lisdexamfetamine	lisdexamfetamine
6	bictegravir/emtricitabine/ tenofovir	bictegravir/emtricitabine/ tenofovir	etanercept inj
7	insulin glargine inj	glecaprevir/pibrentasvir	bictegravir/emtricitabine/ tenofovir
8	somatropin inj	etanercept inj	dupilumab inj
9	dulaglutide inj	insulin glargine inj	glecaprevir/pibrentasvir
10	etanercept inj	lurasidone	empagliflozin

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.
inj = injection; FY = fiscal year
FY 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

Cost Per Claim

The SoonerCare cost per claim of traditional medications decreased by 5.8% in FY 2024 in comparison to FY 2023, and the cost per specialty medication claim decreased by 15.5%. 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 2022**	**FY 2023**	**FY 2024**
Traditional	$82.92	$90.43	$85.22
Specialty	$7,422.39	$7,856.98	$6,638.89

Reimbursement does not reflected rebated prices or net costs.
FY = fiscal year
FY 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

Market Projections[10,11,26,27,28]

As previously noted, specialty medications made up about 1% of the claims for FY 2024 but generated approximately 36% of the total cost. The top 10 drugs by cost are led by specialty products and remain similar year to year, with the top 5 drugs by cost in FY 2024 being identical to the top 5 in FY 2023. Zurzuvae® (zuranolone), an antidepressant that is a gamma-aminobutyric acid (GABA) A receptor positive modulator, was approved by the FDA in August 2023 for postpartum depression, Rezdiffra™ (resmetirom), a thyroid hormone receptor-beta (THR-beta) agonist, was FDA approved in March 2024 for noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis, and Winrevair™ (sotatercept-csrk), an activin signaling inhibitor, was approved by the FDA in March 2024 for pulmonary arterial hypertension (PAH). These 3 new products have the potential to make a substantial impact on reimbursement in the upcoming FY. Oncology medications made up about 33% of novel drug approvals in FY 2024 for various indications, as shown in the following table. With new oncology agents continually entering the market, assessment of the oncology medication classes will need frequent reevaluation. In addition to specialty medications and oncologic medications, 5 new gene therapies were approved in FY 2024 with more expected to be approved in the coming years. Gene therapies have been developed for rare genetic diseases such as Elevidys (delandistrogene moxeparvovec-rokl) for the treatment of Duchenne muscular dystrophy (DMD) and those for sickle cell disease, such as Casgevy® (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel). The cost of these therapies is of concern considering they are typically priced in the millions for a single dose. Gene therapies are going to continue to be FDA approved and launched with increasing cost associated with them and will require ongoing reevaluation.

Table 9: Cellular Therapy, Gene Therapy, and Oncology Medications FDA Approved in FY 2024			
Brand	**Generic**	**Initial Indication(s)**	**Initial FDA Approval Date**
Vanflyta®	quizartinib	acute myeloid leukemia	07/20/2023
Talvey®	talquetamab-tgvs	multiple myeloma	08/09/2023
Akeega™	niraparib/abiraterone	prostate cancer	08/11/2023
Elrexfio™	elranatamab-bcmm	multiple myeloma	08/14/2023
Hepzato Kit™	melphalan	uveal melanoma	08/14/2023
Ojjaara	momelotinib	myelofibrosis	09/15/2023
Loqtorzi™	toripalimab-tpzi	nasopharyngeal carcinoma	10/27/2023
Fruzaqla®	fruquintinib	colorectal cancer	11/08/2023
Augtyro™	repotrectinib	NSCLC	11/15/2023
Trugap™	capivasertib	breast cancer	11/16/2023
Ogsiveo®	nirogacestat	desmoid tumors	11/27/2023
^Casgevy®	exagamglogene autotemcel	sickle cell disease	12/08/2023
^Lyfgenia™	lovotibeglogene autotemcel	sickle cell disease	12/08/2023
Iwilfin™	eflornithine	neuroblastoma	12/13/2023
^Elevidys	delandistrogene moxeparvovec-rokl	DMD	01/10/2024
*Amtagvi™	lifileucel	melanoma	02/16/2024
Tevimbra®	tislelizumab-jsgr	ESCC	03/13/2024
^Lenmeldy	atidarsagene autotemcel	MLD	03/18/2024
Anktiva®	nogapendekin alfa inbakicept-pmln	NMIBC	04/22/2024
Ojemda™	tovorafenib	low-grade glioma	04/23/2024
^Beqvez	fidanacogene elaparvovec-dzkt	hemophilia B	04/25/2024
Imdelltra™	tarlatamab-dlle	ES-SCLC	05/16/2024
Rytelo™	imetelstat	MDS	06/06/2024

*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).
ESCC = esophageal squamous cell carcinoma; ES-SCLC = extensive stage small cell lung cancer; DMD = Duchenne muscular dystrophy; FDA = U.S. Food and Drug Administration; FY = fiscal year; MDS = myelodysplastic syndrome; MLD = metachromatic leukodystrophy; NMIBC = non-muscle invasive bladder cancer; NSCLC = non-small cell lung cancer
FY 2024 = 07/01/2023 to 06/30/2024

Conclusion

New PA categories and continuous evaluation of categories such as oncology, hemophilia medications, and gene therapies, along with new respiratory and anti-diabetic medications that continue to be FDA approved, ensure the most clinically appropriate, cost-effective measures are taken. Modifications to Tier structures and other generic categories reduced elevated spending on high-priced generic products. 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 SoonerCare members with the most appropriate health care in a fiscally responsible manner. For the pharmacy benefit, this is accomplished through DUR services, using PA criteria, quantity limits, monthly total prescription limits and brand name prescription limits for non-institutionalized adult members, continuous product pricing maintenance, and provider outreach and education. Constant market review and response to changes, including evolving gene therapies, growth of the specialty market, and introduction of biosimilars, is necessary. SoonerCare will continue to strive to bring value-based pharmacy services to its members.

Top 50 Reimbursed Drugs: Fiscal Year 2024

Table 10: FY 2024 Top 50 Reimbursed Drugs

Generic	Brand	FY 2024		FY 2023	
		Rank	Amount Paid	Rank	Amount Paid
adalimumab inj	various	**1**	**$71,292,430.93**	1	$73,147,904.39
paliperidone inj	various	**2**	**$52,594,845.63**	2	$53,468,384.65
dulaglutide inj	Trulicity®	**3**	**$40,125,993.39**	3	$35,677,896.30
elexacaftor/tezacaftor/ ivacaftor	Trikafta®	**4**	**$36,691,617.65**	4	$35,616,621.70
lisdexamfetamine	Vyvanse®	**5**	**$25,940,097.95**	5	$31,108,439.83
etanercept inj	Enbrel®	**6**	**$23,378,005.34**	8	$23,843,612.04
bictegravir/emtricitabine/ tenofovir	Biktarvy®	**7**	**$23,097,219.06**	6	$26,615,778.21
dupilumab inj	Dupixent®	**8**	**$20,467,720.43**	11	$17,457,340.16
glecaprevir/pibrentasvir	Mavyret®	**9**	**$19,640,473.30**	7	$26,450,486.98
empagliflozin	Jardiance®	**10**	**$17,022,938.74**	14	$13,899,133.86
aripiprazole	various	**11**	**$15,471,916.51**	12	$16,083,977.59
emicizumab-kxwh inj	Hemlibra®	**12**	**$14,353,472.59**	16	$13,177,124.33
somatropin inj	various	**13**	**$13,468,420.11**	13	$16,029,517.48
cariprazine	Vraylar®	**14**	**$12,786,397.28**	20	$10,876,253.09
apixaban	Eliquis®	**15**	**$11,996,266.84**	22	$10,267,907.48
insulin glargine inj	various	**16**	**$11,124,617.10**	9	$19,172,391.25

Table 10: FY 2024 Top 50 Reimbursed Drugs					
Generic	Brand	FY 2024		FY 2023	
		Rank	Amount Paid	Rank	Amount Paid
ustekinumab inj	Stelara®	**17**	**$10,233,391.08**	15	$13,480,584.12
dexmethylphenidate	various	**18**	**$9,462,718.11**	18	$12,893,945.33
tiotropium	various	**19**	**$8,768,967.79**	24	$9,799,322.54
albuterol	various	**20**	**$8,260,974.63**	17	$13,063,240.29
dapagliflozin	Farxiga®	**21**	**$7,989,813.21**	31	$6,441,635.20
semaglutide	various	**22**	**$7,939,163.35**	33	$5,990,147.74
fluticasone/salmeterol	various	**23**	**$7,832,417.78**	19	$11,679,066.43
budesonide/formoterol	Symbicort®	**24**	**$7,093,340.81**	25	$9,737,351.67
aripiprazole lauroxil inj	Aristada®	**25**	**$6,889,575.80**	27	$7,757,487.56
insulin lispro inj	various	**26**	**$6,829,415.81**	21	$10,795,598.84
valbenazine	Ingrezza®	**27**	**$6,714,318.38**	41	$5,274,377.05
pancrelipase	various	**28**	**$6,575,202.55**	28	$7,597,956.86
insulin aspart inj	Novolog®	**29**	**$6,177,878.64**	23	$10,204,402.06
buprenorphine	various	**30**	**$6,140,659.05**	34	$5,631,678.56
fluticasone propionate HFA	Flovent® HFA	**31**	**$5,878,920.81**	26	$8,803,871.64
sacubitril/valsartan	Entresto®	**32**	**$5,826,194.62**	32	$6,054,405.87
rifaximin	Xifaxan®	**33**	**$5,640,237.88**	36	$5,527,695.90
cannabidiol	Epidiolex®	**34**	**$5,543,553.37**	43	$5,205,723.16
deutetrabenazine	Austedo®	**35**	**$5,484,968.89**	52	$4,774,946.39
upadacitinib	Rinvoq®	**36**	**$5,244,008.08**	58	$3,812,970.67
secukinumab	Cosentyx®	**37**	**$5,217,095.98**	44	$5,141,324.22
dornase alfa	Pulmozyme®	**38**	**$5,166,103.24**	35	$5,620,948.91
risankizumab-rzaa inj	Skyrizi®	**39**	**$4,825,493.37**	66	$3,490,324.30
asfotase alfa inj	Strensiq®	**40**	**$4,760,736.14**	46	$5,079,938.74
ixekizumab inj	Taltz®	**41**	**$4,733,804.39**	60	$3,730,503.21
setmelanotide inj	Imcivree®	**42**	**$4,721,496.90**	37	$5,476,845.64
casimersen inj	Amondys 51	**43**	**$4,313,900.30**	39	$5,435,588.08
darunavir/cobicistat/ emtricitabine/tenofovir	Symtuza®	**44**	**$4,126,824.30**	40	$5,427,936.06
apremilast	Otezla®	**45**	**$4,114,976.98**	54	$4,336,633.80
methylphenidate	various	**46**	**$4,108,544.87**	47	$5,020,730.60
rivaroxaban	Xarelto®	**47**	**$4,023,770.72**	57	$4,052,514.87
sitagliptin	Januvia®	**48**	**$4,014,894.12**	45	$5,104,324.10
tirzepatide inj	Mounjaro®	**49**	**$3,973,718.05**	71	$3,104,559.65
glycerol phenylbutyrate	Ravicti®	**50**	**$3,887,194.98**	62	$3,593,574.60

Includes brand and generic where applicable.
Reimbursement does not reflect rebated costs or net costs.
FY = fiscal year; HFA = hydrofluoroalkane, INJ = injection
FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

Top 50 Medications by Total Number of Claims: Fiscal Year 2024

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	268,894	118,021	$8,260,974.63	2.28	$30.72	0.81%
2	amoxicillin	246,382	182,728	$2,690,496.15	1.35	$10.92	0.26%
3	cetirizine	170,972	81,518	$1,739,161.44	2.10	$10.17	0.17%
4	gabapentin	144,123	38,768	$2,154,723.98	3.72	$14.95	0.21%
5	hydrocodone/APAP	139,732	60,136	$2,040,640.57	2.32	$14.60	0.20%
6	ondansetron	124,989	90,248	$1,499,064.70	1.38	$11.99	0.15%
7	sertraline	110,281	32,395	$1,230,158.70	3.40	$11.15	0.12%
8	fluticasone propionate NS	105,179	61,674	$1,370,194.58	1.71	$13.03	0.14%
9	trazodone	102,301	28,009	$1,013,304.52	3.65	$9.91	0.10%
10	ibuprofen	101,278	70,260	$1,015,446.20	1.44	$10.03	0.10%
11	prednisone	98,589	72,023	$834,862.10	1.37	$8.47	0.08%
12	azithromycin	96,052	76,634	$1,257,422.34	1.25	$13.09	0.12%
13	fluoxetine	90,149	24,805	$953,669.33	3.63	$10.58	0.09%
14	amoxicillin & K clavulanate	89,642	75,644	$1,497,077.70	1.19	$16.70	0.15%
15	montelukast	87,464	31,607	$1,055,970.41	2.77	$12.07	0.10%
16	atorvastatin	87,298	31,472	$979,097.06	2.77	$11.22	0.10%
17	lisdexamfetamine	86,557	16,391	$25,940,097.95	5.28	$299.69	2.55%
18	omeprazole	85,109	33,418	$919,894.44	2.55	$10.81	0.09%
19	clonidine	84,977	18,318	$836,484.05	4.64	$9.84	0.08%
20	lisinopril	82,625	29,667	$801,299.73	2.79	$9.70	0.08%
21	escitalopram	82,478	25,549	$955,185.53	3.23	$11.58	0.09%
22	cefdinir	76,966	60,805	$1,415,563.21	1.27	$18.39	0.14%
23	levothyroxine	76,205	21,032	$1,183,275.96	3.62	$15.53	0.12%
24	hydroxyzine HCl	74,822	29,552	$831,535.32	2.53	$11.11	0.08%
25	metformin	73,073	26,980	$672,322.41	2.71	$9.20	0.07%
26	aripiprazole	72,173	17,873	$15,471,916.51	4.04	$214.37	1.52%
27	bupropion	72,119	21,812	$1,026,338.48	3.31	$14.23	0.10%
28	cephalexin	70,714	61,190	$965,111.47	1.16	$13.65	0.10%
29	methylphenidate	68,325	11,996	$4,108,544.87	5.70	$60.13	0.40%
30	buspirone	66,630	21,675	$790,758.73	3.07	$11.87	0.08%
31	quetiapine	65,915	15,300	$823,230.91	4.31	$12.49	0.08%
32	cyclobenzaprine	63,550	30,300	$578,649.66	2.10	$9.11	0.06%
33	pantoprazole	62,774	25,275	$724,770.11	2.48	$11.55	0.07%
34	amlodipine	61,036	22,132	$577,353.48	2.76	$9.46	0.06%
35	amphetamine/ dextroamphetamine	57,993	11,214	$1,184,543.38	5.17	$20.43	0.12%
36	duloxetine	57,092	16,326	$783,350.46	3.50	$13.72	0.08%
37	guanfacine ER	55,627	10,211	$889,709.73	5.45	$15.99	0.09%

Table 11: FY 2024 Top 50 Medications by Total Number of Claims							
Rank	**Generic Name**	**Claims**	**Members**	**Cost**	**Claims/ Member**	**Cost/ Claim**	**% Cost**
38	triamcinolone TOP	52,195	38,471	$623,866.12	1.36	$11.95	0.06%
39	oxycodone/APAP	51,571	20,534	$870,350.59	2.51	$16.88	0.09%
40	prednisolone	51,432	37,401	$703,741.22	1.38	$13.68	0.07%
41	meloxicam	51,367	24,879	$446,142.24	2.06	$8.69	0.04%
42	lamotrigine	48,661	10,997	$868,272.45	4.42	$17.84	0.09%
43	methylprednisolone	48,485	41,751	$542,734.38	1.16	$11.19	0.05%
44	alprazolam	47,545	8,864	$455,253.77	5.36	$9.58	0.05%
45	mupirocin	47,076	40,304	$614,884.64	1.17	$13.06	0.06%
46	famotidine	44,514	20,671	$832,565.31	2.15	$18.70	0.08%
47	tizanidine	44,291	15,063	$460,913.85	2.94	$10.41	0.05%
48	risperidone	43,779	8,757	$3,795,423.15	5.00	$86.70	0.37%
49	hydroxyzine pamoate	42,950	17,603	$619,645.46	2.44	$14.43	0.06%
50	buprenorphine/naloxone	42,288	6,062	$2,226,052.08	6.98	$52.64	0.22%

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 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

Top 10 Traditional and Specialty Therapeutic Categories by Fiscal Year

Table 12: FY 2024 Top 10 Traditional and Specialty Therapeutic Categories by Reimbursement					
FY 2024			**FY 2023**		
Claims	**Members**	**Reimbursement**	**Claims**	**Members**	**Reimbursement**
TRADITIONAL THERAPEUTIC CATEGORIES					
ANTI-DIABETIC					
289,011	46,729	$125,168,660.32	275,987	42,962	$138,411,888.40
ANTIPSYCHOTIC/ANTIMANIC					
316,056	53,801	$103,399,717.30	327,841	53,605	$120,137,995.42
ANTIVIRAL					
90,527	57,923	$51,093,200.02	94,199	61,676	$61,178,386.05
ONCOLOGY					
19,210	5,016	$47,186,131.24	19,652	5,045	$52,883,199.03
ANTI-ASTHMATIC/BRONCHODILATOR					
512,182	140,375	$46,608,166.62	554,723	150,216	$63,682,493.66
ADHD/ANTI-NARCOLEPSY					
356,297	50,890	$45,718,680.51	371,195	49,132	$55,077,145.69
ANTICONVULSANT					
449,376	81,787	$26,476,135.71	470,211	82,352	$27,315,223.28
DERMATOLOGICAL					
233,227	129,384	$20,446,417.48	244,900	136,809	$18,875,408.68
ANTICOAGULANT					

