OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
July 9, 2025
4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – July 9, 2025

DATE: July 2, 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.

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Enclosed are the following items related to the July 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

Chronic Medication Adherence (CMA) Program Update – Appendix C

Action Item – Vote to Prior Authorize Cobenfy™ (Xanomeline/Trospium), Erzofri® [Paliperidone Palmitate Extended-Release (ER) Injection], and Opipza™ (Aripiprazole Oral Film) and Update the Approval Criteria for the Atypical Antipsychotic Medications – Appendix D

Action Item – Vote 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) and Update the Approval Criteria for the Various Special Formulations – Appendix E

Action Item – Vote to Prior Authorize Avmapki™ Fakzynja ™ Co-Pack (Avutometinib and Defactinib) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications – Appendix F

Annual Review of Colorectal Cancer (CRC) Medications – Appendix G

Action Item – Annual Review of Defencath® (Taurolidine/Heparin) – Appendix H

Action Item – Annual Review of Constipation and Diarrhea Medications – Appendix I

Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Azmiro™ (Testosterone Cypionate 200mg/mL Syringe) and Undecatrex™ (Testosterone Undecanoate Capsule – Appendix J

Annual Review of Epidermolysis Bullosa (EB) Medications and 30-Day Notice to Prior Authorize Zevaskyn™ (Prademagene Zamikeracel) – Appendix K

Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Zunveyl® (Benzgalantamine) – Appendix L

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 9, 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

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

Public Comment for Meeting:

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

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. June 11, 2025 DUR Board Meeting Minutes
   B. June 11, 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 June 2025
   B. Medication Coverage Activity for June 2025

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

5. **Chronic Medication Adherence (CMA) Program Update – See Appendix C**
   A. Introduction
   B. Conclusions

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

6. **Action Item – Vote to Prior Authorize Cobenfy™ (Xanomeline/Trospium), Erzofri® [Paliperidone Palmitate Extended-Release (ER) Injection], and Opipza™ (Aripiprazole Oral Film) and Update the Approval Criteria for the Atypical Antipsychotic Medications – See Appendix D**
   A. Market News and Updates

B. Cobenfy™ (Xanomeline/Trospium) Product Summary
C. Cost Comparisons
D. College of Pharmacy Recommendations

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

7. **Action Item – Vote 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) and Update the Approval Criteria for the Various Special Formulations – See Appendix E**
   A. Introduction
   B. Product Summaries and College of Pharmacy Recommendations
   C. College of Pharmacy Additional Recommendations

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

8. **Action Item – Vote to Prior Authorize Avmapki™ Fakzynja ™ Co-Pack (Avutometinib and Defactinib) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications – See Appendix F**
   A. Market News and Updates
   B. Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Annual Review of Colorectal Cancer (CRC) Medications – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of CRC Medications
   C. Prior Authorization of CRC Medications
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of CRC Medications

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

10. **Action Item – Annual Review of Defencath® (Taurolidine/Heparin) – See Appendix H**
    A. Current Prior Authorization Criteria
    B. Utilization of Defencath® (Taurolidine/Heparin)
    C. Prior Authorization of Defencath® (Taurolidine/Heparin)
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Defencath® (Taurolidine/Heparin)

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

11. **Action Item – Annual Review of Constipation and Diarrhea Medications – See Appendix I**
    A. Current Prior Authorization Criteria
    B. Utilization of Constipation and Diarrhea Medications
    C. Prior Authorization of Constipation and Diarrhea Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Constipation and Diarrhea Medications

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

12. **Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Azmiro™ (Testosterone Cypionate 200mg/mL Syringe) and Undecatrex™ (Testosterone Undecanoate Capsule) – See Appendix J**
    A. Current Prior Authorization Criteria
    B. Utilization of Testosterone Products
    C. Prior Authorization of Testosterone Products
    D. Market News and Updates
    E. Cost Comparison
    F. College of Pharmacy Recommendations
    G. Utilization Details of Testosterone Products

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

13. **Annual Review of Epidermolysis Bullosa (EB) Medications and 30-Day Notice to Prior Authorize Zevaskyn™ (Prademagene Zamikeracel) – See Appendix K**
    A. Current Prior Authorization Criteria
    B. Utilization of EB Medications
    C. Prior Authorization of EB Medications
    D. Market News and Updates
    E. Zevaskyn™ (Prademagene Zamikeracel) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of EB Medications

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

14. **Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Zunveyl® (Benzgalantamine) – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of Alzheimer's Disease Medications
    C. Prior Authorization of Alzheimer's Disease Medications
    D. Market News and Updates
    E. Zunveyl® (Benzgalantamine) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of Alzheimer's Disease Medications

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

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

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

16. **Future Business* (Upcoming Product and Class Reviews)**
    No live DUR Board Meeting is scheduled for August 2025. August 2025 will be a packet-only meeting.
    A. Iron Products
    B. Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications
    C. Topical Corticosteroids
    D. Various Systemic Antibiotics
    *Future product and class reviews subject to change.

17. **Adjournment**

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

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING JUNE 11, 2025

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP	X	
Kenneth Foster, MHS, PA-C	X	
Bret Haymore, M.D.; Chairman	X	
Bethany Holderread, Pharm.D.	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	
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
Gwendolyn Maxey, J.D.; Deputy General Counsel	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	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Sharon Smith, Pharm.D.; Clinical Pharmacist	X	

OTHERS PRESENT:	
Brielle Dozier, Artia Solutions	Amy Breen, Teva Pharmaceuticals
Jason Dickerson, Jazz Pharmaceuticals	Irene Chung, Aetna
Michael Faithe, Jazz Pharmaceuticals	Saurabh Patel, AbbVie
Marc Parker, VS Health Group	Lindsey Walter, Novartis
Rhonda Clark, Indivior	Michele Shirley, Indivior
John Omick, Travere	Megan Loftis, Acadia Pharmaceuticals
Mike Sullivan, Amgen	Lee Stout, Chiesi
Robin Wells, NS Pharma	Brent Fushimi, UCB
Christine Schaffer, SpringWorks Therapeutics	Chrystal Mayes, Sanofi
Rodney Brown	Matt Metcalf, Calliditas Therapeutics
Rick Ludwico, Mayne Pharma	Suzanne Hensley, Shorla Oncology
Nick Trombold, Alexion Pharmaceuticals	Jennifer Lauper, Bristol Myers Squibb
Brent Young, Bristol Myers Squibb	Robb Host, Bristol Myers Squibb
Audrey Rattan, Alexion Pharmaceuticals	Kennerth Berry, Alkermes
Kellie Vazzana, Alkermes	Jacob Jameson, Johnson & Johnson
Glenn Cornish, Alkermes	Brandon Ross, Merck
Scott Burns, Johnson & Johnson	Ben Skoog, Acadia Pharmaceuticals
Rick Kegler, BioMarin	David Mendoza, Otsuka
Amy Coldren, Mental Health Association Oklahoma	Deidra Williams, Humana
Kim Greenberg, Acadia Pharmaceuticals	Matt John, Otsuka
Patti Rohman, Otsuka	David Prather, Novo Nordisk
Kristen Winters, Centene	Bryan Steffan, Boehringer
Amanda Nowakowski, ViiV	Todd Ness, AbbVie
Janie Huff, Madrigal	Tara McKinley, Madrigal
Jonathan Jones, Bristol Myers Squibb	Mark Kaiser, Otsuka