Table 12: FY 2024 Top 10 Traditional and Specialty Therapeutic Categories by Reimbursement					
FY 2024			FY 2023		
Claims	Members	Reimbursement	Claims	Members	Reimbursement
43,573	8,948	$16,591,164.53	30,965	7,467	$15,127,560.73
ANTIDEPRESSANT					
693,153	142,459	$12,952,013.83	765,578	148,192	$13,617,946.43
SPECIALTY THERAPEUTIC CATEGORIES					
ANALGESIC/ANTI-INFLAMMATORY					
17,423	2,938	$111,384,604.36	15,627	2,473	$113,980,864.63
RESPIRATORY					
3,368	265	$45,726,769.37	3,330	260	$48,167,938.93
ENDOCRINE/METABOLIC					
4,583	665	$38,102,139.57	4,519	567	$40,546,655.97
DERMATOLOGICAL					
5,772	1,147	$36,316,544.33	4,900	860	$36,563,596.52
HEMATOLOGICAL					
1,113	151	$25,938,542.02	1,031	139	$24,865,590.96
ANTIVIRAL					
2,036	1,059	$21,928,568.11	2,524	1,256	$30,365,950.28
NEUROMUSCULAR					
308	45	$17,431,616.68	319	44	$18,042,438.99
PSYCHOTHERAPEUTIC/NEUROLOGICAL					
2,320	333	$14,062,264.80	2,317	332	$16,919,754.46
CARDIOVASCULAR					
3,775	506	$13,689,600.27	2,664	346	$14,732,435.84
GASTROINTESTINAL					
674	161	$8,295,300.69	530	116	$6,138,642.47

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 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

Fiscal Year Age Group Comparison

Table 13: Traditional Pharmacy Reimbursement by Age Group			
Age Group (Years)	FY 2022	FY 2023	FY 2024
Age 0 to 2	$9,834,562.85	$10,240,844.78	$6,938,880.80
Age 3 to 5	$59,713,068.33	$63,830,763.45	$50,702,687.79
Age 6 to 9	$47,232,422.88	$52,087,545.76	$40,478,742.38
Age 10 to 14	$46,471,986.07	$61,153,817.57	$50,095,144.86
Age 15 to 18	$70,669,015.39	$94,595,944.32	$79,254,328.32
Age 19 to 25	$14,298,971.36	$16,041,438.91	$12,675,485.95
Age 26 to 34	$177,652,418.14	$244,409,991.17	$223,165,101.75
Age 35 to 54	$107,069,526.67	$153,641,228.00	$143,708,810.73

Age 55 to 64	$36,762,175.40	$41,879,358.70	$32,817,904.29
Age 65+	$14,463,472.94	$19,886,523.17	$22,780,730.12
Total (All Ages)	**$584,167,620.03**	**$757,767,455.83**	**$662,617,816.99**

Reimbursement does not reflect rebated costs or net costs.
FY = fiscal year
FY 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

Table 14: Specialty Pharmacy Reimbursement by Age Group			
Age Group (Years)	**FY 2022**	**FY 2023**	**FY 2024**
Age 0 to 2	$10,199,115.62	$10,298,953.89	$5,808,174.67
Age 3 to 5	$39,158,020.32	$47,784,934.20	$42,726,791.19
Age 6 to 9	$38,184,742.07	$38,905,505.29	$37,915,909.55
Age 10 to 14	$26,680,333.72	$41,942,237.56	$39,698,957.91
Age 15 to 18	$27,301,932.63	$48,737,502.88	$49,520,661.53
Age 19 to 25	$9,466,662.91	$12,360,508.19	$12,441,538.69
Age 26 to 34	$59,763,179.46	$107,574,150.31	$104,904,124.73
Age 35 to 54	$27,175,711.12	$46,786,879.01	$45,013,375.20
Age 55 to 64	$25,379,926.39	$28,962,954.77	$25,436,779.60
Age 65+	$2,359,805.55	$4,262,665.46	$4,991,920.53
Total (All Ages)	**$265,669,429.79**	**$387,616,291.56**	**$368,458,233.60**

Reimbursement does not reflect rebated costs or net costs.
FY = fiscal year
FY 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

Table 15: Total Enrollment by Age Group				
Age Group (Years)	**FY 2022**	**FY 2023**	**FY 2024**	**% Change (2023 vs. 2024)**
Age 0 to 2	101,758	101,306	90,580	-10.59%
Age 3 to 5	101,972	106,192	90,265	-15.00%
Age 6 to 9	134,835	141,099	122,377	-13.27%
Age 10 to 14	163,785	169,070	142,134	-15.93%
Age 15 to 18	118,187	128,267	105,874	-17.46%
Age 19 to 25	108,588	143,844	103,900	-27.77%
Age 26 to 34	114,204	145,032	116,721	-19.52%
Age 35 to 54	171,409	226,413	187,058	-17.38%
Age 55 to 64	74,000	92,513	82,590	-10.73%
Age 65+	73,405	81,551	79,380	-2.66%
Total (All Ages)	**1,162,143**	**1,335,287**	**1,120,879**	**-16.06%**

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 2022 = 07/01/2021 to 06/30/2022; FY 2023 = 07/01/2022 to 06/30/2023; FY 2024 = 07/01/2023 to 06/30/2024

[1] U.S. Department of Health and Human Services (HHS). Covid-19 Public Health Emergency (PHE). Available online at: https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html. Last revised 12/15/2023. Last accessed 06/04/2025.
[2] Dolan R. Understanding the Medicaid Prescription Drug Rebate Program. *Kaiser Family Foundation (KFF)*. https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/. Issued 11/12/2019. Last accessed 06/04/2025.
[3] Office of Inspector General (OIG): Department of Health and Human Services (HHS). States' Collection of Offset and Supplemental Medicaid Rebates. Available online at: http://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf. Issued 12/2014. Last accessed 06/04/2025.
[4] Gibbons DC, Kirschenbaum AM. Bipartisan Budget Bill Extends Medicaid Drug Rebate Program Price Increase Penalty to Generic Drugs. *FDA Law Blog*. Available online at: http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2015/11/bipartisan-budget-bill-extends-medicaid-drug-rebate-program-price-increase-penalty-to-generic-drugs.html. Issued 11/02/2015. Last accessed 06/04/2025.
[5] Social Security Administration. Payment for Covered Outpatient Drugs. Available online at: https://www.ssa.gov/OP_Home/ssact/title19/1927.htm. Last accessed 06/04/2025.
[6] National Association of Medicaid Directors (NAMD). The Role of State Medicaid Programs in Improving the Value of the Health Care System. *Bailit Health*. Available online at: https://medicaiddirectors.org/wp-content/uploads/2022/02/Report-Role-of-State-Medicaid-Programs-in-Improving-the-Value-of-the-Healthcare-System.pdf. Issued 03/22/2016. Last accessed 06/04/2025.
[7] Goodman C, Daniel R, Balch A, Doyle J. Value-Based Health Care for Patients, Providers & Payers – Summary from AMCP Foundation Research Symposium Highlights Webinar. *AMCP Foundation*. Available online at: https://www.amcp.org/value-based-health-care-patients-providers-payers-summary-amcp-foundation-research-symposium. Webinar recorded 11/30/2017. Last accessed 06/04/2025.
[8] Tichy EM, Hoffman JM, Tadrous M, et al. National Trends in Prescription Drug Expenditures and Projections for 2024. *Am J Health Syst Pharm* 2024; 81(14): 583-598. doi: 10.1093/ajhp/zxae105. Online ahead of print.
[9] Centers for Medicare and Medicaid Services (CMS). CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers. Available online at: https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicaid-value-based-arrangements-drug-makers. Issued 06/27/2018. Last accessed 06/04/2025.
[10] U.S. Food and Drug Administration (FDA). First Generic Drug Approvals: 2023. Available online at: https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/2023-first-generic-drug-approvals. Last revised 03/08/2024. Last accessed 05/27/2025.
[11] U.S. FDA. First Generic Drug Approvals: 2024. Available online at: https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals. Last revised 11/25/2024. Last accessed 05/27/2025.
[12] U.S. FDA. Novel Drug Approvals for 2023. Available online at: https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2023. Last revised 01/10/2025. Last accessed 05/27/2025.
[13] U.S. FDA. Novel Drug Approvals for 2024. Available online at: https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2024. Last revised 01/15/2025. Last accessed 05/27/2025.
[14] U.S. FDA. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 05/2025. Last accessed 05/27/2025.
[15] Sage Therapeutics and Biogen.. Zurzuvae® (Zuranolone) Prescribing Information. Available online at: https://documents.sage-biogen.com/us/zurzuvae/pi.pdf. Last revised 07/2024. Last accessed 06/03/2025.
[16] UCB. Zilbrysq® (Zilucoplan) Prescribing Information. Available online at: https://www.ucb-usa.com/zilbrysq-prescribing-information.pdf. Last revised 02/2025. Last accessed 06/03/2025.
[17] Madrigal Pharmaceuticals. Rezdiffra™ (Resmetirom) Prescribing Information. Available online at: https://www.madrigalpharma.com/wp-content/uploads/2025/04/rezdiffra-prescribing-information-07-2024.pdf. Last revised 03/2024. Last accessed 06/03/2025.
[18] ITF Therapeutics. Duvyzat® (Givinostat) Prescribing Information. Available online at: https://itftherapeutics.com/documents/PI.pdf. Last revised 11/2024. Last accessed 06/03/2025.
[19] Merck. Winrevair™ (Sotatercept-csrk) Prescribing Information. Available online at: https://www.merck.com/product/usa/pi_circulars/w/winrevair/winrevair_pi.pdf. Last revised 05/2025. Last accessed 06/03/2025.

[20] Verona Pharma. Ohtuvayre™ (Ensifentrine) Prescribing Information. Available online at: https://ohtuvayrehcp.com/wp-content/uploads/sites/2/2024/11/Ohtuvayre-US-Prescribing-Information.pdf. Last revised 06/2024. Last accessed 06/03/2025.
[21] Beasley D. Prices for New U.S. Drugs Doubled in 4 Years as Focus on Rare Disease Grow. *Reuters*. Available online at: https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-doubled-4-years-focus-rare-disease-grows-2025-05-22/. Issued 05/22/2025. Last accessed 06/04/2025.
[22] Sanofi and Regeneron. Dupixent® (Dupilumab) Prescribing Information. Available online at: https://www.regeneron.com/downloads/dupixent_fpi.pdf. Last revised 04/2025. Last accessed 06/03/2025.
[23] AbbVie. Skyrizi® (Risankizumab-rzaa) Prescribing Information. Available online at: https://www.rxabbvie.com/pdf/skyrizi_pi.pdf. Last revised 05/2025. Last accessed 06/04/2025.
[24] Takeda Pharmaceuticals. Gattex® (Teduglutide) Prescribing Information. Available online at: https://www.shirecontent.com/PI/PDFS/Gattex_USA_ENG.pdf. Last revised 09/2024. Last accessed 06/04/2025.
[25] UCB. Cimzia® (Certolizumab Pegol) Prescribing Information. Available online at: https://www.ucb-usa.com/cimzia-prescribing-information.pdf. Last revised 09/2024. Last accessed 06/04/2025.
[26] U.S. FDA. Oncology (Cancer) / Hematologic Malignancies Approval Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancer-hematologic-malignancies-approval-notifications. Last revised 05/15/2025. Last accessed 05/27/2025.
[27] U.S. FDA. Approved Cellular and Gene Therapy Products. Available online at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products. Last revised 05/15/2025. Last accessed 05/28/2025.
[28] Senior M. Fresh from the Biotech Pipeline: Record-Breaking FDA Approvals. *Nature Biotechnology*. Available online at: https://www.nature.com/articles/s41587-024-02166-7. Issued 02/26/2024. Last accessed 06/04/2025.

Appendix Q

Fiscal Year 2024 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Cobenfy™ (Xanomeline/Trospium), Erzofri® [Paliperidone Palmitate Extended-Release (ER) Injection], and Opipza™ (Aripiprazole Oral Film)

Oklahoma Health Care Authority
June 2025

Current Prior Authorization Criteria

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole IM inj (Abilify Asimtufii®)^	iloperidone (Fanapt®)	asenapine transdermal system (Secuado®)+
aripiprazole IM inj (Abilify Maintena®)^	lurasidone (Latuda®)	brexpiprazole (Rexulti®)
aripiprazole lauroxil IM inj (Aristada®)^	paliperidone (Invega®)	cariprazine (Vraylar®)
aripiprazole lauroxil IM inj (Aristada Initio®)^		clozapine (Fazaclo®)+
clozapine (Clozaril®)◊		clozapine oral susp (Versacloz®)+
olanzapine (Zyprexa®)		lumateperone (Caplyta®)
paliperidone palmitate IM inj (Invega Hafyera®)^		olanzapine/fluoxetine (Symbyax®)+
paliperidone palmitate IM inj (Invega Sustenna®)^		olanzapine/samidorphan (Lybalvi®)β
paliperidone palmitate IM inj (Invega Trinza®)^		quetiapine 150mg tablets+
quetiapine (Seroquel®)		risperidone IM inj (Risperdal Consta®)^∞
quetiapine ER (Seroquel XR®)		risperidone IM inj (Risvan®)^∞
risperidone (Risperdal®)		risperidone IM inj (Rykindo®)^∞
risperidone ER sub-Q inj (Perseris®)^		

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
risperidone sub-Q inj (Uzedy®)^		
ziprasidone (Geodon®)		

*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.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension
¥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.
◊Clozapine does not count towards a Tier-1 trial.
^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 to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
ßUnique 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
   a. Clozapine does not count towards a Tier-1 trial.
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
   a. Clozapine does not count towards a Tier-1 trial; 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 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
7. 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
8. 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.

Abilify MyCite® (Aripiprazole Tablet with Sensor) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must not have dementia-related psychosis; and
3. A patient-specific, clinically significant reason why the member cannot use all oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to apply. Please note, the ability of Abilify MyCite® to improve patient compliance or modify aripiprazole dosage has not been established; and
4. Previous use of aripiprazole tablets and a reason why the Tier-1 aripiprazole tablets are no longer appropriate for the member must be provided; and
5. Prescriber agrees to closely monitor patient adherence; and

6. Patients should be capable and willing to use the MyCite® App and follow the Instructions for Use and ensure the MyCite® App is compatible with their specific smartphone; and
7. Initial approval will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance greater than 80% with prescribed therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to oral aripiprazole tablets or to any of the oral or injectable Tier-1 or Tier-2 medications must be provided. Tier structure rules continue to 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 have a positive clinical response to olanzapine and gained ≥10% from baseline body weight after starting olanzapine (baseline and current weight must be provided); or
4. A patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain profile must be provided; and
5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. 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) 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 Antipsychotic Medications: Fiscal Year 2024

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 2023							
FFS	49,382	296,727	$119,457,826.02	$402.58	$11.38	12,099,408	10,495,507
2023 Total	**49,382**	**296,727**	**$119,457,826.02**	**$402.58**	**$11.38**	**12,099,408**	**10,495,507**
Fiscal Year 2024							
FFS	46,772	254,783	$103,050,020.80	$404.46	$11.21	10,561,943	9,190,447
Aetna	4,451	8,727	$3,539,209.22	$405.55	$10.84	355,574	326,619
Humana	5,384	11,182	$4,809,868.32	$430.14	$11.75	444,240	409,260
OCH	5,682	11,842	$3,539,703.72	$298.91	$8.50	465,890	416,401
2024 Total	**49,842**	**286,534**	**$114,938,802.06**	**$401.13**	**$11.11**	**11,827,647**	**10,342,727**
% Change	**0.90%**	**-3.40%**	**-3.80%**	**-0.40%**	**-2.40%**	**-2.20%**	**-1.50%**
Change	**460**	**-10,193**	**-$4,519,023.96**	**-$1.45**	**-$0.27**	**-271,761**	**-152,780**

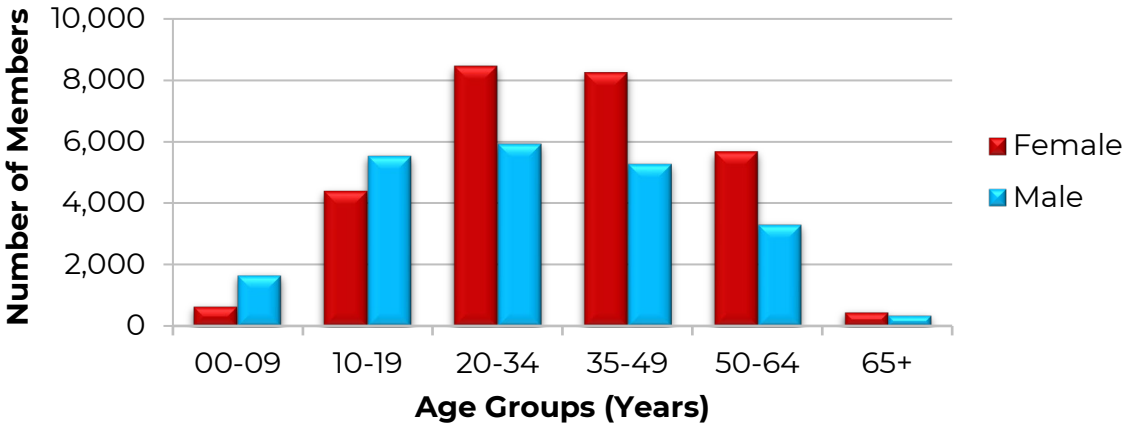
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

- Aggregate drug rebates collected during fiscal year 2024 for atypical antipsychotic medications totaled $75,094,992.97.[Δ] Rebates are

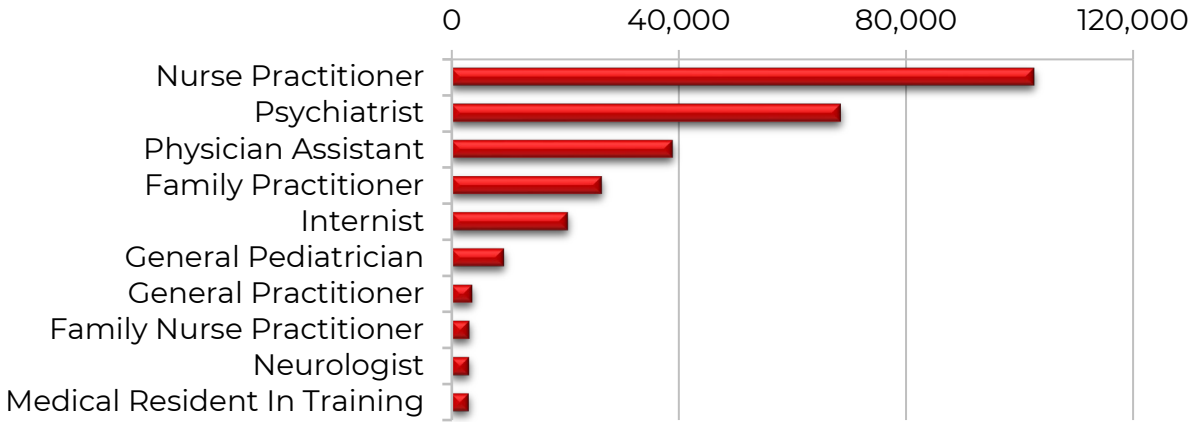
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

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 Atypical Antipsychotic Medications: Pharmacy Claims (All Plans)



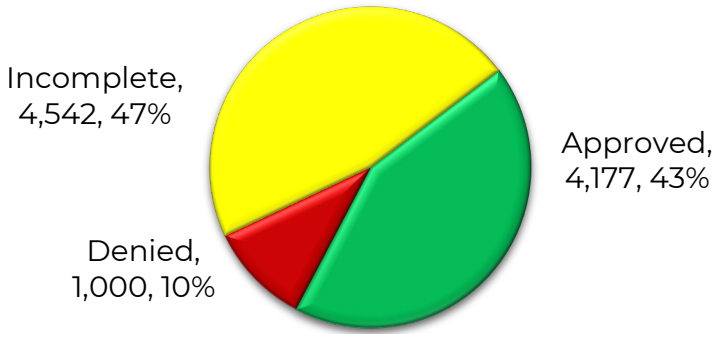
Top Prescriber Specialties of Atypical Antipsychotic Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Atypical Antipsychotic Medications

There were 9,719 prior authorization requests submitted for atypical antipsychotic medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	3,998	43%	4,427	48%	792	9%	**9,217**
Aetna	101	28%	115	31%	150	41%	**366**
Humana	3	75%	0	0%	1	25%	**4**
OCH	75	57%	0	0%	57	43%	**132**
Total	**4,177**	**43%**	**4,542**	**47%**	**1,000**	**10%**	**9,719**

FFS = fee-for-service; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans

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, including mental health, at: https://health.okstate.edu/echo/index.html.
- **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/index.html.

- **Oklahoma Child and Adolescent Psychiatry and Mental Health Access Program (OKCAPMAP):** OKCAPMAP 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://www.okcapmap.org/the-program/. 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]

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): September 2029
- Invega Sustenna® [paliperidone intramuscular (IM) injection]: January 2031
- Risvan® (risperidone IM injection): May 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 MyCite® (aripiprazole tablet with sensor): October 2033
- Abilify Maintena® (aripiprazole IM injection): April 2034
- Invega Trinza® (paliperidone IM injection): April 2036
- Aristada® (aripiprazole lauroxil IM injection): April 2039
- Cobenfy™ (xanomeline/trospium capsule) September 2039
- Erzofri® (paliperidone palmitate ER injection), September 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

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

- **July 2024:** The FDA approved Opipza™ (aripiprazole film) for a New Drug Application (NDA) under the 505(b)(2) pathway for all of the same

indications as aripiprazole oral tablets, except for the acute treatment of manic and mixed episodes associated with bipolar I disorder. The efficacy of Opipza™ was based on prior adequate and well-controlled studies of oral aripiprazole tablets. Two relative bioavailability studies were conducted comparing Opipza™ films to oral aripiprazole tablets, and the results showed adequate evidence of the effectiveness and pharmacokinetics (PK) of Opipza™.

- **July 2024:** The FDA approved Erzofri® (paliperidone palmitate ER injection) for an NDA under the 505(b)(2) pathway for the treatment of schizophrenia in adults and for treating schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants. Erzofri® is dosed once monthly and was studied in an open-label, randomized, multiple-dose trial to evaluate the PK profile of Erzofri® and its relative bioavailability to Invega Sustenna® (paliperidone palmitate 1-month ER injection). Erzofri® was found to be bioequivalent to Invega Sustenna® at steady state after multiple injections. Invega Sustenna® requires initial dosing on day 1 and day 8, but the initial dose of Erzofri® was optimized to remove the day 8 dose and resulted in comparable total drug exposure. It was announced in April 2025 that Erzofri® has now launched in the United States.
- **September 2024:** The FDA approved Cobenfy™ (xanomeline/trospium) for the treatment of schizophrenia in adults. Cobenfy™ is a first-in-class muscarinic agonist for the treatment of schizophrenia that selectively targets muscarinic receptors 1 (M1) and 4 (M4) without blocking dopamine 2 (D2) receptors.

News:

- **February 2025:** The FDA announced the removal of the Clozapine Risk Evaluation and Mitigation Strategies (REMS) program and the reporting of absolute neutrophil count (ANC) blood tests prior to a pharmacy dispensing clozapine. Although the risk of severe neutropenia still applies for clozapine, the FDA determined that the REMS program is no longer necessary to ensure the benefits outweigh the risks. The *Boxed Warning* for severe neutropenia associated with the use of clozapine will remain, and it is still recommended that prescribers monitor patients' ANC throughout treatment per the package labeling. The removal of the REMS program is in an effort to decrease the burden on health care delivery systems and improve access to clozapine.

Pipeline:

- **Bysanti™ (Milsaperidone):** Bysanti™ is an investigational atypical antipsychotic that is an active metabolite of iloperidone that is being studied for indications of bipolar I disorder with manic and mixed

episodes and schizophrenia. Milsaperidone, when administered orally, quickly interconverts to iloperidone and in clinical studies has been shown to be bioequivalent at both low and high doses to iloperidone. The efficacy and safety of Bysanti™ for these indications are supported by prior clinical trials for Fanapt® (iloperidone). An NDA has been submitted to the FDA for these 2 indications, and a Prescription Drug User Fee Amendment (PDUFA) date has been set for February 21, 2026. Additionally, Bysanti™ is being studied as an adjunctive treatment for major depressive disorder (MDD) with results expected in 2026.

- **Caplyta® (Lumateperone):** Caplyta® is being studied for a new indication as an adjunctive treatment to antidepressants for adults with MDD. Two Phase 3 trials, 501 and 502, met their primary endpoint for a reduction in the Montgomery-Asberg Depression Rating Scale (MADRS) score versus placebo. Trials 501 and 502 showed Caplyta® led to a 4.9-point reduction and a 4.5-point reduction, respectively, in total MADRS score versus placebo. A supplemental NDA (sNDA) has been submitted to the FDA for this indication. Caplyta® is currently FDA approved for the treatment of schizophrenia and for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate in adults.
- **Cobenfy™ (Xanomeline/Trospium):** Cobenfy™ is being studied as an adjunctive treatment to atypical antipsychotics in adults with inadequately controlled symptoms of schizophrenia. The Phase 3 ARISE trial showed a 2-point reduction in the Positive and Negative Syndrome Scale (PANSS) total score versus placebo at week 6 but this did not demonstrate statistical significance for the primary endpoint. Bristol Myers Squibb is planning to complete a full evaluation of the ARISE trial with the intent to present detailed results at an upcoming medical conference. Cobenfy™ was recently FDA approved in September 2024 for the treatment of schizophrenia in adults where it was studied as monotherapy. Additionally, a Phase 3 trial evaluating the safety and efficacy of Cobenfy™ as a treatment for psychosis associated with Alzheimer's disease is currently in the beginning stages.
- **Uzedy® (Risperidone Sub-Q Injection):** Uzedy® is currently being studied for the maintenance treatment of bipolar I disorder in adults. An sNDA has been submitted to the FDA for this indication, and the sNDA is based on existing clinical data for Uzedy® and on previous safety and efficacy data of risperidone formulations approved for bipolar I disorder. Uzedy® is currently FDA approved for the treatment of schizophrenia in adults.

Cobenfy™ (Xanomeline/Trospium) Product Summary[14,15,16]

Therapeutic Class: Combination muscarinic agonist and muscarinic antagonist

Indication(s): Treatment of schizophrenia in adults

How Supplied: 50mg/20mg, 100mg/20mg, and 125mg/30mg oral capsules

Dosing and Administration:

- Prior to initiating treatment with Cobenfy™, liver enzymes, bilirubin, and heart rate should be assessed at baseline and as clinically indicated during treatment.
- The recommended starting dose of Cobenfy™ is 50mg/20mg orally twice daily for at least 2 days followed by an increase in dose to 100mg/20mg twice daily for at least 5 days. The dose may be increased to the maximum recommended dose of 125mg/30mg twice daily based on patient tolerability and response.

Efficacy: Cobenfy™ was studied in 2 identically designed Phase 3, randomized, double-blind placebo-controlled, multicenter inpatient trials, EMERGENT-2 and EMERGENT-3, to examine the efficacy, safety, and tolerability of Cobenfy™ in adult patients with schizophrenia experiencing acute psychosis or recent worsening of psychosis warranting hospital admission.

- Key Inclusion Criteria:
  - *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) diagnosis of schizophrenia
  - Experiencing acute exacerbation or relapse in psychotic symptoms requiring hospitalization or if already inpatient, has been hospitalized for <2 weeks
  - PANSS score of ≥80 and Clinical Global Impression–Severity (CGI-S) score of ≥4
  - Free of all oral antipsychotic medications for ≥2 weeks before baseline assessment or if on a long-acting injectable antipsychotic, the patient could not have received a dose for at least 1.5 injection cycles before baseline assessment
  - No history of treatment-resistant schizophrenia or a requirement of clozapine in the last 12 months
- Intervention(s): Patients were randomized 1:1 to receive Cobenfy™ or placebo for 5 weeks.
  - Cobenfy™ was titrated up to 125mg/30mg twice daily or patients could return to 100mg/20mg twice daily if 125mg/30mg was not tolerated.
- Primary Endpoint(s):

        - Change from baseline in PANSS total score at week 5
    - Results:
        - EMERGENT-2:
            - Change from baseline in PANSS total score was -21.2 in the Cobenfy™ group vs. -11.6 in the placebo group [treatment difference: -9.6; 95% confidence interval (CI): -13.9, -5.2; P<0.0001]
        - EMERGENT-3:
            - Change from baseline in PANSS total score was -20.6 in the Cobenfy™ group vs. -12.2 in the placebo group (treatment difference: -8.4; 95% CI: -12.4, -4.3; P<0.0001)

Cost Comparison:

Product	Cost Per Unit	Cost Per Month*	Cost Per Year
Cobenfy™ (xanomeline/trospium) 125mg/30mg capsule	**$29.60**	**$1,776.00***	**$21,312.00**
Vraylar® (cariprazine) 6mg capsule	$48.57	$1,457.10[α]	$17,485.20
lurasidone 80mg tablet (generic)	$0.48	$28.80[+]	$345.60
risperidone 4mg tablet (generic)	$0.09	$10.80[β]	$129.60

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).
*Cost per month based on the maximum FDA approved dosing of 125mg/30mg twice daily
[α]Cost per month based on the maximum FDA approved dosing for schizophrenia of 6mg once daily
[+]Cost per month based on the maximum FDA approved dosing for schizophrenia of 160mg once daily
[β]Cost per month based on the maximum FDA approved dosing for schizophrenia of 16mg/day

Cost Comparison: Oral Aripiprazole Products

Product	Cost Per Unit	Cost Per Month*	Cost Per Year
Opipza™ (aripiprazole) 10mg film	**$76.52**	**$6,886.80**	**$82,641.60**
aripiprazole 15mg ODT (generic)	$2.96	$177.60	$2,131.20
aripiprazole 30mg tablet (generic)	$0.18	$5.40	$64.80

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).
ODT = oral disintegrating tablet; Unit = film, ODT, or tablet
*Cost per month based on the maximum FDA approved dose of 30mg per day

Cost Comparison: Paliperidone Palmitate Long-Acting Injectable Products

Medication	Cost Per Unit	Cost Per Year
Erzofri® (paliperidone palmitate) 234mg/1.5mL PFS	**$3,448.92**	**$44,835.96**
Invega Sustenna® (paliperidone palmitate) 234mg/1.5mL PFS	$3,428.51	$44,570.63

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition

Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Acquisition Cost (SPAC).
PFS = pre-filled syringe; unit = PFS
*Cost per month based on the maximum FDA approved dosing of 234mg once monthly

Recommendations[17]

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 chart and criteria):

1. Prior authorization of Cobenfy™ (xanomeline/trospium) and Erzofri® (paliperidone palmitate ER injection) and placement into Tier-3; and
2. Prior authorization of Opipza™ (aripiprazole oral film) and placement into Tier-3 with the following additional criteria; and
3. Removing the verbiage of clozapine not counting as a Tier-1 trial from the Tier-2 and Tier-3 criteria based on the removal of the Clozapine REMS program; and
4. Updating the Lybalvi® (olanzapine/samidorphan) approval criteria based on recent data from long-term extension trials and to be consistent with clinical practice.

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole IM inj (Abilify Asimtufii®)^	iloperidone (Fanapt®)	**aripiprazole oral film (Opipza™)+**
aripiprazole IM inj (Abilify Maintena®)^	lurasidone (Latuda®)	asenapine transdermal system (Secuado®)+
aripiprazole lauroxil IM inj (Aristada®)^	paliperidone (Invega®)	brexpiprazole (Rexulti®)
aripiprazole lauroxil IM inj (Aristada Initio®)^		cariprazine (Vraylar®)
clozapine (Clozaril®)♦		clozapine (Fazaclo®)+
olanzapine (Zyprexa®)		clozapine oral susp (Versacloz®)+
paliperidone palmitate IM inj (Invega Hafyera®)^		lumateperone (Caplyta®)
paliperidone palmitate IM inj (Invega Sustenna®)^		olanzapine/fluoxetine (Symbyax®)+
paliperidone palmitate IM inj (Invega Trinza®)^		olanzapine/samidorphan (Lybalvi®)β
quetiapine (Seroquel®)		**paliperidone palmitate ER inj (Erzofri®)^∞**

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
quetiapine ER (Seroquel XR®)		quetiapine 150mg tablets⁺
risperidone (Risperdal®)		risperidone IM inj (Risperdal Consta®)^∞
risperidone ER sub-Q inj (Perseris®)^		risperidone IM inj (Risvan®)^∞
risperidone sub-Q inj (Uzedy®)^		risperidone IM inj (Rykindo®)^∞
ziprasidone (Geodon®)		
Unique Mechanisms of Action		
		xanomeline/trospium (Cobenfy™)

*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.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension
¥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.
~~*Clozapine does not count towards a Tier-1 trial.~~
^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 to Abilify MyCite® (aripiprazole tablets with sensor).
⁺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
    ~~a. Clozapine does not count towards a Tier-1 trial.~~
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
    ~~a. Clozapine does not count towards a Tier-1 trial; 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) or 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.

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 have a positive clinical response to olanzapine and experienced weight gain ~~gained~~ ≥7% from baseline body weight or other metabolic complications [e.g., increased waist circumference, increased metabolic parameters, worsening diabetes (i.e., increased A1c despite optimal adherent therapy for diabetes)] after starting olanzapine (baseline and current weight must be provided or documentation of metabolic complications); or