PRESENT FOR PUBLIC COMMENT:	
Ben Skoog, Acadia Pharmaceuticals	Nick Trombold, Alexion Pharmaceuticals
Jonathon Jones, Bristo Myers Squibb	Kenneth Berry, Alkermes
Jacob Jameson, Johnson & Johnson	Amy Coldren, Mental Health Association Oklahoma

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. 15 BEN SKOOG
2B: AGENDA ITEM NO. 16 NICK TROMBOLD
2C: AGENDA ITEM NO 19 KENNETH BERRY

2D: AGENDA ITEM NO. 19 JONATHAN JONES
2E: AGENDA ITEM NO. 19 JACOBE JAMESON
2F: AGENDA ITEM NO. 19 AMY COLDREN
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 3:</u> APPROVAL OF DUR BOARD MEETING MINUTES
3A: MAY 14, 2025 DUR MINUTES
Materials included in agenda packet; presented by Dr. Haymore
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 4:</u> UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT
4A: PHARMACY HELPDESK ACTIVITY FOR MAY 2025
4B: MEDICATION COVERAGE ACTIVITY FOR MAY 2025
Non-presentation item; materials included in agenda packet by Dr. DeRemer
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 5:</u> DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITOR UTILIZATION UPDATE
5A: INTRODUCTION
5B: DPP-4 INHIBITOR UTILIZATION IN THE SOONERCARE POPULATION
5C: CONCLUSIONS
5D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 6:</u> VOTE TO PRIOR AUTHORIZE DAXXIFY® (DAXIBOTULINUMTOXINA-LANM) AND UPDATE THE APPROVAL CRITERIA FOR THE BOTULINUM TOXINS
6A: MARKET NEWS AND UPDATES
6B: DAXXIFY® (DAXIBOTULINUMTOXINA-LANM) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 7:</u> 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
7A: MARKET NEWS AND UPDATES
7B: COST COMPARISONS
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> 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
8A: MARKET NEWS AND UPDATES
8B: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> VOTE TO PRIOR AUTHORIZE SOFDRA™ (SOFPIRONIUM)
9A: MARKET NEWS AND UPDATES
9B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> 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
10A: MARKET NEWS AND UPDATES
10B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> 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
11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COST COMPARISON: ORAL CARBIDOPA/LEVODOPA PRODUCTS
11D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> VOTE TO PRIOR AUTHORIZE VANRAFIA® (ATRASENTAN) AND UPDATE THE APPROVAL CRITERIA FOR THE PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IGAN) MEDICATIONS
12A: MARKET NEWS AND UPDATES
12B: VANRAFIA® (ATRASENTAN) PRODUCT SUMMARY
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> 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
13A: MARKET NEWS AND UPDATES
13B: PRODUCT SUMMARY
13C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Sinko
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ANTIVIRAL MEDICATIONS
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ANTIVIRAL MEDICATIONS
14C: PRIOR AUTHORIZATION OF ANTIVIRAL MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: COST COMPARISON: PREVYMIS® (LETERMOVIR) PRODUCTS
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF ANTIVIRAL MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Regarding the approval criteria for Zovirax® (acyclovir) 5% cream, Dr. Kupiec recommended changing the order of the required trials to list oral therapy as option "a" so that providers will read the preferred therapy option first.
Dr. Kupiec moved to amend the approval criteria; seconded by Dr. Muñoz
The DUR Board voted on the amended criteria.
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 15: ANNUAL REVIEW OF DAYBUE™ (TROFINETIDE)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF DAYBUE™ (TROFINETIDE)
15C: PRIOR AUTHORIZATION OF DAYBUE™ (TROFINETIDE)
15D: MARKET NEWS AND UPDATES
15E: COLLEGE OF PHARMACY RECOMMENDATIONS
15F: UTILIZATION DETAILS OF DAYBUE™ (TROFINETIDE)
Materials included in agenda packet; presented by Dr. Wilson
Regarding the approval criteria for Daybue™ (trofinetide), Dr. Kupiec recommended changing criteria #3 due to neurologist access to allow for prescribing in consultation with a specialist with the name of the specialist provided and an attestation that the specialist is in agreement with the diagnosis and treatment plan.
Dr. Kupiec moved to amend the approval criteria; seconded by Dr. Muñoz
The DUR Board voted on the amended criteria.
Dr. Patatanian moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 16: ANNUAL REVIEW OF STRENSIQ® (ASFOTASE ALFA)
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF STRENSIQ® (ASFOTASE ALFA)
16C: PRIOR AUTHORIZATION OF STRENSIQ® (ASFOTASE ALFA)
16D: MARKET NEWS AND UPDATES
16E: COLLEGE OF PHARMACY RECOMMENDATIONS
16F: UTILIZATION DETAILS OF STRENSIQ® (ASFOTASE ALFA)
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 17: ANNUAL REVIEW OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR

AUTHORIZE AVMAPKI™ (FAKZYNJA™ CO-PACK (AVUTOMETINIB AND DEFACTINIB)

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
17C: PRIOR AUTHORIZATION OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: AVMAPKI™ FAKZYNJA™ CO-PACK (AVUTOMETINIB AND DEFACTINIB) PRODUCT SUMMARY
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS

Materials included in agenda packet; presented by Dr. Sinko

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

<u>AGENDA ITEM NO. 18:</u> ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT

18A: SUMMARY
18B: MEDICAID DRUG REBATE PROGRAM
18C: ALTERNATIVE PAYMENT MODELS
18D: DRUG APPROVAL TRENDS
18E: TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
18F: TOP 10 TRADITIONAL THERAPEUTIC CATEGORIES BY REIMBURSEMENT
18G: TOP 10 SPECIALTY THERAPEUTIC CATEGORIES BY REIMBURSEMENT
18H: TOP 10 MEDICATIONS BY REIMBURSEMENT
18I: COST PER CLAIM
18J: MARKET PROJECTIONS
18K: CONCLUSION
18L: FISCAL YEAR COMPARISON

Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 19:</u> 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)

19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
19C: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS
19D: OKLAHOMA RESOURCES
19E: MARKET NEWS AND UPDATES
19F: COBENFY™ (XANOMELINE/TROSPIUM) PRODUCT SUMMARY
19G: COST COMPARISONS
19H: COLLEGE OF PHARMACY RECOMMENDATIONS
19I: UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS

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

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

<u>AGENDA ITEM NO. 20:</u> 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 SOUTION), 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)

20A: INTRODUCTION
20B: CURRENT PRIOR AUTHORIZATION CRITERIA
20C: UTILIZATION OF VARIOUS SPECIAL FORMULATIONS
20D: PRIOR AUTHORIZATION OF VARIOUS SPECIAL FORMULATIONS
20E: PRODUCT SUMMARIES
20F: COLLEGE OF PHARMACY RECOMMENDATIONS
20G: UTILIZATION DETAILS OF VARIOUS SPECIAL FORMULATIONS

Materials included in agenda packet; presented by Dr. Moss

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

AGENDA ITEM NO. 21: ANNUAL REVIEW OF REZDIFFRA™ (RESMETIROM)

21A: CURRENT PRIOR AUTHORIZATION CRITERIA
21B: UTILIZATION OF REZDIFFRA™ (RESMETIROM)
21C: PRIOR AUTHORIZATION OF REZDIFFRA™ (RESMETIROM)
21D: MARKET NEWS AND UPDATES
21E: COLLEGE OF PHARMACY RECOMMENDATIONS
21F: UTILIZATION DETAILS OF REZDIFFRA™ (RESMETIROM)

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 22: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 23: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)

23A: ALZHEIMER'S DISEASE MEDICATIONS
23B: COLORECTAL CANCER (CRC) MEDICATIONS
23C: EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS
23D: TESTOSTERONE PRODUCTS

*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 24: ADJOURNMENT

The meeting was adjourned at 5:47pm.

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

Memorandum

Date: June 13, 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 June 11, 2025

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Utilization Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Daxxify® (DaxibotulinumtoxinA-lanm) and Update the Approval Criteria for the Botulinum Toxins

MOTION CARRIED by unanimous approval.

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.

Recommendation 4: 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

MOTION CARRIED by unanimous approval.

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 type 2 diabetes mellitus (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 glucagon-like peptide-1 (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.

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™)***

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
DPP-4 Inhibitors/SGLT-2 Inhibitors			
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®)
	empagliflozin/		sotagliflozin (Inpefa®)*

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	metformin ER (Synjardy® XR)		
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 American Diabetes Association (ADA) guidelines and clinical practice (changes 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.

Recommendation 5: Vote to Prior Authorize Onyda™ XR [Clonidine Extended-Release (ER) Suspension] and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) Medications

MOTION CARRIED by unanimous approval.

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
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®)			

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
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®)	methylphenidate ER (Relexxii®)Δ methylphenidate chew tab (Methylin®)Δ methylphenidate ER chew tab (QuilliChew ER®)Δ
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 trial~~s~~ (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®.~~

Recommendation 6: Vote to Prior Authorize Sofdra™ (Sofpironium 12.45% Topical Gel)

MOTION CARRIED by unanimous approval.

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
   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.

Recommendation 7: 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

MOTION CARRIED by unanimous approval.

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 in adults:
   a. Neovascular (wet) age-related macular degeneration (AMD); 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), Pavblu™ (aflibercept-ayyh)] 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.

Recommendation 8: 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

MOTION CARRIED by unanimous approval.

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.~~

Recommendation 9: Vote to Prior Authorize Vanrafia™ (Atrasentan) and Update the Approval Criteria for the Primary Immunoglobulin A Nephropathy (IgAN) Medications

MOTION CARRIED by unanimous approval.

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 Kidney Disease Improving Global Outcomes (KDIGO) IgAN/IgA vasculitis (IgAV) 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.

Recommendation 10: 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

MOTION CARRIED by unanimous approval.

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 National Comprehensive Cancer Network (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.~~

Recommendation 11: Fiscal Year 2024 Annual Review of Antiviral Medications

MOTION CARRIED by unanimous approval.

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, including amending criteria #2a and #2b to list the oral products first, followed by the topical products as recommended by and approved unanimously by the DUR Board (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. Oral acyclovir, famciclovir, or valacyclovir tablets; and
    b. Zovirax® (acyclovir ointment)

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.

Recommendation 12: Fiscal Year 2024 Annual Review of Daybue® (Trofinetide)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Daybue® (trofinetide) approval criteria based on the recent FDA approved label updates with the following changes, including amending criteria #3 to add "in consultation with" to the specialist requirement and to add #3a regarding additional information needed if Daybue® is prescribed in consultation with a specialist as recommended by and approved unanimously by the DUR Board (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, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and

a. If prescribed in consultation with a specialist, the name of the specialist must be provided and the prescriber must attest that the specialist is in agreement with the diagnosis and treatment plan; 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.

Recommendation 13: Fiscal Year 2024 Annual Review of Strensiq® (Asfotase Alfa)

MOTION CARRIED by unanimous approval.

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.

Recommendation 14: 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)

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

Recommendation 15: Fiscal Year 2024 Annual Review of the SoonerCare Pharmacy Benefit

NO ACTION REQUIRED.

Recommendation 16: 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))

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

Recommendation 17: 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)

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

Recommendation 18: Fiscal Year 2024 Annual Review of Rezdiffra™ (Resmetirom)

NO ACTION REQUIRED.

Recommendation 19: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

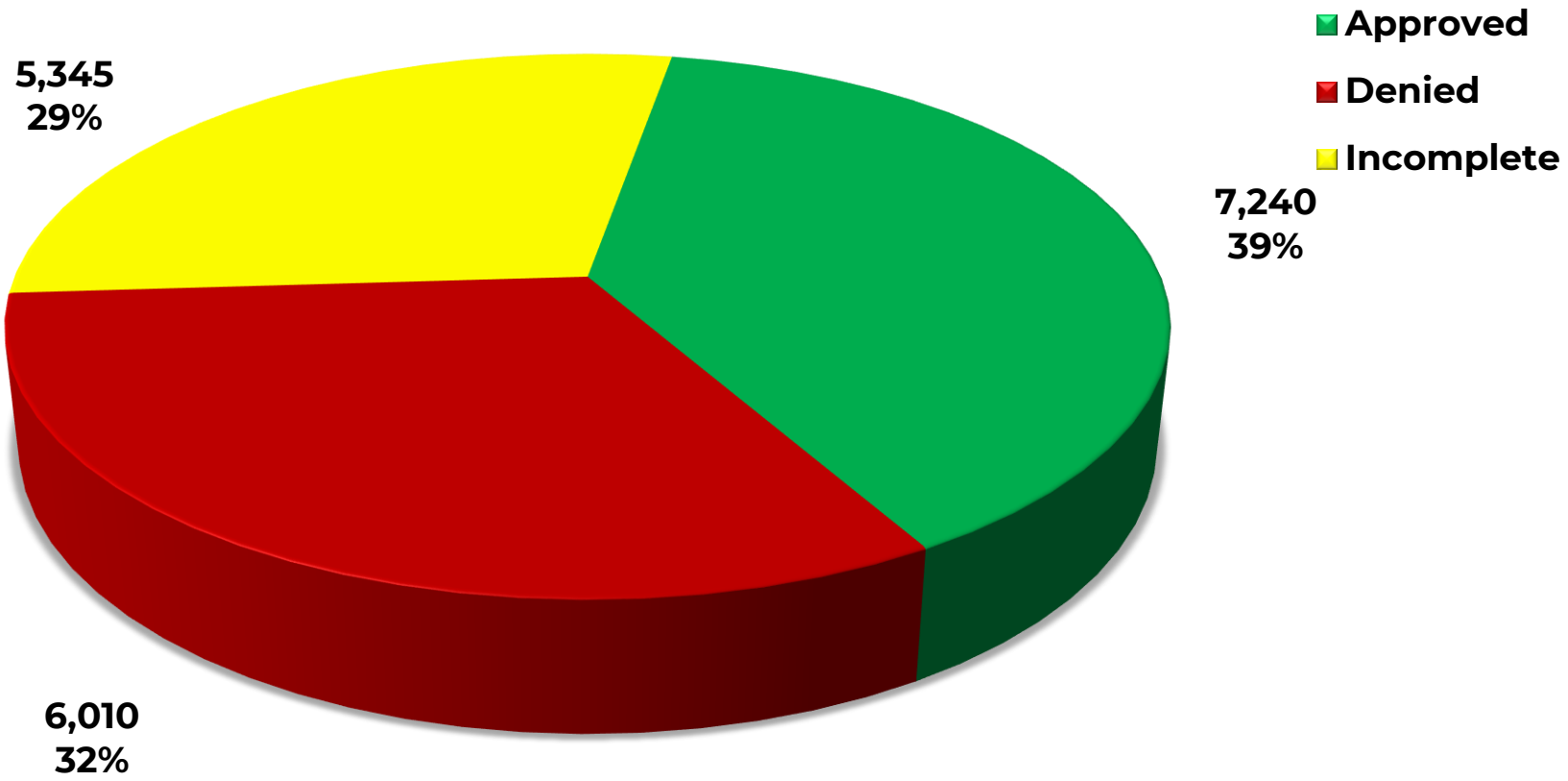
NO ACTION REQUIRED.

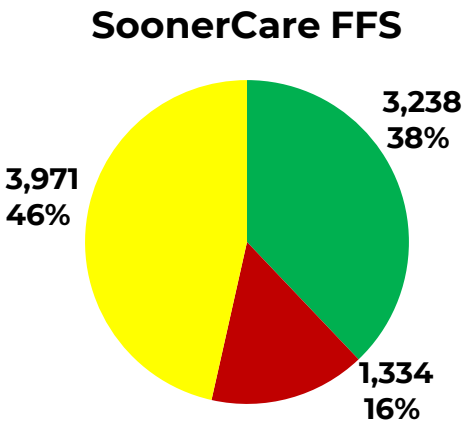
Recommendation 20: Future Business

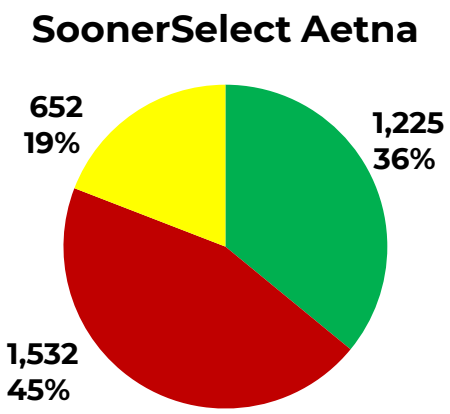
NO ACTION REQUIRED.

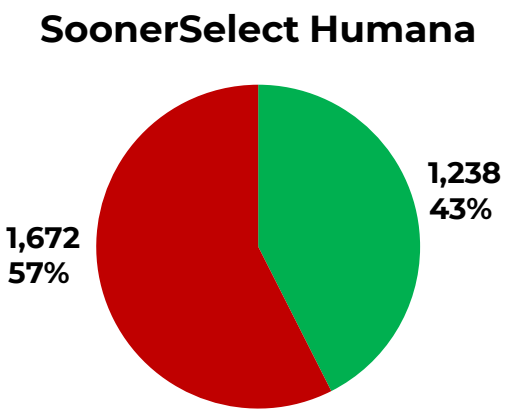
Appendix B

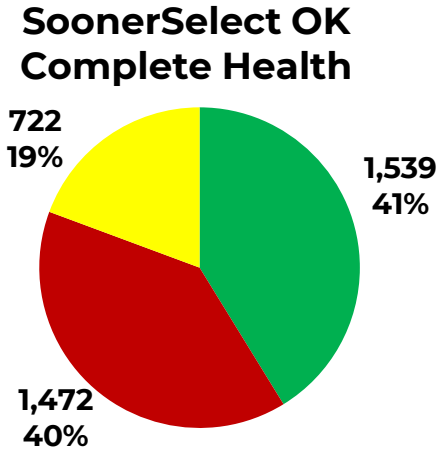
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JUNE 2025