4. If member has not had a trial with olanzapine and is expected to experience weight gain ≥7-10% from baseline body weight or metabolic complications, a patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain or metabolic profile must be provided (e.g., ziprasidone, aripiprazole, lurasidone); and
5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. 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 Antipsychotic Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ARIPIRAZOLE ORAL PRODUCTS						
ARIPIPRAZOLE TAB 5MG	21,612	7,710	$312,860.40	$14.48	2.8	0.27%
ARIPIPRAZOLE TAB 10MG	17,373	6,076	$259,412.53	$14.93	2.86	0.23%
ARIPIPRAZOLE TAB 2MG	9,159	3,526	$140,399.81	$15.33	2.6	0.12%
ARIPIPRAZOLE TAB 15MG	9,080	2,857	$136,751.10	$15.06	3.18	0.12%
ARIPIPRAZOLE TAB 20MG	5,331	1,467	$94,145.30	$17.66	3.63	0.08%
ARIPIPRAZOLE TAB 30MG	2,836	691	$51,009.06	$17.99	4.1	0.04%
ARIPIPRAZOLE SOL 1MG/ML	551	103	$74,681.54	$135.54	5.35	0.06%
ARIPIPRAZOLE ODT 10MG	17	5	$4,785.21	$281.48	3.4	0.00%
ABILIFY TAB 15MG	9	1	$5,356.89	$595.21	9	0.00%
ABILIFY TAB 30MG	9	2	$14,105.04	$1,567.23	4.5	0.01%
ABILIFY TAB 10MG	2	1	$3,525.62	$1,762.81	2	0.00%
ABILIFY TAB 20MG	1	1	$801.66	$801.66	1	0.00%
SUBTOTAL	**65,980**	**22,440**	**$1,097,834.16**	**$16.64**	**2.94**	**0.96%**
QUETIAPINE ORAL PRODUCTS						
QUETIAPINE TAB 100MG	15,986	5,264	$192,691.22	$12.05	3.04	0.17%
QUETIAPINE TAB 50MG	13,968	4,940	$172,197.74	$12.33	2.83	0.15%
QUETIAPINE TAB 25MG	9,746	3,656	$120,288.89	$12.34	2.67	0.10%
QUETIAPINE TAB 200MG	8,823	2,624	$122,156.25	$13.85	3.36	0.11%
QUETIAPINE TAB 300MG	6,995	1,819	$114,776.66	$16.41	3.85	0.10%
QUETIAPINE TAB 400MG	5,903	1,360	$110,654.21	$18.75	4.34	0.10%
QUETIAPINE TAB 50MG ER	1,069	417	$16,996.40	$15.90	2.56	0.01%
QUETIAPINE TAB 300MG ER	964	240	$20,412.35	$21.17	4.02	0.02%
QUETIAPINE TAB 150MG ER	915	299	$15,721.36	$17.18	3.06	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
QUETIAPINE TAB 400MG ER	873	191	$22,185.61	$25.41	4.57	0.02%
QUETIAPINE TAB 200MG ER	620	182	$11,362.75	$18.33	3.41	0.01%
SEROQUEL TAB 400MG	13	2	$14,737.75	$1,133.67	6.5	0.01%
SEROQUEL TAB 300MG	1	1	$482.67	$482.67	1	0.00%
SUBTOTAL	**65,876**	**20,995**	**$934,663.86**	**$14.19**	**3.14**	**0.81%**
RISPERIDONE ORAL PRODUCTS						
RISPERIDONE TAB 1MG	12,659	3,483	$150,974.71	$11.93	3.63	0.13%
RISPERIDONE TAB 0.5MG	9,679	2,562	$119,154.47	$12.31	3.78	0.10%
RISPERIDONE TAB 2MG	8,685	2,313	$106,202.10	$12.23	3.75	0.09%
RISPERIDONE TAB 0.25MG	3,606	1,027	$41,815.18	$11.60	3.51	0.04%
RISPERIDONE TAB 3MG	3,595	843	$44,389.46	$12.35	4.26	0.04%
RISPERIDONE TAB 4MG	1,937	417	$25,541.79	$13.19	4.65	0.02%
RISPERIDONE SOL 1MG/ML	1,243	256	$37,338.21	$30.04	4.86	0.03%
RISPERIDONE ODT 0.5MG	383	102	$16,445.68	$42.94	3.75	0.01%
RISPERIDONE ODT 1MG	207	75	$10,488.50	$50.67	2.76	0.01%
RISPERIDONE ODT 0.25MG	197	63	$19,024.46	$96.57	3.13	0.02%
RISPERIDONE ODT 2MG	110	32	$4,909.31	$44.63	3.44	0.00%
RISPERIDONE ODT 3MG	56	17	$3,148.31	$56.22	3.29	0.00%
RISPERIDONE ODT 4MG	15	7	$1,129.10	$75.27	2.14	0.00%
RISPERDAL TAB 0.5MG	3	1	$633.88	$211.29	3	0.00%
RISPERDAL SOL 1MG/ML	3	1	$7,326.78	$2,442.26	3	0.01%
RISPERDAL TAB 1MG	2	1	$378.89	$189.45	2	0.00%
RISPERDAL TAB 3MG	1	1	$287.47	$287.47	1	0.00%
SUBTOTAL	**42,381**	**11,201**	**$589,188.30**	**$13.90**	**3.78**	**0.51%**
OLANZAPINE ORAL PRODUCTS						
OLANZAPINE TAB 10MG	10,722	3,435	$154,887.49	$14.45	3.12	0.13%
OLANZAPINE TAB 20MG	7,835	1,725	$124,924.70	$15.94	4.54	0.11%
OLANZAPINE TAB 5MG	7,543	2,894	$108,041.30	$14.32	2.61	0.09%
OLANZAPINE TAB 15MG	3,907	1,120	$58,048.85	$14.86	3.49	0.05%
OLANZAPINE TAB 2.5MG	2,261	912	$30,390.63	$13.44	2.48	0.03%
OLANZAPINE TAB 7.5MG	1,314	378	$18,777.56	$14.29	3.48	0.02%
OLANZAPINE ODT 5MG	895	419	$20,305.52	$22.69	2.14	0.02%
OLANZAPINE ODT 10MG	881	372	$23,888.08	$27.11	2.37	0.02%
OLANZAPINE ODT 20MG	389	120	$14,251.71	$36.64	3.24	0.01%
OLANZAPINE ODT 15MG	255	80	$9,478.98	$37.17	3.19	0.01%
ZYPREXA TAB 10MG	6	1	$5,508.16	$918.03	6	0.00%
ZYPREXA TAB 20MG	3	2	$7,084.96	$2,361.65	1.5	0.01%
SUBTOTAL	**36,011**	**11,458**	**$575,587.94**	**$15.98**	**3.14**	**0.50%**
PALIPERIDONE INJECTABLE PRODUCTS						
INVEGA SUST INJ 234MG/1.5ML	8,953	1,824	$29,105,359.81	$3,250.91	4.91	25.32%
INVEGA SUST INJ 156MG/ML	3,438	1,209	$7,470,848.64	$2,173.02	2.84	6.50%
INVEGA TRINZ INJ 819MG/2.63ML	1,222	463	$11,949,146.72	$9,778.35	2.64	10.40%
INVEGA SUST INJ 117MG/0.75ML	774	191	$1,261,934.92	$1,630.41	4.05	1.10%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INVEGA TRINZ INJ 546MG/1.75ML	452	167	$2,949,980.86	$6,526.51	2.71	2.57%
INVEGA HAFYE INJ 1,560MG/5ML	137	95	$2,787,134.39	$20,344.05	1.44	2.42%
INVEGA SUST INJ 78MG/0.5ML	135	33	$138,187.37	$1,023.61	4.09	0.12%
INVEGA TRINZ INJ 410MG/1.32ML	131	51	$638,616.96	$4,874.94	2.57	0.56%
INVEGA HAFYE INJ 1,092MG/3.5ML	76	52	$1,027,690.75	$13,522.25	1.46	0.89%
INVEGA TRINZ INJ 273MG/0.88ML	32	13	$100,289.05	$3,134.03	2.46	0.09%
INVEGA SUST INJ 39MG/0.25ML	26	8	$12,394.22	$476.70	3.25	0.01%
SUBTOTAL	**15,376**	**4,106**	**$57,441,583.69**	**$3,735.79**	**3.74**	**49.98%**
CLOZAPINE ORAL PRODUCTS						
CLOZAPINE TAB 100MG	5,512	514	$262,190.73	$47.57	10.72	0.23%
CLOZAPINE TAB 50MG	2,630	275	$91,084.79	$34.63	9.56	0.08%
CLOZAPINE TAB 200MG	1,956	215	$121,442.45	$62.09	9.1	0.11%
CLOZAPINE TAB 25MG	1,369	160	$32,859.29	$24.00	8.56	0.03%
CLOZARIL TAB 100MG	25	2	$38,373.71	$1,534.95	12.5	0.03%
SUBTOTAL	**11,492**	**1,166**	**$545,950.97**	**$47.51**	**9.86**	**0.47%**
ZIPRASIDONE ORAL PRODUCTS						
ZIPRASIDONE CAP 40MG	2,062	624	$50,919.10	$24.69	3.3	0.04%
ZIPRASIDONE CAP 20MG	1,895	731	$44,734.12	$23.61	2.59	0.04%
ZIPRASIDONE CAP 80MG	1,712	342	$52,604.00	$30.73	5.01	0.05%
ZIPRASIDONE CAP 60MG	1,281	348	$37,704.06	$29.43	3.68	0.03%
SUBTOTAL	**6,950**	**2,045**	**$185,961.28**	**$26.76**	**3.4**	**0.16%**
ARIPIPRAZOLE INJECTABLE PRODUCTS						
ABILIFY MAIN INJ 400MG PFS	4,604	937	$12,136,958.88	$2,636.18	4.91	10.56%
ABILIFY MAIN INJ 300MG PFS	755	196	$1,473,355.05	$1,951.46	3.85	1.28%
ABILIFY MAIN INJ 400MG VIAL	439	137	$1,129,578.81	$2,573.07	3.2	0.98%
ABILIFY ASIM INJ 960MG/3.2ML	254	118	$1,388,783.01	$5,467.65	2.15	1.21%
ABILIFY ASIM INJ 720MG/2.4ML	76	36	$314,005.45	$4,131.65	2.11	0.27%
ABILIFY MAIN INJ 300MG VIAL	65	22	$120,064.78	$1,847.15	2.95	0.10%
SUBTOTAL	**6,193**	**1,446**	**$16,562,745.98**	**$2,674.43**	**4.28**	**14.41%**
ARIPIPRAZOLE LAUROXIL INJECTABLE PRODUCTS						
ARISTADA INJ 882MG/3.2ML	1,488	272	$4,302,912.58	$2,891.74	5.47	3.74%
ARISTADA INJ 1,064MG/3.9ML	578	194	$2,014,769.36	$3,485.76	2.98	1.75%
ARISTADA INJ 662MG/2.4ML	355	80	$764,608.52	$2,153.83	4.44	0.67%
ARISTADA INJ 441MG/1.6ML	181	44	$259,981.50	$1,436.36	4.11	0.23%
ARISTADA INJ INITIO 675MG/2.4ML	133	121	$289,480.75	$2,176.55	1.1	0.25%
SUBTOTAL	**2,735**	**711**	**$7,631,752.71**	**$2,790.40**	**3.85**	**6.64%**
RISPERIDONE INJECTABLE PRODUCTS						
PERSERIS INJ 120MG	762	205	$2,048,490.03	$2,688.31	3.72	1.78%
PERSERIS INJ 90MG	328	116	$648,730.14	$1,977.84	2.83	0.56%
UZEDY INJ 100MG/0.28ML	142	51	$356,654.15	$2,511.65	2.78	0.31%
UZEDY INJ 125MG/0.35ML	88	42	$272,406.26	$3,095.53	2.1	0.24%
UZEDY INJ 250MG/0.7ML	20	9	$126,813.80	$6,340.69	2.22	0.11%
UZEDY INJ 200MG/0.56ML	19	11	$93,995.03	$4,947.11	1.73	0.08%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
UZEDY INJ 50MG/0.14ML	16	8	$19,417.35	$1,213.58	2	0.02%
UZEDY INJ 75MG/0.21ML	13	7	$24,907.33	$1,915.95	1.86	0.02%
UZEDY INJ 150MG/0.42ML	10	7	$35,410.02	$3,541.00	1.43	0.03%
SUBTOTAL	**1,398**	**456**	**$3,626,824.11**	**$2,594.29**	**3.07**	**3.16%**
OLANZAPINE INJECTABLE PRODUCTS						
OLANZAPINE INJ 10MG	9	8	$665.11	$73.90	1.13	0.00%
ZYPREXA RELP INJ 210MG	2	1	$1,202.18	$601.09	2	0.00%
ZYPREXA RELP INJ 405MG	1	1	$1,144.65	$1,144.65	1	0.00%
SUBTOTAL	**12**	**10**	**$3,011.94**	**$251.00**	**1.2**	**0.00%**
ZIPRASIDONE INJECTABLE PRODUCTS						
ZIPRASIDONE INJ 20MG	1	1	$105.41	$105.41	1	0.00%
SUBTOTAL	**1**	**1**	**$105.41**	**$105.41**	**1**	**0.00%**
TIER-1 SUBTOTAL	**254,405**	**76,035**	**$89,195,210.35**	**$350.60**	**3.35**	**77.60%**
TIER-2 PRODUCTS						
LURASIDONE ORAL PRODUCTS						
LURASIDONE TAB 40MG	4,083	1,479	$89,318.86	$21.88	2.76	0.08%
LURASIDONE TAB 20MG	3,381	1,410	$61,657.86	$18.24	2.4	0.05%
LURASIDONE TAB 80MG	2,458	599	$71,768.91	$29.20	4.1	0.06%
LURASIDONE TAB 60MG	2,236	702	$56,783.07	$25.39	3.19	0.05%
LURASIDONE TAB 120MG	954	234	$33,881.29	$35.51	4.08	0.03%
LATUDA TAB 40MG	251	92	$398,394.18	$1,587.23	2.73	0.35%
LATUDA TAB 20MG	249	95	$403,844.71	$1,621.87	2.62	0.35%
LATUDA TAB 80MG	214	59	$345,176.42	$1,612.97	3.63	0.30%
LATUDA TAB 60MG	186	71	$309,976.36	$1,666.54	2.62	0.27%
LATUDA TAB 120MG	66	28	$183,139.24	$2,774.84	2.36	0.16%
SUBTOTAL	**14,078**	**4,769**	**$1,953,940.90**	**$138.79**	**2.95**	**1.70%**
PALIPERIDONE ORAL PRODUCTS						
PALIPERIDONE TAB ER 6MG	970	262	$84,824.41	$87.45	3.7	0.07%
PALIPERIDONE TAB ER 3MG	628	220	$40,663.18	$64.75	2.85	0.04%
PALIPERIDONE TAB ER 9MG	472	117	$40,920.63	$86.70	4.03	0.04%
PALIPERIDONE TAB ER 1.5MG	133	42	$7,292.76	$54.83	3.17	0.01%
INVEGA TAB 3MG	4	1	$4,279.04	$1,069.76	4	0.00%
SUBTOTAL	**2,207**	**642**	**$177,980.02**	**$80.64**	**3.44**	**0.15%**
ASENAPINE ORAL PRODUCTS						
ASENAPINE SUB 10MG	428	94	$67,547.64	$157.82	4.55	0.06%
ASENAPINE SUB 5MG	321	108	$44,445.51	$138.46	2.97	0.04%
ASENAPINE SUB 2.5MG	153	68	$26,336.49	$172.13	2.25	0.02%
SAPHRIS SUB 10MG	27	4	$30,137.90	$1,116.22	6.75	0.03%
SAPHRIS SUB 5MG	12	7	$12,215.11	$1,017.93	1.71	0.01%
SAPHRIS SUB 2.5MG	2	2	$2,424.44	$1,212.22	1	0.00%
SUBTOTAL	**943**	**283**	**$183,107.09**	**$194.18**	**3.33**	**0.16%**
ILOPERIDONE ORAL PRODUCTS						
FANAPT TAB 8MG	95	17	$157,470.44	$1,657.58	5.59	0.14%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FANAPT TAB 12MG	88	16	$257,151.96	$2,922.18	5.5	0.22%
FANAPT TAB 6MG	66	13	$125,458.86	$1,900.89	5.08	0.11%
FANAPT TAB 10MG	51	9	$141,018.20	$2,765.06	5.67	0.12%
FANAPT TAB 4MG	50	7	$65,733.90	$1,314.68	7.14	0.06%
FANAPT TAB 2MG	22	4	$30,664.01	$1,393.82	5.5	0.03%
FANAPT TAB 1MG	4	4	$3,531.24	$882.81	1	0.00%
FANAPT 1/2/4/6MG PACK	4	4	$986.36	$246.59	1	0.00%
SUBTOTAL	**380**	**74**	**$782,014.97**	**$2,057.93**	**5.14**	**0.68%**
TIER-2 SUBTOTAL	**17,608**	**5,768**	**$3,097,042.98**	**$175.89**	**3.05**	**2.69%**
TIER-3 PRODUCTS						
CARIPRAZINE ORAL PRODUCTS						
VRAYLAR CAP 3MG	3,477	1,012	$5,515,588.37	$1,586.31	3.44	4.80%
VRAYLAR CAP 1.5MG	3,454	1,319	$5,407,986.60	$1,565.72	2.62	4.71%
VRAYLAR CAP 4.5MG	1,434	389	$2,292,739.84	$1,598.84	3.69	1.99%
VRAYLAR CAP 6MG	1,171	257	$1,858,408.41	$1,587.03	4.56	1.62%
VRAYLAR CAP 1.5-3MG	3	3	$990.58	$330.19	1	0.00%
SUBTOTAL	**9,539**	**2,980**	**$15,075,713.80**	**$1,580.43**	**3.2**	**13.12%**
BREXPIPRAZOLE ORAL PRODUCTS						
REXULTI TAB 1MG	770	292	$1,256,137.20	$1,631.35	2.64	1.09%
REXULTI TAB 2MG	685	223	$1,169,179.45	$1,706.83	3.07	1.02%
REXULTI TAB 3MG	451	115	$772,321.01	$1,712.46	3.92	0.67%
REXULTI TAB 4MG	273	58	$435,100.83	$1,593.78	4.71	0.38%
REXULTI TAB 0.5MG	252	108	$416,596.08	$1,653.16	2.33	0.36%
REXULTI TAB 0.25MG	21	11	$28,864.19	$1,374.49	1.91	0.03%
SUBTOTAL	**2,452**	**807**	**$4,078,198.76**	**$1,663.21**	**3.04**	**3.55%**
LUMATEPERONE ORAL PRODUCTS						
CAPLYTA CAP 42MG	1,350	321	$2,067,508.44	$1,531.49	4.21	1.80%
CAPLYTA CAP 21MG	141	57	$216,588.52	$1,536.09	2.47	0.19%
CAPLYTA CAP 10.5MG	33	16	$51,197.97	$1,551.45	2.06	0.04%
SUBTOTAL	**1,524**	**394**	**$2,335,294.93**	**$1,532.35**	**3.87**	**2.03%**
OLANZAPINE/SAMIDORPHAN COMBINATION PRODUCTS						
LYBALVI TAB 10-10MG	158	54	$231,509.48	$1,465.25	2.93	0.20%
LYBALVI TAB 20-10MG	155	32	$218,937.82	$1,412.50	4.84	0.19%
LYBALVI TAB 15-10MG	129	39	$178,775.71	$1,385.86	3.31	0.16%
LYBALVI TAB 5-10MG	113	45	$167,988.71	$1,486.63	2.51	0.15%
SUBTOTAL	**555**	**170**	**$797,211.72**	**$1,436.42**	**3.26**	**0.69%**
CLOZAPINE ORALLY DISINTEGRATING PRODUCTS						
CLOZAPINE ODT 100MG	114	9	$32,154.21	$282.05	12.67	0.03%
CLOZAPINE ODT 150MG	41	9	$32,389.67	$789.99	4.56	0.03%
CLOZAPINE ODT 25MG	13	1	$1,815.35	$139.64	13	0.00%
CLOZAPINE ODT 200MG	8	3	$16,252.52	$2,031.57	2.67	0.01%
CLOZAPINE ODT 12.5MG	1	1	$23.88	$23.88	1	0.00%
SUBTOTAL	**177**	**23**	**$82,635.63**	**$466.87**	**7.7**	**0.07%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RISPERIDONE INJECTABLE PRODUCTS						
RISPERDAL CONSTA INJ 50MG	125	11	$190,695.62	$1,525.56	11.36	0.17%
RISPERDAL CONSTA INJ 25MG	17	5	$16,763.51	$986.09	3.4	0.01%
RISPERDAL CONSTA INJ 37.5MG	16	2	$27,914.34	$1,744.65	8	0.02%
RISPERIDONE INJ 50MG ER	6	2	$10,374.74	$1,729.12	3	0.01%
RISPERDAL CONSTA INJ 12.5MG	3	1	$1,798.73	$599.58	3	0.00%
RISPERIDONE INJ 25MG ER	1	1	$1,073.37	$1,073.37	1	0.00%
RISPERIDONE INJ 37.5MG	1	1	$1,600.41	$1,600.41	1	0.00%
SUBTOTAL	**169**	**23**	**$250,220.72**	**$1,480.60**	**7.35**	**0.22%**
OLANZAPINE/FLUOXETINE COMBINATION PRODUCTS						
OLANZ/FLUOX CAP 12-50MG	28	3	$9,505.36	$339.48	9.33	0.01%
OLANZ/FLUOX CAP 12-25MG	11	1	$3,717.34	$337.94	11	0.00%
OLANZ/FLUOX CAP 6-50MG	10	1	$1,840.74	$184.07	10	0.00%
OLANZ/FLUOX CAP 6-25MG	10	3	$1,407.14	$140.71	3.33	0.00%
OLANZ/FLUOX CAP 3-25MG	1	1	$104.53	$104.53	1	0.00%
SUBTOTAL	**60**	**9**	**$16,575.11**	**$276.25**	**6.67**	**0.01%**
QUETIAPINE ORAL PRODUCTS						
QUETIAPINE TAB 150MG	39	28	$2,395.12	$61.41	1.39	0.00%
SUBTOTAL	**39**	**28**	**$2,395.12**	**$61.41**	**1.39**	**0.00%**
ASENAPINE TRANSDERMAL SYSTEM PRODUCTS						
SECUADO PATCH 3.8MG/24HR	5	1	$6,903.71	$1,380.74	5	0.01%
SECUADO PATCH 7.6MG/24HR	1	1	$1,399.23	$1,399.23	1	0.00%
SUBTOTAL	**6**	**2**	**$8,302.94**	**$1,383.82**	**3**	**0.01%**
TIER-3 SUBTOTAL	**14,521**	**4,436**	**$22,646,548.73**	**$1,559.57**	**3.27**	**19.70%**
TOTAL	**286,534**	**49,842***	**$114,938,802.06**	**$401.13**	**5.75**	**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; SUST = Sustenna; SUB = sublingual; TAB = tablet; TRINZ = Trinza
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