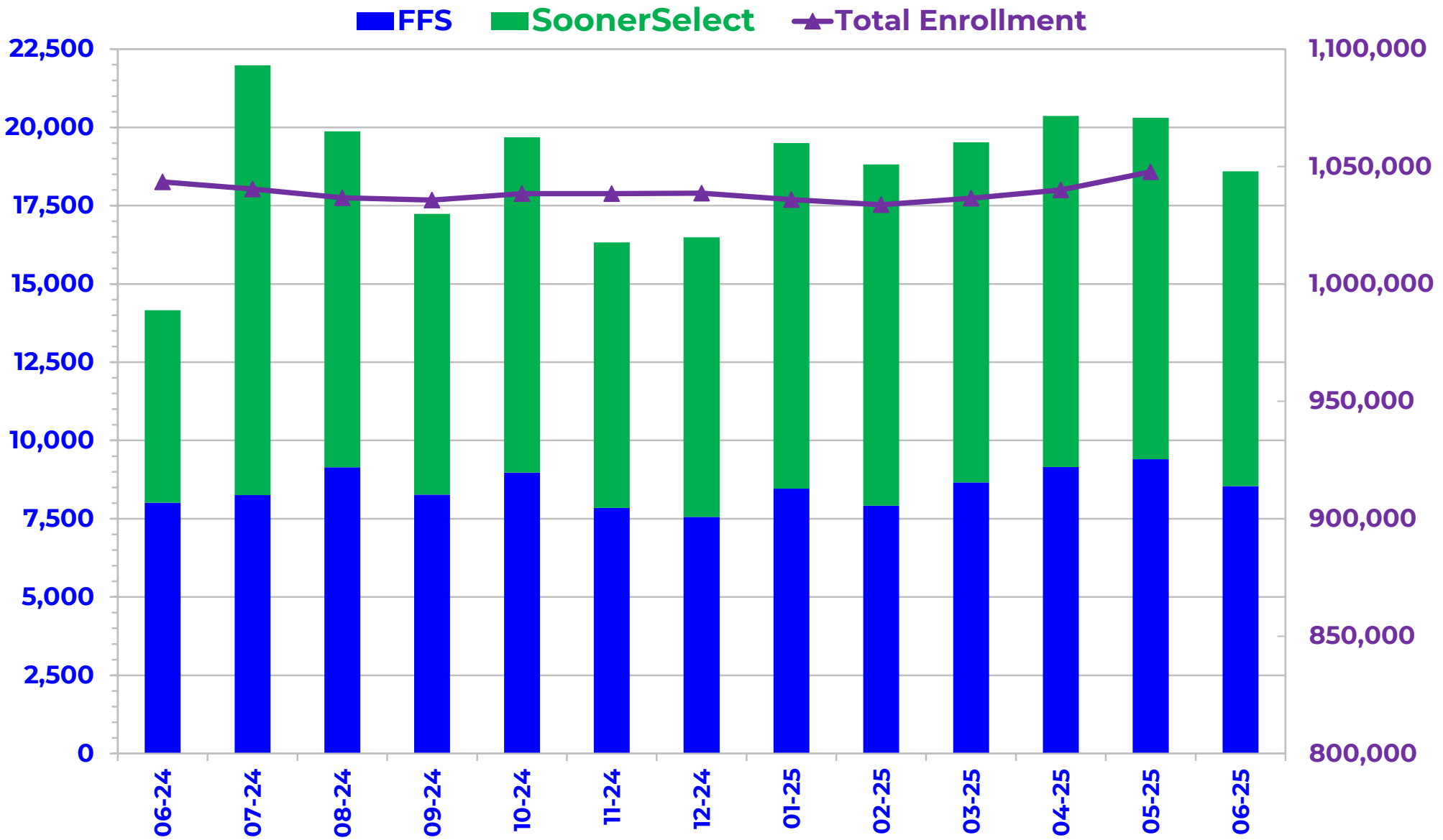






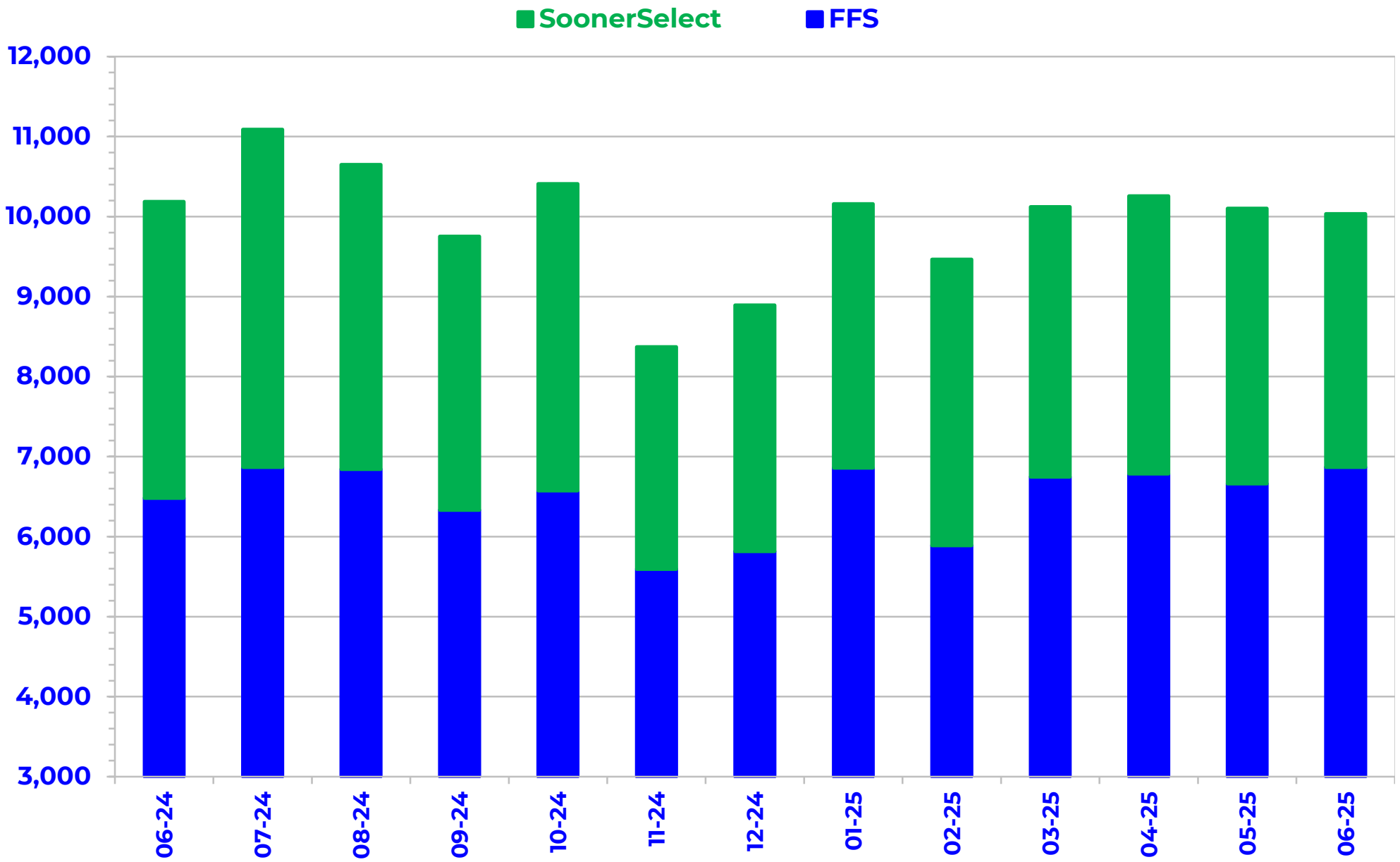
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JUNE 2024 – JUNE 2025



SoonerCare FFS Prior Authorization Activity

6/1/2025 Through 6/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	3	1	0	2	360
Amphetamines	606	399	9	198	355
Analgesics - Anti-Inflammatory	219	85	28	106	315
Analgesics - Nonnarcotic	7	2	1	4	26
Analgesics - Opioid	335	142	30	163	128
Androgens - Anabolic	79	15	23	41	349
Anorectal and Related Products	3	0	2	1	0
Antacids	1	1	0	0	361
Anthelmintics	11	3	1	7	8
Anti-Infective Agents - Misc.	21	9	3	9	320
Anti-Obesity Agents	102	8	77	17	193
Antianginal Agents	1	1	0	0	360
Antianxiety Agents	29	4	2	23	146
Antiasthmatic and Bronchodilator Agents	490	79	94	317	320
Antibiotics	18	7	0	11	261
Anticoagulants	11	0	0	11	0
Anticonvulsants	200	97	11	92	330
Antidepressants	198	50	24	124	283
Antidiabetics	1,331	350	294	687	347
Antidotes and Specific Antagonists	6	1	1	4	357
Antiemetics	19	2	0	17	100
Antifungals	7	2	0	5	52
Antihistamines	17	5	7	5	275
Antihyperlipidemics	37	9	11	17	292
Antihypertensives	8	2	0	6	359
Antimalarials	3	0	1	2	0
Antimyasthenic/Cholinergic Agents	2	0	1	1	0
Antineoplastics and Adjunctive Therapies	221	140	11	70	183
Antiparkinson and Related Therapy Agents	11	3	3	5	359
Antipsychotics/Antimanic Agents	300	112	25	163	359
Antivirals	15	5	3	7	9
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	238	155	13	70	341
Beta Blockers	11	3	1	7	352
Calcium Channel Blockers	7	2	1	4	250
Cardiotonics	3	0	0	3	0
Cardiovascular Agents - Misc.	107	46	13	48	339
Contraceptives	24	10	4	10	357
Corticosteroids	15	2	7	6	222
Cough/Cold/Allergy	1	0	1	0	0
Dermatologicals	411	123	121	167	244
Diagnostic Products	52	17	5	30	136
Digestive Aids	5	3	1	1	360
Diuretics	19	6	1	12	300

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	0	1	0
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	180	82	22	76	254
Estrogens	21	3	5	13	359
Gastrointestinal Agents - Misc.	321	81	87	153	241
Genitourinary Agents - Misc.	16	2	8	6	356
Gout Agents	4	2	0	2	359
Hematological Agents - Misc.	7	2	0	5	269
Hematopoietic Agents	41	17	6	18	148
Histamine H3-Receptor Antagonist/Inverse Agonists	3	1	1	1	356
Hypnotics/Sedatives/Sleep Disorder Agents	66	5	12	49	220
Laxatives	25	9	8	8	243
Medical Devices and Supplies	264	48	67	149	280
Migraine Products	335	76	61	198	240
Minerals and Electrolytes	9	2	1	6	182
Miscellaneous Therapeutic Classes	65	31	4	30	274
Multivitamins	2	0	0	2	0
Musculoskeletal Therapy Agents	48	9	11	28	179
Nasal Agents - Systemic and Topical	20	2	4	14	223
Neuromuscular Agents	82	40	19	23	341
Nutrients	1	1	0	0	360
Ophthalmic Agents	56	12	10	34	145
Other*	54	14	3	37	235
Otic Agents	62	27	3	32	11
Passive Immunizing and Treatment Agents	2	0	0	2	0
Pharmaceutical Adjuvants	2	1	1	0	360
Progestins	3	0	1	2	0
Psychotherapeutic and Neurological Agents - Misc.	212	75	30	107	218
Respiratory Agents - Misc.	16	9	1	6	339
Stimulants - Misc.	218	102	19	97	329
Thyroid Agents	10	1	0	9	117
Ulcer Drugs/Antispasmodics/Anticholinergics	113	20	16	77	178
Urinary Antispasmodics	39	8	6	25	359
Vaccines	1	0	1	0	0
Vaginal and Related Products	2	0	0	2	0
Vasopressors	1	0	0	1	0
Vitamins	34	1	25	8	362
Total	**7,540**	**2,584**	**1,262**	**3,694**	
Overrides					
Brand	21	11	0	10	282
Compound	11	8	1	2	14
Diabetic Supplies	3	3	0	0	72
Dosage Change	144	127	4	13	16
High Dose	3	2	0	1	268

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Ingredient Duplication	7	3	1	3	65
Lost/Broken Rx	56	53	2	1	27
MAT Override	14	7	2	5	91
NDC vs Age	161	85	32	44	296
NDC vs Sex	26	21	0	5	316
Nursing Home Issue	35	33	0	2	21
Opioid MME Limit	55	8	3	44	158
Opioid Quantity	22	12	1	9	178
Other	41	30	7	4	17
Prescriber Temp Unlock	1	1	0	0	360
Quantity vs Days Supply	339	213	13	113	276
STBS/STBSM	18	11	4	3	70
Step Therapy Exception	5	3	1	1	360
Stolen	3	3	0	0	14
Third Brand Request	38	20	1	17	21
Overrides Total	**1,003**	**654**	**72**	**277**	
Total Regular PAs + Overrides	**8,543**	**3,238**	**1,334**	**3,971**	