---

[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 05/2025. Last accessed 05/21/2025.
[2] U.S. FDA. Drugs@FDA. Drug Approval Package: Opipza™: Multi-Discipline Review. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/216655Orig1s000MultidisciplineR.pdf. Issued 07/19/2024. Last accessed 05/21/2025.
[3] Opipza™ (Aripiprazole) Prescribing Information. Xiamen Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216655s000lbl.pdf. Last revised 07/2024. Last accessed 05/21/2025.
[4] Erzofri® (Paliperidone Palmitate) – New Drug Approval. OptumRx®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_erzofri_2024-0729.pdf. Issued 07/28/2024. Last accessed 05/21/2025.

[5] Luye Pharma. Luye Pharma Announces U.S. FDA Approval of Erzofri® (Paliperidone Palmitate) Extended-Release Injectable Suspension for Treating Schizophrenia and Schizoaffective Disorder. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/luye-pharma-announces-us-fda-approval-of-erzofri-paliperidone-palmitate-extended-release-injectable-suspension-for-treating-schizophrenia-and-schizoaffective-disorder-302208155.html. Issued 07/28/2024. Last accessed 05/21/2025.

[6] Luye Pharma. Luye Pharma Announces U.S. Launch of Erzofri® (Paliperidone Palmitate) Extended-Release Injectable Suspension for the Treatment of Schizophrenia and Schizoaffective Disorder. Available online at: https://www.luye.cn/lvye_en/view.php?id=2314. Issued 04/06/2025. Last accessed 05/21/2025.

[7] Bristol Myers Squibb. U.S. Food and Drug Administration Approves Bristol Myers Squibb's Cobenfy™ (Xanomeline and Trospium Chloride), a First-In-Class Muscarinic Agonist for the Treatment of Schizophrenia in Adults. Available online at: https://news.bms.com/news/corporate-financial/2024/U.S.-Food-and-Drug-Administration-Approves-Bristol-Myers-Squibbs-COBENFY-xanomeline-and-trospium-chloride-a-First-In-Class-Muscarinic-Agonist-for-the-Treatment-of-Schizophrenia-in-Adults/default.aspx. Issued 09/26/2024. Last accessed 05/21/2025.

[8] U.S. FDA. Postmarket Drug Safety Information for Patient and Providers: Information on Clozapine. Available online at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-clozapine. Issued 02/25/2025. Last accessed 05/21/2025.

[9] Vanda Pharmaceuticals. Vanda Announces Bysanti™ NDA Filing; FDA Decision Expected in Early 2026. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/vanda-announces-bysanti-nda-filing-fda-decision-expected-in-early-2026-302445753.html. Issued 05/05/2025. Last accessed 05/21/2025.

[10] Intra-Cellular Therapies. Intra-Cellular Therapies Submits Supplemental New Drug Application (sNDA) to FDA for Caplyta® (Lumateperone) for the Treatment of Major Depressive Disorder as Adjunctive Therapy. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2024/12/03/2990492/30597/en/Intra-Cellular-Therapies-Submits-Supplemental-New-Drug-Application-sNDA-to-FDA-for-CAPLYTA-lumateperone-for-the-Treatment-of-Major-Depressive-Disorder-as-Adjunctive-Therapy.html. Issued 12/03/2024. Last accessed 05/21/2025.

[11] Bristol Myers Squibb. Bristol Myers Squibb Announces Topline Results from Phase 3 ARISE Trial Evaluating Cobenfy™ (Xanomeline and Trospium Chloride) as an Adjunctive Treatment to Atypical Antipsychotics in Adults with Schizophrenia. Available online at: https://news.bms.com/news/details/2025/Bristol-Myers-Squibb-Announces-Topline-Results-from-Phase-3-ARISE-Trial-Evaluating-Cobenfy-xanomeline-and-trospium-chloride-as-an-Adjunctive-Treatment-to-Atypical-Antipsychotics-in-Adults-with-Schizophrenia/default.aspx. Issued 04/22/2025. Last accessed 05/21/2025.

[12] BMS Science. Clinical Trials. Available online at: https://www.bmsscience.com/. Last accessed 05/21/2025.

[13] Teva Pharmaceuticals. Teva and Medincell Announce FDA Acceptance of Supplemental New Drug Application for Uzedy® (Risperidone) Extended-Release Injectable Suspension as a Treatment for Patients with Bipolar I Disorder. Available online at: https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2025/Teva-and-Medincell-Announce-FDA-Acceptance-of-Supplemental-New-Drug-Application-for-UZEDYR-risperidone-Extended-Release-Injectable-Suspension-as-a-Treatment-for-Patients-with-Bipolar-I-Disorder/default.aspx. Issued 02/25/2025. Last accessed 05/21/2025.

[14] Cobenfy™ (Xanomeline/Trospium) Prescribing Information. Bristol Myers Squibb. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216158s000lbl.pdf. Last revised 09/2024. Last accessed 05/21/2025.

[15] Kaul I, Sawchak S, Correll C, et.al. Efficacy and Safety of the Muscarinic Receptor Agonist KarXT (xanomeline–trospium) in Schizophrenia (EMERGENT-2) in the USA: Results from a Randomised, Double-Blind, Placebo-Controlled, Flexible-Dose Phase 3 Trial. *Lancet* 2024; 403: 160-170. doi: 10.1016/S0140-6736(23)02190-6.

[16] Kaul I, Sawchak S, Walling D, et.al. Efficacy and Safety of Xanomeline-Trospium Chloride in Schizophrenia: A Randomized Clinical Trial. *JAMA Psychiatry* 2024; 81(8): 749-756. doi: 10.1001/jamapsychiatry. 2024.0785.

[17] Kahn R, Silverman B, DiPetrillo L, et.al. A Phase 3, Multicenter Study to Assess the 1-Year Safety and Tolerability of a Combination of Olanzapine and Samidorphan in Patients with Schizophrenia: Results from the ENLIGHTEN-2 Long-Term Extension. *Schizophr Res* 2021; 232: 45-53. doi: 10.1016/j.schres.2021.04.009

Appendix R

Fiscal Year 2024 Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Bucapsol™ (Buspirone Capsule), Carbamazepine 200mg Chewable Tablet, Femlyv™ [Norethindrone Acetate/Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Focinvez™ (Fosaprepitant Injection), Imkeldi (Imatinib Oral Solution), IVRA (Melphalan 90mg/mL Injection), Myhibbin™ (Mycophenolate Mofetil Oral Suspension), Ondansetron 16mg ODT, Tezruly™ (Terazosin Oral Solution), Topiramate 50mg Sprinkle Capsule, Veltassa® (Patiromer) 1g Powder Packet, and Vigafyde™ (Vigabatrin Oral Solution)

Oklahoma Health Care Authority
June 2025

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 2024 (07/01/2023 to 06/30/2024). Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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.

Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules] Approval Criteria:

1. An FDA approved diagnosis of chronic angina; and
2. A patient-specific, clinically significant reason why the member cannot use ranolazine ER tablets must be provided.

Ermeza™ (Levothyroxine Oral Solution), Levothyroxine Capsule (Generic Tirosint®) 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.

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.

GoNitro™ (Nitroglycerin Sublingual Powder) Approval Criteria:

1. An FDA approved indication of acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease; and
2. A patient-specific, clinically significant reason why the member cannot use nitroglycerin sublingual tablets or nitroglycerin lingual spray must be provided.

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. Acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen; or
    b. Mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or
    c. Relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or
    d. Rheumatoid arthritis; or
    e. Severe psoriasis; and
2. Member must be 18 years of age or older; and
3. 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.

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 a prior authorization must be provided.

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.

Purixan® (Mercaptopurine Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of acute lymphoblastic leukemia (ALL); and
2. An age restriction for members older than 10 years of age applies. Purixan® does not require prior authorization for members 10 years of age and younger; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

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.

Soltamox® (Tamoxifen Citrate 10mg/5mL Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of metastatic breast cancer in women and men; or
    b. Adjuvant treatment of node-positive breast cancer in postmenopausal women and for the adjuvant treatment of axillary node-negative breast cancer in women following total mastectomy or segmental mastectomy, axillary dissection, and breast irradiation; or

c. To reduce the risk of invasive breast cancer in women with ductal carcinoma in situ (DCIS), following breast surgery and radiation; or
d. To reduce the incidence of breast cancer in women at high risk for breast cancer; and

2. A patient-specific, clinically significant reason why the member cannot use tamoxifen oral tablets 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.

Utilization of Various Special Formulations: Fiscal Year 2024

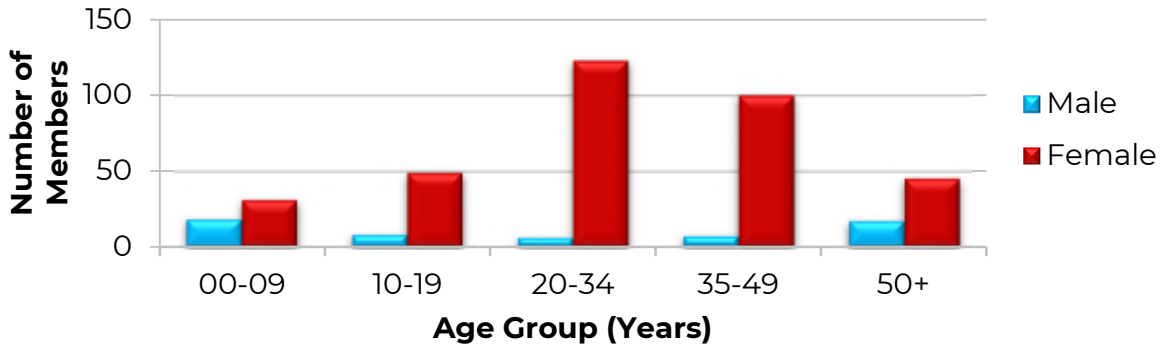
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	196	818	$296,639.80	$362.64	$9.50	35,651	31,225
2023 Total	**196**	**818**	**$296,639.80**	**$362.64**	**$9.50**	**35,651**	**31,225**
Fiscal Year 2024							
FFS	194	788	$291,971.28	$370.52	$9.57	32,365	30,504
Aetna	67	97	$20,043.62	$206.64	$7.45	3,044	2,689
Humana	64	91	$24,361.74	$267.71	$8.09	3,275	3,013
OCH	134	187	$65,659.89	$351.12	$8.22	8,464	7,983
2024 Total	**404**	**1,163**	**$402,036.53**	**$345.69**	**$9.10**	**47,148**	**44,189**
% Change	**106.10%**	**42.20%**	**35.50%**	**-4.70%**	**-4.20%**	**32.20%**	**41.50%**
Change	**208**	**345**	**$105,396.73**	**-$16.95**	**-$0.40**	**11,497**	**12,964**

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 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

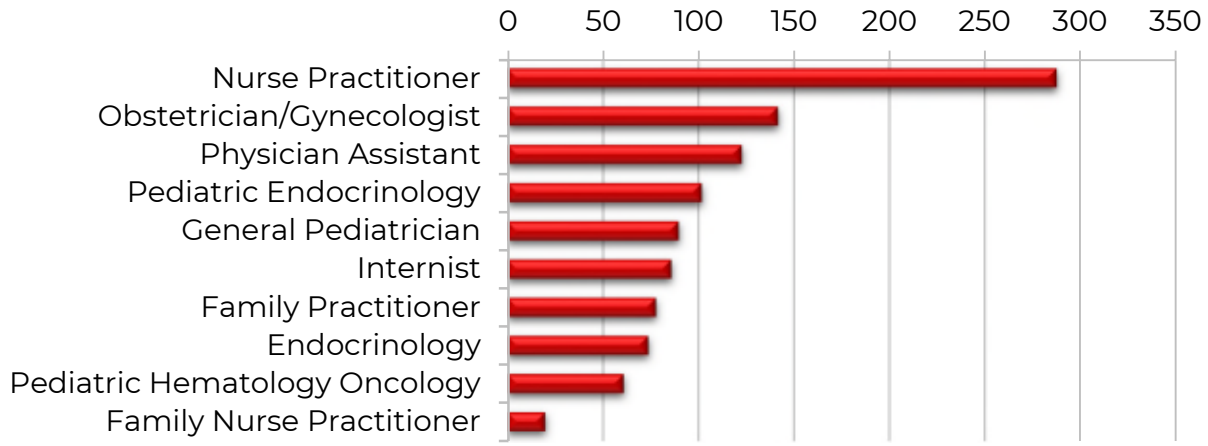
- Due to the evolving nature of this category, fiscal year comparisons may not reflect the same product utilization from year to year.
- There were no paid medical claims for various special formulations during fiscal year 2024.
- Aggregate drug rebates collected during fiscal year 2024 for the various special formulations totaled $192,819.39.[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 1,062 prior authorization requests submitted for various special formulations during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	213	22%	574	60%	177	18%	**964**
Aetna	14	33%	1	2%	28	65%	**43**
Humana	7	14%	0	0%	42	86%	**49**
OCH	1	17%	0	0%	5	83%	**6**
Total	**235**	**22%**	**575**	**54%**	**252**	**24%**	**1,062**

FFS = fee-for-service; OCH = OK Complete Health

Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

Bucapsol™ (Buspirone Capsule) Product Summary[1,2,3]

Therapeutic Class: Antianxiety agent

Indication(s): Anxiety

How Supplied: 7.5mg, 10mg, 15mg oral capsules

Dosing and Administration:

- The initial recommended dose is 7.5mg twice daily, titrated every 2 to 3 days to optimal therapeutic response, as needed. The maximum daily dose is 60mg/day.
- For patients who have difficulty swallowing capsules, Bucapsol™ may be opened and the contents sprinkled on a small amount (about 1-2 tablespoons) of applesauce, which should be swallowed immediately.