Denial Reasons	
Unable to verify required trials.	3,456
Does not meet established criteria.	1,372
Lack required information to process request.	545
Other PA Activity	
Duplicate Requests	1,109
Letters	42,041
No Process	0
Helpdesk Initiated Prior Authorizations	389
PAs Missing Information	325
Pharmacotherapy	52
Changes to Existing PAs	494

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

SoonerSelect Aetna Prior Authorization Activity

6/1/2025 Through 6/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	0	1	0
Amphetamines	231	177	17	37	359
Analgesics - Anti-Inflammatory	120	83	29	8	332
Analgesics - Nonnarcotic	11	1	7	3	365
Analgesics - Opioid	155	85	45	25	190
Androgens - Anabolic	67	11	55	1	365
Anorectal and Related Products	3	1	1	1	42
Anthelmintics	7	2	5	0	18
Antianginal Agents	4	0	0	4	0
Antianxiety Agents	24	8	9	7	278
Antiarrhythmics	1	0	1	0	0
Antiasthmatic and Bronchodilator Agents	148	28	89	31	316
Antibiotics	19	4	6	9	113
Anticoagulants	5	2	0	3	274
Anticonvulsants	60	21	18	21	307
Antidepressants	139	46	55	38	284
Antidiabetics	593	173	324	96	329
Antidiarrheal/Probiotic Agents	1	0	1	0	0
Antidotes and Specific Antagonists	2	1	1	0	0
Antiemetics	7	1	3	3	30
Antifungals	5	1	2	2	183
Antihistamines	17	5	12	0	319
Antihyperlipidemics	36	5	18	13	294
Antihypertensives	14	0	1	13	0
Anti-Infective Agents - Misc.	20	11	4	5	101
Antineoplastics and Adjunctive Therapies	23	8	0	15	278
Anti-Obesity Agents	87	3	77	7	29
Antiparkinson and Related Therapy Agents	3	0	0	3	0
Antipsychotics/Antimanic Agents	118	38	53	27	305
Antivirals	3	1	1	1	92
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	72	55	16	1	354
Beta Blockers	16	0	2	14	0
Calcium Channel Blockers	8	2	2	4	365
Cardiovascular Agents - Misc.	33	9	20	4	342
Contraceptives	17	2	13	2	365
Corticosteroids	55	46	5	4	94
Dermatologicals	262	98	129	35	225
Diagnostic Products	51	28	9	14	297
Digestive Aids	4	3	0	1	365
Diuretics	7	1	1	5	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	4	0	4	0	0
Endocrine and Metabolic Agents - Misc.	40	22	15	3	241
Estrogens	6	2	2	2	365
Gastrointestinal Agents - Misc.	103	25	72	6	206
General Anesthetics	8	8	0	0	23
Genitourinary Agents - Misc.	2	0	2	0	0
Gout Agents	2	1	0	1	7
Hematological Agents - Misc.	8	5	0	3	207

*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
Hematopoietic Agents	10	5	2	3	331
Hypnotics/Sedatives/Sleep Disorder Agents	26	0	12	14	0
Laxatives	17	1	12	4	1
Medical Devices and Supplies	111	39	39	33	355
Migraine Products	191	50	124	17	241
Minerals and Electrolytes	16	2	3	11	365
Miscellaneous Therapeutic Classes	12	8	2	2	365
Multivitamins	4	1	3	0	365
Musculoskeletal Therapy Agents	32	1	9	22	103
Nasal Agents - Systemic and Topical	10	1	3	6	365
Neuromuscular Agents	12	8	3	1	224
Nutrients	3	0	3	0	0
Ophthalmic Agents	23	6	12	5	242
Other*	3	0	0	3	0
Otic Agents	16	4	12	0	16
Passive Immunizing and Treatment Agents	18	11	7	0	159
Pharmaceutical Adjuvants	4	4	0	0	61
Progestins	3	2	0	1	365
Psychotherapeutic and Neurological Agents - Misc.	26	8	12	6	275
Respiratory Agents - Misc.	1	1	0	0	92
Stimulants - Misc.	58	32	21	5	345
Thyroid Agents	7	1	4	2	365
Ulcer Drugs/Antispasmodics/Anticholinergics	113	9	70	34	167
Urinary Antispasmodics	10	0	6	4	0
Vaginal and Related Products	4	0	1	3	0
Vasopressors	1	0	0	1	0
Vitamins	56	8	46	2	284
****Total**	**3,409**	**1,225**	**1,532**	**652**	

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

Overrides					
Brand	2	2	0	0	365
Other	650	0	0	650	0
Quantity Level Limit	31	31	0	0	277
Step Therapy Met	1	1	0	0	30
Overrides Total	**684**	**34**	**0**	**650**	

Denial Reason	
Benefit	116
Experimental/Investigational	167
Lack Required Infomation to Process Request	122
Medical Necessity	1,114
Other	13
Other PA Activity	
Duplicate Requests	23
Letters	4,186
No Process	298
Changes to existing PAs	0
Helpdesk initiated PA	2
PAs missing info	9

*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

6/1/2025 Through 6/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	1	0	0	183
Amebicides	1	0	1	0	0
Amphetamines	3	2	1	0	365
Analgesics - Anti-Inflammatory	49	39	10	0	315
Analgesics - Nonnarcotic	5	1	4	0	183
Analgesics - Opioid	100	65	35	0	246
Androgens - Anabolic	55	14	41	0	171
Anthelmintics	5	1	4	0	364
Antianxiety Agents	1	0	1	0	0
Antiasthmatic and Bronchodilator Agents	115	49	66	0	219
Antibiotics	6	2	4	0	365
Anticonvulsants	16	10	6	0	304
Antidepressants	47	25	22	0	260
Antidiabetics	249	105	144	0	243
Antiemetics	4	0	4	0	0
Antifungals	4	1	3	0	365
Antihyperlipidemics	23	12	11	0	201
Anti-Infective Agents - Misc.	5	4	1	0	292
Antineoplastics and Adjunctive Therapies	35	33	2	0	231
Anti-Obesity Agents	54	5	49	0	32
Antiparkinson and Related Therapy Agents	1	0	1	0	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	17	9	8	0	225
Beta Blockers	2	0	2	0	0
Cardiovascular Agents - Misc.	36	16	20	0	285
Contraceptives	26	14	12	0	266
Corticosteroids	5	2	3	0	91
Dermatologicals	159	59	100	0	200
Diagnostic Products	6	3	3	0	304
Digestive Aids	1	1	0	0	365
Diuretics	1	1	0	0	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	1	1	0	183
Endocrine and Metabolic Agents - Misc.	40	24	16	0	237
Estrogens	6	1	5	0	486
Gastrointestinal Agents - Misc.	54	32	22	0	185
Genitourinary Agents - Misc.	1	1	0	0	365
Gout Agents	4	2	2	0	365
Hematopoietic Agents	7	2	5	0	213
Hypnotics/Sedatives/Sleep Disorder Agents	12	1	11	0	365
Laxatives	5	1	4	0	122
Migraine Products	114	62	52	0	214
Miscellaneous Therapeutic Classes	5	2	3	0	183
Multivitamins	7	6	1	0	334
Musculoskeletal Therapy Agents	27	16	11	0	310
Nasal Agents - Systemic and Topical	1	0	1	0	0
Neuromuscular Agents	16	11	5	0	252
Ophthalmic Agents	17	5	12	0	173
Other*	2	1	1	0	183