Other Formulation(s) Available:

- Buspirone 5mg, 7.5mg, 10mg, 15mg, 30mg tablets:
  - Bucapsol™ and buspirone tablets have the same indication and recommended dose.
  - Buspirone tablets may be crushed and compounded into an oral solution.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
Bucapsol™ (buspirone) 15mg capsule	**$49.72**	**$2,983.20**	**$35,798.40**
buspirone 15mg tablet (generic)	$0.05	$3.00	$36.00

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).
*Cost per 30 days is based on an FDA approved dose of 30mg daily.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of Bucapsol™ during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
BUSPIRONE TAB 10MG	21,880	8,599	$248,619.72	2.54	$11.36
BUSPIRONE TAB 15MG	17,996	6,091	$261,321.47	2.95	$14.52
BUSPIRONE TAB 5MG	13,760	6,161	$148,702.62	2.23	$10.81
BUSPIRONE TAB 30MG	7,364	2,039	$151,694.67	3.61	$20.60
BUSPIRONE TAB 7.5MG	5,630	2,460	$115,778.96	2.29	$20.56
TOTAL	**66,630**	**21,675***	**$926,117.44**	**3.07**	**$13.90**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet

Carbamazepine 200mg Chewable Tablet Product Summary[4]

Therapeutic Class: Anticonvulsant

Indication(s):
- Epilepsy
- Treatment of the pain associated with trigeminal neuralgia

How Supplied: 200mg chewable tablet with cherry fragrance

Dosing and Administration:
- Epilepsy:
  - Adults and Children ≥12 Years of Age: Initial 400mg/day; maintenance 800 to 1,200mg/day
    - Dosage generally should not exceed 1,000mg/day in children 12 to 15 years of age or 1,200mg/day in patients older than 15 years of age. Doses up to 1,600mg/day have been used in adults in rare instances.
  - Children 6 to 12 years of Age: Initial 200mg/day; maintenance 400 to 800mg/day
    - Dosage should generally not exceed 1,000mg/day.
  - Children under 6 years of Age: Initial 10mg/kg/day to 20mg/kg/day; maintenance up to 35mg/kg/day
    - Dosage should not exceed 35mg/kg/day as the safety has not been established.
- Trigeminal neuralgia:
  - Adults: Initial 100mg orally twice daily, may increase by 100mg every 12 hours as needed for pain control with a maximum dose of 1,200mg/day

Other Formulation(s) Available:
- Carbamazepine 100mg chewable tablet
- Carbamazepine 200mg tablet
- Carbamazepine 100mg, 200mg, and 400mg ER tablets
- Carbamazepine 100mg, 200mg, and 300mg ER capsules
- Carbamazepine 100mg/5mL oral suspension

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
carbamazepine 200mg chewable (generic)	**$1.50**	**$360.00**	**$4,320.00**
carbamazepine 100mg chewable (generic)	$0.25	$120.00	$1,440.00
carbamazepine 200mg (generic)	$0.13	$31.20	$374.40

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 30 days is based on an FDA approved maximum dose for an adult with epilepsy of 1,600mg per day.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of carbamazepine 200mg chewable tablet during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
CARBAMAZEPINE TAB 200MG	2,713	665	$67,668.34	4.08	$24.94
CARBAMAZEPINE TAB 400MG ER	490	96	$48,401.77	5.1	$98.78
CARBAMAZEPINE CHW 100MG	320	83	$15,782.29	3.86	$49.32
CARBAMAZEPINE TAB 200MG ER	284	88	$16,605.97	3.23	$58.47
CARBAMAZEPINE TAB 100MG ER	277	101	$10,193.36	2.74	$36.80
CARBAMAZEPINE CAP 300MG ER	247	57	$28,441.99	4.33	$115.15
CARBAMAZEPINE CAP 200MG ER	207	55	$27,492.72	3.76	$132.82
CARBAMAZEPINE SUS 100MG/5ML	196	22	$14,455.38	8.91	$73.75
CARBAMAZEPINE CAP 100MG ER	112	46	$8,211.80	2.43	$73.32
TEGRETOL TAB 200MG	36	5	$20,150.45	7.2	$559.73
TEGRETOL-XR TAB 400MG	27	5	$19,271.56	5.4	$713.76
TEGRETOL-XR TAB 200MG	24	7	$10,680.96	3.43	$445.04
EPITOL TAB 200MG	24	18	$407.56	1.33	$16.98
TEGRETOL SUS 100MG/5ML	22	4	$13,660.30	5.5	$620.92
CARBATROL CAP 200MG	15	3	$2,061.38	5	$137.43
CARBATROL CAP 300MG	8	2	$1,582.68	4	$197.84
TEGRETOL-XR TAB 100MG	3	2	$715.18	1.5	$238.39
CARBATROL CAP 100MG	1	1	$166.96	1	$166.96
TOTAL	**5,006**	**1,098***	**$305,950.65**	**4.56**	**$61.12**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CHW = chewable; ER = extended release; SUS = suspension; TAB = tablet; XR = extended release

Femlyv™ (Norethindrone Acetate/Ethinyl Estradiol ODT) Product Summary[5,6]

Therapeutic Class: Contraceptives

Indication(s): For use by females of reproductive potential to prevent pregnancy

How Supplied:

- 24 ODTs each containing 1mg of norethindrone acetate and 20mcg of ethinyl estradiol
- 4 inert ODTs
- Each ODT is spearmint flavored

Dosing and Administration:

- Place 1 tablet on the tongue, allow it to disintegrate and then follow with 8oz of water
- Take at the same time daily without regards to meals
- Take ODTs in the order directed on the blister pack

Other Formulation(s) Available:

- Norethindrone acetate-ethinyl estradiol 1mg-20mcg tablets

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per Year
Femlyv™ (noreth/ethinyl estradiol 1mg/20mcg ODT)	**$7.04**	**$2,562.56***
noreth/ethinyl estradiol 1mg/20mcg tablet (generic)	$0.17	$46.41[+]

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).
noreth = norethindrone acetate; ODT = orally disintegrating tablet
*Cost per year based on the FDA approved dose of 1 ODT daily.
[+]Cost per year based on the FDA approved dose of 1 tablet daily for 21 days with 7 days off.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of Femlyv™ during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
NORETH/ETHIN TAB 1MG/20MCG	1,892	677	$40,653.34	2.79	$18.68
MICROGESTIN TAB 1MG/20MCG	986	290	$18,418.31	3.4	$20.70
JUNEL 1MG/20MCG TAB	252	93	$5,216.05	2.71	$17.15
LOESTRIN TAB 1MG/20MCG-21	8	4	$137.20	2	$16.68
LARIN TAB 1MG/20MCG	1	1	$16.68	1	$20.53
TOTAL	**3,139**	**1,011***	**$64,441.58**	**3.1**	**$18.68**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ETHIN = ethinyl estradiol; NORETH = norethindrone acetate; TAB = tablet

Focinvez™ (Fosaprepitant Injection) Product Summary[7,8]

Therapeutic Class: Substance P/neurokin-1 (NK1) receptor antagonist

Indication(s): For adults and pediatric patients 6 months of age and older, in combination with other antiemetic agents, for the prevention of the following:

- Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin
- Delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)

How Supplied: 150mg/5mL (3mg/mL) of fosaprepitant, in a single-dose vial for injection

Dosing and Administration:

- The recommended dose for adults is 150mg intravenously (IV) over 20 to 30 minutes for both HEC and MEC.

- Dexamethasone and a 5-HT_3 antagonist should be administered with Focinvez™ see full prescribing information for dosing of each and for pediatric dosing.

Other Formulation(s) Available:

- Fosaprepitant 150mg Vial (generic Emend® IV):
  - Emend® IV and Focinvez™ have the same indications and dose; however, Emend® IV needs to be reconstituted before use, while Focinvez™ is in a ready to use solution for injection.

Formulation Cost Comparison:

Product	Cost Per Vial
Focinvez™ (fosaprepitant 150mg/50mL injection)	**$453.00**
fosaprepitant 150mg/vial injection (generic)	$289.12[α]

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Acquisition Cost (SPAC).
[α]Cost per vial varies per NDC.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of Emend® IV or Focinvez™ during fiscal year 2024.

Imkeldi (Imatinib Oral Solution) Product Summary[9,10]

Therapeutic Class: Kinase inhibitor

Indication(s):

- Newly diagnosed Philadelphia positive chronic myeloid leukemia (Ph+ CML)
- Ph+ CML in blast crisis (BC), accelerated phase (AP) or chronic phase (CP) after interferon-alpha (IFN) therapy
- Adult patients with Ph+ acute lymphoblastic leukemia (ALL)
- Pediatric patients with Ph+ ALL
- Myelodysplastic/myeloproliferative diseases (MDS/MPD)
- Aggressive systemic mastocytosis (ASM)
- Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL)
- Dermatofibrosarcoma protuberans (DFSP)
- Kit+ gastrointestinal stromal tumors (GIST)
- Adjuvant treatment of GIST

How Supplied: 80mg/mL strawberry flavored oral solution in a 140mL bottle

Dosing and Administration:

- The recommended dose varies based on the diagnosis. See package labeling for details.

- All doses of Imkeldi should be taken with a meal and a large glass of water.
- Doses of 400mg or 600mg should be administered once daily, and a dose of 800mg should be administered as 400mg twice daily.
- The maximum dose is 800mg per day.

Other Formulation(s) Available:

- Imatinib 100mg and 400mg Tablets:
  - Imatinib tablets have the same indications and dosing as Imkeldi.
  - Imatinib tablets can be dispersed in a glass of water or apple juice for patients who are unable to swallow the film-coated tablets.
  - The required number of tablets should be placed in the appropriate volume of beverage (approximately 50mL for a 100mg tablet and 200mL for a 400mg tablet) and stirred with a spoon.
  - The suspension should be administered immediately after complete disintegration of the tablet(s).

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Imkeldi (imatinib 80mg/mL oral solution)	**$16.79**	**$5,037.00**	**$60,444.00**
imatinib 400mg tablet (generic)	$2.63	$157.80	$1,893.60

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 = mL or tablet
*Cost per 30 days is based on an FDA approved maximum dose of 800mg per day.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of Imkeldi during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
IMATINIB MES TAB 400MG	142	25	$8,784.36	5.68	$61.86
IMATINIB MES TAB 100MG	54	9	$2,542.22	6	$47.08
TOTAL	**196**	**31***	**$11,326.58**	**6.32**	**$57.79**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
MES = mesylate; TAB = tablet

IVRA (Melphalan 90mg/mL Injection) Product Summary[11,12]

Therapeutic Class: Alkylating agent

Indication(s): Palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

How Supplied: 90mg/mL multi-dose vial for injection

Dosing and Administration:

- The recommended dose is 16mg/m^2 IV over 15 to 20 minutes at 2-week intervals for 4 doses, then at 4-week intervals until unacceptable toxicity.
- IVRA must be diluted in 0.9% sodium chloride to obtain a solution with a concentration not greater than 0.45mg/mL.
- The diluted product is stable for 1 hour at room temperature.
- It should be infused over 15 to 20 minutes via an injection port or central venous catheter.

Other Formulation(s) Available:

- Melphalan 50mg Vials:
  - The 50mg vials have the same indication and dosing as IVRA.
  - The difference between IVRA and melphalan 50mg vials is that the 50mg vials must be reconstituted with 10mL of diluent before being diluted in 0.9% sodium chloride to a concentration not greater than 0.45mg/mL.
  - The diluted product should be administered over a minimum of 15 minutes and the administration should be completed within 60 minutes of reconstitution.

Formulation Cost Comparison:

Product	Cost Per Vial
IVRA (melphalan 90mg/mL injection)	**$5,500.00**
melphalan 50mg vial for injection (generic)	$157.10

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), State Maximum Allowable Costs (SMAC), or Specialty Pharmaceutical Acquisition Cost (SPAC).

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of IVRA or melphalan 50mg/10mL vials during fiscal year 2024.

Myhibbin™ (Mycophenolate Mofetil Oral Suspension) Product Summary[13,14]

Therapeutic Class: Immunosuppressive agent

Indication(s): Prophylaxis of organ rejection, in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart, or liver transplants in combination with other immunosuppressants

How Supplied: 200mg/mL raspberry flavored oral suspension in 175mL bottle

Dosing and Administration:

- Kidney Transplant:
  - The recommended dosage for adult patients is 1g orally, administered twice daily.
  - Pediatric dosing is based on body surface area (BSA). The recommended dosage for pediatric patients ≥3 months old is 600mg/m^2, administered twice daily (maximum daily dose of 2g or 10mL of the oral suspension).
- Heart or Liver Transplant:
  - The recommended dosage for adult patients is 1.5g orally administered twice daily.
  - The recommended starting dosage for pediatric patients ≥3 months is 600mg/m^2, administered twice daily. If well tolerated, the dose can be increased to a maintenance dosage of 900mg/m^2 administered twice daily (maximum total daily dose of 3g or 15mL of the oral suspension).
  - The dose may be individualized based on clinical assessment.

Other Formulation(s) Available:

- Mycophenolate Mofetil 200mg/mL for Oral Suspension:
  - The mycophenolate mofetil 200mg/mL for oral suspension has the same indication and dosing as Myhibbin™.
  - It is supplied as a white to off-white granular powder blend for reconstitution that has a gum-fruit flavor.
  - The difference between the 2 products is mycophenolate mofetil 200mg/mL for oral suspension needs to be reconstituted before use, and Myhibbin™ is a ready to use product that does not need to be reconstituted.

Formulation Cost Comparison:

Product	Cost Per mL	Cost Per 30 Days*	Cost Per Year
Myhibbin™ (mycophen 200mg/mL oral sus)	**$4.36**	**$1,962.00**	**$23,544.00**
mycophen 200mg/mL for oral sus (generic)	$1.71	$769.50	$9,234.00

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).
MYCOPHEN = mycophenolate mofetil; SUS = suspension
*Cost per 30 days based on the FDA maximum dose of 3g daily for heart or liver transplant patients.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of Myhibbin™ during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
MYCOPHEN SUS 200MG/ML	227	50	$84,234.65	4.54	$371.08
TOTAL	**227**	**50***	**$84,234.65**	**4.54**	**$371.08**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
MYCOPHEN = mycophenolate mofetil; SUS = suspension

Ondansetron 16mg ODT Product Summary[15,16]

Therapeutic Class: 5-HT_3 receptor antagonist

Indication(s):

- Prevention of nausea and vomiting associated with:
  - HEC, including cisplatin greater than or equal to 50 mg/m^2
  - Initial and repeat courses of MEC
  - Radiotherapy in patients receiving either total body irradiation, single high-dose faction to the abdomen, or daily fractions to the abdomen
- Prevention of postoperative nausea and vomiting

How Supplied: 16mg ODT

Dosing and Administration:

- HEC: 24mg dose administered 30 minutes before the start of chemotherapy
- MEC: 8mg administered 30 minutes before the start of chemotherapy, with subsequent 8-mg dose 8 hours after the first dose, then administer 8mg twice a day (every 12 hours) for 1 to 2 days after completion of chemotherapy
- Radiotherapy: 8mg administered 1 to 2 hours before radiotherapy; subsequent doses depend on the type of radiation
- Postoperative: 16mg administered 1 hour before the induction of anesthesia

Other Formulation(s) Available:

- Ondansetron 4mg and 8mg ODT:
  - Ondansetron 16mg ODT is only indicated for the prevention of postoperative nausea and vomiting.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per Dose*
ondansetron 16mg ODT (generic)	**$41.52**	**$41.52**
ondansetron 4mg ODT (generic)	$0.17	$0.68
ondansetron 8mg ODT (generic)	$0.18	$0.36

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 dose is based on the FDA approved dosing for the prevention of postoperative nausea and vomiting of 16mg administered 1 hour before induction of anesthesia.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of ondansetron 16mg ODT during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
ONDANSETRON 4MG ODT	104,746	79,516	$1,449,444.01	1.32	$13.84
ONDANSETRON 8MG ODT	20,243	13,372	$288,398.85	1.51	$14.25
TOTAL	**124,989**	**90,248***	**$1,737,842.86**	**1.38**	**$13.90**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ODT = orally disintegrating tablet

Tezruly™ (Terazosin Oral Solution) Product Summary[17,18,19]

Therapeutic Class: Alpha-1 adrenoceptor antagonist

Indication(s):
- Benign prostatic hyperplasia (BPH)
- Hypertension (HTN)

How Supplied: 1mg/mL cherry flavored oral solution

Dosing and Administration:
- For the treatment of BPH:
  - Initiate therapy at 1mg orally once daily at bedtime.
  - Titrate the dose upwards stepwise from 2mg to 10mg once daily.
  - Doses of 10mg once daily are generally required for a clinical response.
  - Data is insufficient to support doses greater than 20mg once daily.
- For the treatment of HTN:
  - Initiate therapy at 1mg orally once daily at bedtime.
  - The usual recommended dose range is 1mg to 5mg once daily.
  - If response is substantially diminished at 24 hours, increase the dose or use twice daily.
  - Dose may be titrated as needed up to 20mg once daily.

Other Formulation(s) Available:
- Terazosin 1mg, 2mg, 5mg, and 10mg Capsules:
  - Terazosin capsules have the same indications and dosing as Tezruly™.
  - The package labeling does not specify whether the terazosin capsules may be opened for patients with difficulties swallowing.
- Silodosin 4mg and 8mg Capsules:
  - Silodosin is indicated for the treatment of BPH, and the recommended dose is 8mg daily.
  - The capsules may be opened and the powder sprinkled on applesauce for patients with difficulties swallowing.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Tezruly™ (terazosin 1mg/mL oral solution)	**$3.17**	**$1,902.00***	**$22,824.00**
silodosin 8mg capsule (generic)	$0.52	$15.60+	$187.20
terazosin 10mg capsule (generic)	$0.15	$9.00*	$108.00

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 mL
*Cost per 30 days is based on the FDA approved maximum dose of 20mg daily for both BPH and HTN.
+Cost per 30 days is based on the FDA approved maximum dose of 8mg daily for BPH.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of Tezruly™ during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TERAZOSIN CAP 1MG	327	135	$5,009.06	2.42	$15.32
TERAZOSIN CAP 2MG	223	84	$4,158.40	2.65	$18.65
TERAZOSIN CAP 5MG	178	56	$3,540.09	3.18	$19.89
TERAZOSIN CAP 10MG	84	26	$1,610.14	3.23	$19.17
SILODOSIN CAP 8MG	71	23	$2,327.17	3.09	$32.78
SILODOSIN CAP 4MG	9	5	$252.70	1.8	$28.08
TOTAL	**892**	**305***	**$16,897.56**	**2.92**	**$18.94**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule

Topiramate 50mg Sprinkle Capsule Product Summary[20,21]

Therapeutic Class: Anticonvulsant

Indication(s):
- Epilepsy
- Migraine

How Supplied: 50mg oral sprinkle capsule

Dosing and Administration:
- Epilepsy:
  - The recommended daily dose for patients ≥17 years of age is 200mg/day to 400mg/day in 2 divided doses depending on the type of seizures.
  - The recommended daily dose for pediatric patients 2 to 16 years of age is 5mg/kg/day to 9mg/kg/day in 2 divided doses with the dose not exceeding 400mg/day.

- Preventative Treatment of Migraine:
  - The recommended daily dose for patients ≥12 years of age is 100mg/day administered in 2 divided doses.
- The topiramate dose should be titrated in 25mg/day to 50mg/day every week depending on the diagnosis.
- Topiramate capsules may be swallowed whole or may be administered by carefully opening the capsule and sprinkling the entire contents on a small amount (teaspoon) of soft food.
- This drug/food mixture should be swallowed immediately and not chewed.
- It should not be stored for future use.

Other Formulation(s) Available:

- Topiramate 15mg and 25mg sprinkle capsules
- Topiramate 25mg, 50mg, 100mg, 200mg tablets

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
topiramate 50mg sprinkle capsules (generic)	**$4.38**	**$1,051.20**	**$12,614.40**
topiramate 25mg sprinkle capsules (generic)	$0.43	$206.40	$2,476.80
topiramate 100mg tablet (generic)	$0.06	$7.20	$86.40

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).
Unit = capsule or tablet
*Cost per 30 days is based on the FDA approved maximum dose of 400mg/day.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of topiramate 50mg sprinkle capsule during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
TOPIRAMATE TAB 50MG	13,291	4,862	$158,234.14	2.73	$11.91
TOPIRAMATE TAB 25MG	12,995	5,870	$148,813.45	2.21	$11.45
TOPIRAMATE TAB 100MG	8,331	2,385	$119,155.48	3.49	$14.30
TOPIRAMATE TAB 200MG	2,597	571	$43,968.83	4.55	$16.93
TOPIRAMATE SPRINKLE CAP 25MG	279	65	$30,736.00	4.29	$110.16
TOPIRAMATE SPRINKLE CAP 15MG	172	50	$7,328.31	3.44	$42.61
TOPAMAX TAB 200MG	23	3	$39,865.67	7.67	$1,733.29
TOPAMAX TAB 100MG	15	2	$46,159.46	7.5	$3,077.30
TOPAMAX TAB 50MG	7	1	$875.02	7	$125.00
TOPAMAX SPRINKLE CAP 25MG	1	1	$13,495.31	1	$13,495.31
TOTAL	**37,711**	**11,640***	**$608,631.67**	**3.24**	**$16.14**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet

Veltassa® (Patiromer) 1g Powder Packet Product Summary[22]

Therapeutic Class: Potassium binder

Indication(s): Treatment of hyperkalemia in adults and pediatric patients aged 12 years and older

How Supplied: Single-use packets containing 1g of Veltassa® for oral suspension

Dosing and Administration:

- Adults: The recommended starting dose of Veltassa® is 8.4g orally once daily. The dose can be up-titrated based on serum potassium level at 1-week or longer intervals, in increments of 8.4g.
- Pediatric Patients Ages 12 years and older: The recommended starting dose of Veltassa® is 4g orally once daily. The dose can be titrated based on serum potassium level at 1-week or longer intervals, in increments of 4g.
- The maximum dose is 25.2g once daily in both adults and pediatric patients aged 12 years and older.
- Each dose should be prepared immediately prior to administration by mixing with water or soft foods (e.g., apple sauce, yogurt, or pudding). Follow preparation instructions in package labeling.

Other Formulation(s) Available: Veltassa® is also supplied in single-use packets containing 8.4g, 16.8g, and 25.2g for oral suspension

Formulation Cost Comparison:

Product	Cost Per Packet	Cost Per 30 Days	Cost Per Year
Veltassa® (patiromer) 1g packet	**$8.88**	**$1,065.60***	**$12,787.20**
Veltassa® (patiromer) 25.2g packet	$34.16	$1,024.80+	$12,297.60
Veltassa® (patiromer) 16.8g packet	$34.09	$1,022.70+	$12,272.40
Veltassa® (patiromer) 8.4g packet	$34.06	$1,021.80+	$12,261.60

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).
*Cost per 30 days is based on the recommended starting dose of 4g orally once daily.
+Cost per 30 days is based on the use of 1 packet daily.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of Veltassa® 1g or 25.2g packets during fiscal year 2024

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
VELTASSA POW 8.4G	78	27	$58,626.34	2.89	$751.62
VELTASSA POW 16.8G	2	2	$1,917.36	1	$958.68
TOTAL	**80**	**29***	**$60,543.70**	**2.76**	**$756.80**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
POW = powder

Vigafyde™ (Vigabatrin Oral Solution) Product Summary[23,24]

Therapeutic Class: Antiepileptic

Indication(s): Monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss

How Supplied: 100mg/mL peppermint flavored oral solution in 150mL bottle

Dosing and Administration:

- Vigafyde™ is a concentrated formulation as compared to other vigabatrin products. The strength and the dose of the product should be verified prior to prescribing, dispensing, and administering.
- Initial Dosing: 50mg/kg/day in 2 divided doses (25mg/kg twice daily)
- Subsequent Dosing: May titrate by increasing the total daily dosage every 3 days, in increments of 25mg/kg/day to 50mg/kg/day, up to a maximum daily dosage of 150mg/kg/day (75mg/kg twice daily)

Other Formulation(s) Available:

- Sabril® (Vigabatrin) for Oral Solution:
  - Sabril® is indicated for both infantile spasms and refractory complex partial seizures (CPS).
  - Sabril® is supplied in packets containing a 500mg powder of Sabril® that should be mixed with 10mL of water making a 50mg/mL solution. It should be administered immediately after mixing and any unused portion should be discarded.
  - The recommended dose for infantile spasms is the same for both Sabril® and Vigafyde™; however, the concentration is different between the products and Sabril® must be reconstituted before use while Vigafyde™ is a ready to use solution.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Vigafyde™ (vigabatrin) 100mg/mL sol	**$23.70**	**$17,064.00**	**$204,768.00**
Sabril® (vigabatrin) 500mg powder for oral sol	$201.82[+]	$29,059.20	$348,710.40

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).
Unit = mL or packet; sol = solution
*Cost per 30 days is based on the FDA maximum dose for infantile spasms of 150mg/kg/day for a 16kg patient.
[+]Each packet provides 10mL of a 50mg/mL solution once reconstituted.

Fiscal Year 2024 Utilization: There was no SoonerCare utilization of Vigafyde™ during fiscal year 2024.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
VIGABATRIN PAK 500MG	163	28	$328,707.89	5.82	$2,016.61
SABRIL POW 500MG	38	20	$945,004.18	1.9	$24,868.53
VIGADRONE POW 500MG	3	1	$25,929.99	3	$8,643.33
TOTAL	**204**	**32***	**$1,299,642.06**	**6.38**	**$6,370.79**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
PAK = packet; POW = powder

Recommendations

The College of Pharmacy recommends the prior authorization of Bucapsol™ (buspirone capsules) and carbamazepine 200mg chewable tablet with the following criteria (shown in red):

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.

Carbamazepine 200mg Chewable Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other forms of carbamazepine that are available without a prior authorization, including using 2 of the 100mg chewable tablets to achieve the 200mg dose, must be provided; and
2. A quantity limit of 720 chewable tablets per 90 days will apply.

The College of Pharmacy also recommends the prior authorization of Femlyv™ (norethindrone acetate and ethinyl estradiol ODT) with criteria similar to Nextstellis® (drospirenone/estetrol tablet) and Slynd® (drospirenone tablet) with the following criteria (shown in red):

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 a prior authorization must be provided.

Additionally, the College of Pharmacy recommends the prior authorization of Focinvez™ (fosaprepitant) with criteria similar to Anzemet® (dolasetron), Cinvanti® and Emend® (aprepitant), Emend® IV (fosaprepitant), and Kytril® and Sancuso® (granisetron) with the following additional updates to be consistent with clinical practice and net costs (changes shown in red):

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 ~~of Emend® (aprepitant)~~ 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.

The College of Pharmacy recommends the prior authorization of Imkeldi (imatinib oral solution), IVRA (melphalan 90mg/mL), Myhibbin™ (mycophenolate mofetil oral suspension), and ondansetron 16mg ODT with the following criteria (shown in red):

Imkeldi (Imatinib Oral Solution) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use imatinib tablets, which are available without a prior authorization, must be provided. Imatinib tablets may be dispersed in a glass of water or apple juice to form a suspension for members who cannot swallow the film-coated tablets.

IVRA (Melphalan 90mg/mL) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason why the member cannot use generic melphalan 50mg/10mL vial which is 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.

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.

The College of Pharmacy also recommends the prior authorization of Tezruly™ (terazosin oral solution) with placement into the Special Prior Authorization (PA) Tier of the Benign Prostatic Hyperplasia (BPH) Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

Tezruly™ (Terazosin Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH) or hypertension (HTN); and
2. A patient specific, clinically significant reason why the member cannot use terazosin capsules must be provided; and
3. For a diagnosis of BPH, a patient specific, clinically significant reason why the member cannot use Rapaflo® (silodosin), which may be opened and sprinkled on applesauce for patients with difficulties swallowing, must be provided; and
4. A quantity limit of 600mL per 30 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of topiramate 50mg sprinkle capsule with the following criteria (shown in red):

Topiramate 50mg Sprinkle Capsule Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use other available generic topiramate products, including using 2 topiramate 25mg sprinkle capsules to achieve the 50mg dose, must be provided; and
3. Members 12 years of age and older will require a patient-specific, clinically significant reason why a special formulation product is needed; and
4. A quantity limit of 240 capsules per 30 days will apply.

The College of Pharmacy also recommends the prior authorization of Veltassa® (patiromer) 1 gram packet with criteria similar to the other Veltassa® strengths with the following additional criteria (changes shown in red):

Veltassa® (Patiromer) Approval Criteria:

1. An FDA approved diagnosis of hyperkalemia; and
2. Medications known to cause hyperkalemia [e.g., aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the lowest effective dose where clinically appropriate; and
3. A trial of a potassium-eliminating diuretic or documentation why a diuretic is not appropriate for the member; and
4. Documentation of a low potassium diet; and
5. A patient-specific, clinically significant reason why the member cannot use Lokelma® (sodium zirconium cyclosilicate) must be provided; and
6. Quantity limits will apply as follows:
    a. 1g Packets: A quantity limit of 120 packets per 30 days will apply; or
    b. 8.4g, 16.8g, and 25.2g Packets: A quantity limit of 30 packets per month will apply.

The College of Pharmacy recommends the prior authorization of Vigafyde™ (vigabatrin oral solution) with the following criteria and updating the Sabril® (vigabatrin) criteria based on the Vigafyde™ FDA approval (changes shown in red):

Vigafyde™ (Vigabatrin Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of infantile spasms in children 1 month to 2 years of age; and
2. A patient-specific, clinically significant reason why the member cannot use brand name Sabril® (vigabatrin) for oral solution must be provided; and
3. Prescription must be written by, or in consultation with, a neurologist; and
4. Member, prescriber, and pharmacy must all register in the Vigabatrin REMS program and maintain enrollment throughout therapy.

Sabril® (Vigabatrin) Approval Criteria:

1. An FDA approved diagnosis of refractory complex seizures in adults and pediatric patients 2 years of age or older, or infantile spasms in children 1 month to 2 years of age; and
2. Authorization of generic vigabatrin (in place of brand Sabril®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
3. Members with refractory complex seizures must have previous trials of at least three other antiepileptic medications; or
4. Prescription must be written by, or in consultation with a neurologist; and

5. Member, prescriber, and pharmacy must all register in the Vigabatrin ~~SABRIL~~ REMS program and maintain enrollment throughout therapy.

The College of Pharmacy recommends updating the Jylamvo™ (methotrexate oral solution) based on the FDA label expansion to allow use of Jylamvo™ in pediatric patients for a diagnosis of acute lymphoblastic leukemia (ALL) or polyarticular juvenile idiopathic arthritis (pJIA) (changes shown in red):

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. Member must be 18 years of age or older; and~~

3. A patient-specific clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.

Finally, the College of Pharmacy recommends removal of SoonerCare coverage and of the prior authorization criteria for Aspruzyo Sprinkle™ due to product discontinuation (shown in red):

~~**Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules] Approval Criteria:**~~

~~1. An FDA approved diagnosis of chronic angina; and~~

~~2. A patient-specific, clinically significant reason why the member cannot use ranolazine ER tablets must be provided.~~

Utilization Details of Various Special Formulations: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LEVOTHYROXINE PRODUCTS						
TIROSINT CAP 125MCG	41	10	$6,775.98	$165.27	4.1	1.69%
TIROSINT-SOL 75MCG/ML	33	5	$4,906.12	$148.67	6.6	1.22%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIROSINT CAP 200	30	7	$11,250.53	$375.02	4.29	2.80%
TIROSINT CAP 112MCG	28	10	$6,347.09	$226.68	2.8	1.58%
TIROSINT-SOL 62.5MCG/ML	28	5	$4,193.69	$149.77	5.6	1.04%
TIROSINT-SOL 200MCG/ML	27	5	$3,820.67	$141.51	5.4	0.95%
TIROSINT CAP 25MCG	26	6	$6,373.83	$245.15	4.33	1.59%
TIROSINT CAP 100MCG	20	7	$5,712.90	$285.65	2.86	1.42%
TIROSINT CAP 75MCG	20	6	$5,172.36	$258.62	3.33	1.29%
TIROSINT CAP 137MCG	19	8	$4,790.07	$252.11	2.38	1.19%
TIROSINT-SOL 100MCG/ML	16	4	$2,338.73	$146.17	4	0.58%
TIROSINT CAP 50MCG	16	4	$3,593.22	$224.58	4	0.89%
TIROSINT CAP 150MCG	15	5	$2,918.39	$194.56	3	0.73%
LEVOTHYROXINE CAP 75MCG	13	6	$2,604.79	$200.37	2.17	0.65%
TIROSINT-SOL 37.5MCG/ML	13	2	$1,937.48	$149.04	6.5	0.48%
TIROSINT-SOL 125MCG/ML	12	4	$1,764.43	$147.04	3	0.44%
LEVOTHYROXINE CAP 112MCG	12	3	$2,812.71	$234.39	4	0.70%
TIROSINT CAP 175MCG	11	5	$2,077.75	$188.89	2.2	0.52%
TIROSINT-SOL 50MCG/ML	11	2	$1,245.00	$113.18	5.5	0.31%
TIROSINT-SOL 88MCG/ML	10	3	$1,495.19	$149.52	3.33	0.37%
TIROSINT-SOL 44MCG/ML	9	3	$1,353.69	$150.41	3	0.34%
TIROSINT CAP 37.5MCG	9	5	$1,290.03	$143.34	1.8	0.32%
LEVOTHYROXINE CAP 50MCG	8	6	$1,150.33	$143.79	1.33	0.29%
TIROSINT-SOL 25MCG/ML	7	3	$1,040.82	$148.69	2.33	0.26%
TIROSINT CAP 88MCG	6	4	$818.71	$136.45	1.5	0.20%
LEVOTHYROXINE CAP 88MCG	5	4	$580.45	$116.09	1.25	0.14%
TIROSINT-SOL 112MCG/ML	5	2	$752.05	$150.41	2.5	0.19%
LEVOTHYROXINE CAP 100MCG	5	3	$652.86	$130.57	1.67	0.16%
TIROSINT-SOL 150MCG/ML	5	3	$857.95	$171.59	1.67	0.21%
LEVOTHYROXINE CAP 13MCG	4	3	$747.51	$186.88	1.33	0.19%
LEVOTHYROXINE CAP 150MCG	4	2	$447.16	$111.79	2	0.11%
ERMEZA SOL 150MCG/5ML	4	2	$397.11	$99.28	2	0.10%
LEVOTHYROXINE CAP 25MCG	3	2	$383.83	$127.94	1.5	0.10%
TIROSINT-SOL 137MCG/ML	2	1	$282.76	$141.38	2	0.07%
TIROSINT CAP 44MCG	1	1	$148.41	$148.41	1	0.04%
TIROSINT CAP 62.5MCG	1	1	$143.06	$143.06	1	0.04%
LEVOTHYROXINE CAP 125MCG	1	1	$111.79	$111.79	1	0.03%
SUBTOTAL	**480**	**153**	**$93,289.45**	**$194.35**	**3.14**	**23.20%**
DROSPIRENONE PRODUCTS						
SLYND TAB 4MG	205	116	$73,562.23	$358.84	1.77	18.30%
SUBTOTAL	**205**	**116**	**$73,562.23**	**$358.84**	**1.77**	**18.30%**
METHOTREXATE PRODUCTS						
XATMEP SOL 2.5MG/ML	50	16	$26,638.83	$532.78	3.13	6.63%
RASUVO INJ 25MG	42	9	$20,904.35	$497.72	4.67	5.20%
RASUVO INJ 7.5MG	36	5	$20,094.76	$558.19	7.2	5.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RASUVO INJ 15MG	25	6	$12,552.19	$502.09	4.17	3.12%
RASUVO INJ 20MG	12	7	$6,509.40	$542.45	1.71	1.62%
RASUVO INJ 12.5MG	4	1	$2,245.08	$561.27	4	0.56%
RASUVO INJ 10MG	4	2	$2,224.40	$556.10	2	0.55%
OTREXUP INJ 25MG	3	1	$273.87	$91.29	3	0.07%
OTREXUP INJ 17.5MG	2	1	$1,494.02	$747.01	2	0.37%
OTREXUP INJ 10MG	1	1	$783.05	$783.05	1	0.19%
RASUVO INJ 22.5MG	1	1	$555.41	$555.41	1	0.14%
SUBTOTAL	**180**	**50**	**$94,275.36**	**$523.75**	**3.6**	**23.45%**
MERCAPTOPURINE PRODUCTS						
PURIXAN SUS 20MG/ML	67	18	$81,750.85	$1,220.16	3.72	20.33%
SUBTOTAL	**67**	**18**	**$81,750.85**	**$1,220.16**	**3.72**	**20.33%**
DROSPIRENONE/ESTETROL PRODUCTS						
NEXTSTELLIS TAB 3MG/14.2MG	**59**	26	$14,891.52	$252.40	6	3.70%
SUBTOTAL	**59**	**26**	**$14,891.52**	**$252.40**	**6**	**3.70%**
POTASSIUM PRODUCTS						
KLOR-CON PAK 20MEQ	50	27	$2,910.75	$58.22	1.85	0.72%
POT CHLORIDE POW 20MEQ	6	5	$302.74	$50.46	1.2	0.08%
SUBTOTAL	**56**	**32**	**$3,213.49**	**$57.38**	**1.75**	**0.80%**
GABAPENTIN PRODUCTS						
HORIZANT TAB 600MG ER	9	4	$10,045.66	$1,116.18	2.25	2.50%
GABAPENTIN DLY TAB 600MG	7	3	$2,049.25	$292.75	2.33	0.51%
GRALISE TAB 600MG	7	2	$2,807.30	$401.04	3.5	0.70%
GABAPENTIN DLY TAB 300MG	5	3	$1,344.94	$268.99	1.67	0.33%
GRALISE TAB 900MG	1	1	$923.27	$923.27	1	0.23%
SUBTOTAL	**29**	**13**	**$17,170.42**	**$592.08**	**2.23**	**4.27%**
PREGABALIN PRODUCTS						
PREGABALIN ER TAB 165MG	18	7	$2,538.52	$141.03	2.57	0.63%
PREGABALIN ER TAB 330MG	8	1	$1,984.53	$248.07	8	0.49%
SUBTOTAL	**26**	**8**	**$4,523.05**	**$173.96**	**3.25**	**1.13%**
NORETHINDRONE ACE/ETHINYL ESTRADIOL/FE PRODUCTS						
GEMMILY CAP 1MG/20MCG	13	2	$551.87	$42.45	6.5	0.14%
TAYTULLA CAP 1MG/20MCG	7	1	$1,612.31	$230.33	7	0.40%
NORE/ETH/FE CAP 1MG/20MCG	1	1	$73.91	$73.91	1	0.02%
SUBTOTAL	**21**	**4**	**$2,238.09**	**$106.58**	**5.25**	**0.56%**
LACTULOSE PRODUCTS						
KRISTALOSE PAK 10GM	11	10	$1,835.13	$166.83	1.1	0.46%
KRISTALOSE PAK 20GM	6	5	$2,004.33	$334.06	1.2	0.50%
SUBTOTAL	**17**	**15**	**$3,839.46**	**$225.85**	**1.13**	**0.96%**
LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE PRODUCTS						
PHEXXI GEL 1.8/1/0.4%	15	10	$5,153.99	$343.60	1.5	1.28%
SUBTOTAL	**15**	**10**	**$5,153.99**	**$343.60**	**1.5**	**1.28%**
PILOCARPINE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VUITY SOL 1.25% OP	4	2	$514.48	$128.62	2	0.13%
SUBTOTAL	**4**	**2**	**$514.48**	**$128.62**	**2**	**0.13%**
ISOTRETINOIN PRODUCTS						
ABSORICA LD CAP 24MG	2	1	$5,041.66	$2,520.83	2	1.25%
SUBTOTAL	**2**	**1**	**$5,041.66**	**$2,520.83**	**2**	**1.25%**
METOCLOPRAMIDE PRODUCTS						
GIMOTI SPR 15MG	1	1	$1,934.41	$1,934.41	1	0.48%
SUBTOTAL	**1**	**1**	**$1,934.41**	**$1,934.41**	**1**	**0.48%**
PYRIDOSTIGMINE PRODUCTS						
PYRIDOSTIGMINE TAB 30MG	1	1	$638.07	$638.07	1	0.16%
SUBTOTAL	**1**	**1**	**$638.07**	**$638.07**	**1**	**0.16%**
TOTAL	**1,163**	**404***	**$402,036.53**	**$345.69**	**2.88**	**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; INJ = injection; LD = low-dose; NORE = norethindrone; OP = ophthalmic; PAK = packet; POT = potassium; POW = powder; SPR = spray; SOL = solution; SUS = suspension; TAB = tablet

- There were no SoonerCare paid pharmacy claims for fiscal year 2024 for the following various special formulation products: Aspruzyo Sprinkle™ (ranolazine ER granules), GoNitro™ (nitroglycerin sublingual powder), Jylamvo® (methotrexate oral solution), Khapzory® (levoleucovorin injection), Lodoco® (colchicine), Metozolv® ODT [metoclopramide orally disintegrating tablet (ODT)], Pokonza™ (potassium chloride 10mEq packet), RediTrex® (methotrexate injection solution), Soltamox® (tamoxifen citrate 10mg/5mL oral solution), and Thyquidity® (levothyroxine oral solution).

[1] Bucapsol™ Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f101c5f3-d533-474d-a8bf-90d054933d16. Last revised 05/01/2025. Last accessed 05/29/2025.
[2] Buspirone Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=07a789a9-c9e8-4737-a56d-7d5405fe8100. Last revised 01/19/2023. Last accessed 05/29/2025.
[3] Allen L. Buspirone 2.5mg/mL Oral Liquid. *US Pharm.* 2015;40(11):58-59.
[4] Carbamazepine Tablet and Suspension Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0526a054-3eda-49b4-b390-7d5d16e30af8. Last revised 10/29/2024. Last accessed 04/25/2025.
[5] Femlyv™ (Norethindrone Acetate and Ethinyl Estradiol Orally Disintegrating Tablets) Prescribing Information. Millicent U.S., Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218718s000lbl.pdf. Last revised 07/2024. Last accessed 05/01/2025.

[6] Norethindrone Acetate and Ethinyl Estradiol Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5a44f7a2-45f1-4d28-b9fb-61d9f2456422. Last revised 06/26/2024. Last accessed 05/01/2025.
[7] Focinvez™ (Fosaprepitant Injection) Prescribing Information. Spes Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216686s000lbl.pdf. Last revised 08/2023. Last accessed 05/02/2025.
[8] Fosaprepitant for Injection Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3f942e4c-e26a-4155-9e14-344b2970b189. Last revised 02/28/2024. Last accessed 05/29/2025.
[9] Imkeldi (Imatinib Oral Solution) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=26658bb7-9ba1-a10e-e063-6394a90a172e. Last revised 12/05/2024. Last accessed 05/01/2025.
[10] Imatinib Mesylate Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c0611fc0-b217-4988-acd4-b8c629ce489b. Last revised 04/09/2025. Last accessed 05/01/2025.
[11] IVRA (Melphalan Hydrochloride Injection) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=c23e868a-dc62-2181-5099-76c9226602b2&version=3. Last revised 03/19/2025. Last accessed 05/01/2025.
[12] Melphalan Hydrochloride for Injection Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6c957ec5-2ab4-49c0-9f36-1df4f93e3d58. Last revised 07/27/2022. Last accessed 05/01/2025.
[13] Myhibbin™ (Mycophenolate Mofetil Suspension) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d9af72d6-7b3e-4c08-94b9-1d8b499cb7f9. Last revised 05/07/2024. Last accessed 05/01/2025.
[14] Mycophenolate Mofetil Powder for Oral Suspension Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at; https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=df3ba2e9-00bb-40af-8658-2c5fd2e398ef. Last revised 08/31/2023. Last accessed 05/01/2025.
[15] Ondansetron 16mg ODT Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c66d63cf-a0e5-4cb5-bdf8-9d1115cba23e. Last revised 06/24/24. Last accessed 05/23/2025.
[16] Ondansetron ODT Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ed1132ec-c2cd-4646-b69d-26663bb937a4. Last revised 02/10/2022. Last accessed 05/23/2025.
[17] Tezruly™ (Terazosin Oral Solution) Prescribing Information. ANI Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218139s000lbl.pdf. Last revised 07/2024. Last accessed 05/01/2025.
[18] Terazosin Capsules Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=130c84dc-b598-660f-e063-6294a90a8e46. Last revised 12/20/2024. Last accessed 05/01/2025.
[19] Silodosin Capsules Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e863be56-d303-43bb-915a-1b2568674e31. Last revised 11/24/2021. Last accessed 05/01/2025.
[20] Topiramate Capsule Coated Pellets Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e4886adf-199d-4b19-a4ef-75f8f94cb54e. Last revised 04/16/2025. Last accessed 05/13/2025.
[21] Topiramate Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=41a5a961-8756-464c-aef3-22f2c9047609. Last revised 08/26/2021. Last accessed 05/13/2025.
[22] Veltassa® (Patiromer) Prescribing Information. Vifor Pharma, Inc. Available online at: https://www.veltassa.com/pi. Last revised 01/2025. Last accessed 05/15/2025.
[23] Vigafyde™ (Vigabatrin) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=8d3d6316-33ab-41e8-9485-4495c218be56. Last revised 02/06/2025. Last accessed 05/15/2025.
[24] Sabril® (Vigabatrin Powder) Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a88ac1b4-e2c9-45c0-b321-47859021 72e3. Last revised 10/20/2021. Last accessed 05/15/2025.

Appendix S

Fiscal Year 2024 Annual Review of Rezdiffra™ (Resmetirom)

Oklahoma Health Care Authority
June 2025

Current Prior Authorization Criteria

Rezdiffra™ (Resmetirom) Approval Criteria:

1. An FDA approved indication of noncirrhotic nonalcoholic steatohepatitis (NASH); and
2. Member must be 18 years of age or older; and
3. Member must have moderate-to-advanced liver fibrosis (e.g., stage F2 or F3) confirmed by at least 1 of the following:
   a. FibroScan with vibration controlled transient elastography (VCTE) ≥8.5kPa and controlled attenuation parameter (CAP) ≥280dB/m; or
   b. Enhanced Liver Fibrosis (ELF) biochemical test score ≥9; or
   c. Liver biopsy showing stage F2 or F3 fibrosis with NASH; and
4. Member must not have known liver cirrhosis (e.g., stage F4); and
5. Must be used in conjunction with diet and exercise (clinical documentation of member's diet and exercise program must be included with the request); and
6. Prescriber must attest that metabolic comorbidities are being appropriately managed, including treatment for all of the following, if applicable:
   a. Type 2 diabetes; and
   b. Dyslipidemia; and
   c. Hypertension; and
7. Member must not be taking strong CYP2C8 inhibitors (e.g., gemfibrozil) or OATP1B1/OATP1B3 inhibitors (e.g., cyclosporine) concurrently with Rezdiffra™; and
8. If member is taking a moderate CYP2C8 inhibitor (e.g., clopidogrel) concurrently with Rezdiffra™, prescriber must agree to reduce the dose as required in the package labeling; and
9. If the member is taking a statin, prescriber must agree to adjust the statin dosage (when necessary) and monitor for statin-related adverse reactions; and
10. Must be prescribed by a gastroenterologist or hepatologist (or an advanced care practitioner with a supervising physician who is a gastroenterologist or hepatologist); and
11. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) will be approved if the prescriber

documents the member is tolerating and responding well to the medication; and

12. A quantity limit of 30 tablets per 30 days will apply.

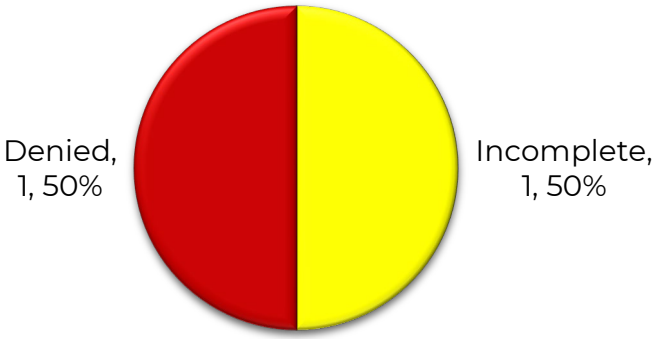
Utilization of Rezdiffra™ (Resmetirom): Fiscal Year 2024

There was no SoonerCare utilization of Rezdiffra™ (resmetirom) during fiscal year 2024 (07/01/2023 to 06/30/2024).

Prior Authorization of Rezdiffra™ (Resmetirom)

There were 2 prior authorization requests submitted for Rezdiffra™ (resmetirom) during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	0	0%	1	50%	1	50%	**2**
Aetna	0	N/A	0	N/A	0	N/A	**0**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**0**	**0%**	**1**	**50%**	**1**	**50%**	**2**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health
Please note: Only data from 04/01/2024 to 06/30/2024 are available for SoonerSelect plans.

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Rezdiffra™ (resmetirom): September 2033

Pipeline:

- **Wegovy® (Semaglutide):** Injectable semaglutide is being studied for the treatment of metabolic dysfunction-associated steatohepatitis (MASH). In April 2025, Novo Nordisk announced that the results of the

Phase 3 ESSENCE trial have been published in *The New England Journal of Medicine*. When compared to placebo, a statistically higher proportion of patients who received semaglutide 2.4mg once weekly achieved resolution of steatohepatitis with no worsening of liver fibrosis or improvement in liver fibrosis with no worsening of steatohepatitis at week 72. Additionally, Novo Nordisk announced that the U.S. Food and Drug Administration (FDA) has accepted their application and granted Priority Review for Wegovy® for the treatment of MASH. A Prescription Drug User Fee Act (PDUFA) date has not yet been announced.

Recommendations

The College of Pharmacy does not recommend any changes to the current Rezdiffra™ (resmetirom) prior authorization criteria at this time.

[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/index.cfm. Last revised 05/2025. Last accessed 05/21/2025.
[2] Novo Nordisk, Inc. ESSENCE Phase 3 Trial of Semaglutide Showed Significant Improvements at 72 Weeks in Adults with MASH, Published in NEJM. Available online at: https://www.prnewswire.com/news-releases/essence-phase-3-trial-of-semaglutide-showed-significant-improvements-at-72-weeks-in-adults-with-mash-published-in-nejm-302443359.html. Issued 04/30/2025. Last accessed 05/29/2025.

Appendix T

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 16, 2025

FDA Clears First Blood Test Used in Diagnosing Alzheimer's Disease

The FDA cleared the first in vitro diagnostic device that tests blood to aid in diagnosing Alzheimer's disease. The Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio is for the early detection of amyloid plaques associated with Alzheimer's disease in adult patients, aged 55 years and older, exhibiting signs and symptoms of the disease.

Alzheimer's disease is a brain disorder known to slowly destroy memory and thinking skills, and, eventually, the ability to carry out the simplest tasks. It is progressive, meaning that the disease gets worse over time. In most people with Alzheimer's disease, clinical symptoms first appear later in life. Amyloid plaques in a patient's brain are a hallmark sign of Alzheimer's disease. While amyloid plaques can occur in other diseases, being able to detect the presence of plaque, along with other evaluations, helps determine the probable cause of the patient's symptoms and findings. These plaques can be detected and visualized using amyloid positron emission tomography (PET) brain scans, often years before clinical symptom onset, to aid in diagnosing Alzheimer's disease. PET scans, however, are a costly and time-consuming option and expose patients to radiation.

The Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio measures 2 proteins, pTau217 and β-amyloid 1-42, found in human plasma and calculates the numerical ratio of the levels of the 2 proteins. This ratio correlates the presence or absence of amyloid plaques in the patient's brain, reducing the need for a PET scan. Similar FDA-authorized/cleared tests, 1 from the same company as this new test, are used with cerebrospinal fluid (CSF) samples, which are collected through an invasive lumbar puncture, also called a spinal tap. This new Lumipulse® test only requires a simple blood draw, making it less invasive and much easier for patients to access.

During review of the Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio, the FDA evaluated data from a multi-center clinical study of 499 individual plasma samples from adults who were cognitively impaired. The samples were tested by the Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio and compared with amyloid PET scan or CSF test results.

In this clinical study, 91.7% of individuals with Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio positive results had the presence of amyloid plaques by PET scan or CSF test result, and 97.3 % of individuals with negative results had a negative amyloid PET scan or CSF test result. Less than 20% of

the 499 patients tested received an indeterminate Lumipulse® G pTau217/β-Amyloid 1-42 Plasma Ratio result.

These findings indicate that the new blood test can reliably predict the presence or absence of amyloid pathology associated with Alzheimer's disease at the time of the test in patients who are cognitively impaired. The test is intended for patients presenting at a specialized care setting with signs and symptoms of cognitive decline. The results must be interpreted in conjunction with other patient clinical information.

The risks associated with the Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio are mainly the possibility of false positive and false negative test results. False positive results, in conjunction with other clinical information, could lead to an inappropriate diagnosis of, and unnecessary treatment for, Alzheimer's disease. This could lead to psychological distress, delay in receiving a correct diagnosis as well as expense and the risk for side effects from unnecessary treatment. False negative results could result in additional unnecessary diagnostic tests and potential delay in effective treatment. Importantly, the Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio is not intended as a screening or stand-alone diagnostic test, and other clinical evaluations or additional tests should be used for determining treatment options.

The FDA reviewed the Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio through the 510(k) premarket notification pathway. A 510(k) notification is a premarket submission made to the FDA to demonstrate that a new device is substantially equivalent to a legally marketed predicate device. The FDA found that the Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio is substantially equivalent to the Lumipulse® G β-amyloid Ratio (1-42/1-40), which is the previously authorized test that uses CSF samples. The Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio was granted Breakthrough Device designation, a process designed to expedite the development and review of devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The FDA issued clearance of the Lumipulse® G pTau217/ß-Amyloid 1-42 Plasma Ratio to Fujirebio Diagnostics, Inc.

FDA NEWS RELEASE

For Immediate Release: May 13, 2025

FDA Begins Action to Remove Ingestible Fluoride Prescription Drug Products for Children from the Market

The FDA announced that it is initiating action to remove concentrated ingestible fluoride prescription drug products for children from the market. Unlike toothpaste with fluoride or fluoride rinses, these products are swallowed and ingested by infants and toddlers. They have also never been approved by the FDA. Ingested fluoride has been shown to alter the gut microbiome, which is of magnified concern given the early development of

the gut microbiome in childhood. Other studies have suggested an association between fluoride and thyroid disorders, weight gain, and possibly decreased IQ.

The FDA has set a goal date of October 31, 2025 for completing a safety review and public comment period and for taking appropriate action regarding removal of these products from the market. In conjunction with this evaluation, the U.S. Department of Health and Human Services plans to disseminate best practices for dental hygiene in children that are feasible, effective, and do not alter gut health. Several states have taken action to stop fluoridation of drinking water, and fluoride is not added to drinking water in most of Europe or other countries of the world.

Current Drug Shortages Index (as of May 28, 2025):

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***

Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide 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***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Indocyanine Green Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lactated Ringers Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***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***
Mefloquine Hydrochloride Tablet	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***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***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Oxazepam Capsule	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***

Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Peritoneal Dialysis Solution	***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***
Sodium Chloride 0.9% Irrigation	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Somatropin 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***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***