*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
Otic Agents	3	0	3	0	0
Pharmaceutical Adjuvants	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	23	16	7	0	270
Respiratory Agents - Misc.	4	3	1	0	304
Stimulants - Misc.	10	8	2	0	365
Thyroid Agents	5	1	4	0	364
Ulcer Drugs/Antispasmodics/Anticholinergics	31	9	22	0	174
Urinary Antispasmodics	16	5	11	0	114
Vitamins	35	1	34	0	37
Total	**1,480**	**686**	**794**	**0**	
Overrides					
High Dose	1	1	0	0	365
Ingredient Duplication	113	64	49	0	228
NDC vs Age	322	180	142	0	204
Opioid MME Limit	7	5	2	0	191
Opioid Quantity	3	2	1	0	365
Other	128	59	69	0	171
Quantity vs Days Supply	199	115	84	0	212
STBS/STBSM	409	17	392	0	18
Step Therapy Exception	248	109	139	0	163
Overrides Total	**1,430**	**552**	**878**	**0**	
Total Regular PAs + Overrides	**2,910**	**1,238**	**1,672**	**0**	
Denial Reasons					
Benefit					760
Medical Necessity					912

*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

6/1/2025 Through 6/30/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	2	0	1	1	0
Amphetamines	196	125	18	53	230
Analgesics - Anti-Inflammatory	91	58	23	10	352
Analgesics - Nonnarcotic	8	0	6	2	0
Analgesics - Opioid	317	97	157	63	209
Androgens - Anabolic	63	8	48	7	355
Anorectal and Related Products	4	0	0	4	0
Anorexiants Non-Amphetamine	1	0	0	1	0
Anthelmintics	8	2	5	1	365
Antianxiety Agents	12	2	9	1	284
Antiasthmatic and Bronchodilator Agents	237	69	133	35	302
Antibiotics	13	6	4	3	329
Anticoagulants	5	1	3	1	365
Anticonvulsants	46	17	24	5	323
Antidepressants	123	56	52	15	324
Antidiabetics	608	306	211	91	337
Antidotes and Specific Antagonists	2	2	0	0	280
Antiemetics	12	5	1	6	246
Antifungals	1	1	0	0	203
Antihistamines	22	7	10	5	365
Antihyperlipidemics	18	6	11	1	337
Antihypertensives	1	0	0	1	0
Anti-Infective Agents - Misc.	9	4	5	0	306
Antineoplastics and Adjunctive Therapies	87	47	17	23	223
Anti-Obesity Agents	74	2	37	35	28
Antiparkinson and Related Therapy Agents	1	1	0	0	365
Antipsychotics/Antimanic Agents	130	61	52	17	328
Antivirals	6	1	3	2	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	78	49	24	5	295
Beta Blockers	11	8	0	3	198
Calcium Channel Blockers	5	0	3	2	0
Cardiovascular Agents - Misc.	26	9	11	6	342
Contraceptives	13	6	3	4	263
Corticosteroids	9	3	2	4	90
Cough/Cold/Allergy	2	1	0	1	365
Dermatologicals	398	126	172	100	219
Diagnostic Products	52	28	13	11	273
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	3	2	0	1	280
Diuretics	2	1	1	0	365
Endocrine and Metabolic Agents - Misc.	43	17	20	6	230
Estrogens	10	6	2	2	274
Gastrointestinal Agents - Misc.	92	26	50	16	290
Genitourinary Agents - Misc.	4	1	2	1	365
Gout Agents	4	1	3	0	209

*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
Hematological Agents - Misc.	7	3	2	2	181
Hematopoietic Agents	26	5	14	7	277
Hypnotics/Sedatives/Sleep Disorder Agents	26	12	12	2	222
Laxatives	4	2	1	1	195
Medical Devices and Supplies	128	80	27	21	346
Migraine Products	168	52	92	24	254
Minerals and Electrolytes	3	0	1	2	0
Miscellaneous Therapeutic Classes	17	11	4	2	244
Multivitamins	10	5	3	2	325
Musculoskeletal Therapy Agents	24	6	10	8	272
Nasal Agents - Systemic and Topical	12	2	9	1	280
Neuromuscular Agents	20	12	3	5	227
Nutrients	1	0	0	1	0
Ophthalmic Agents	29	5	16	8	274
Other*	32	5	4	23	264
Otic Agents	35	3	22	10	365
Passive Immunizing and Treatment Agents	3	2	1	0	106
Progestins	2	0	2	0	0
Psychotherapeutic and Neurological Agents - Misc.	37	10	23	4	222
Respiratory Agents - Misc.	9	6	0	3	318
Stimulants - Misc.	182	110	32	40	298
Thyroid Agents	4	4	0	0	204
Ulcer Drugs/Antispasmodics/Anticholinergics	83	26	48	9	320
Urinary Antispasmodics	15	8	7	0	251
Vaccines	1	0	1	0	0
Vaginal and Related Products	4	1	2	1	205
Vasopressors	1	1	0	0	195
****Total**	**3,733**	**1,539**	**1,472**	**722**	

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

Denial Reasons	
Benefit	4
Medical Necessity	1,468

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

Appendix C

Chronic Medication Adherence (CMA) Program Update

Oklahoma Health Care Authority
July 2025

Prescriber Mailing: Diabetes Mellitus (DM) and Cardiovascular (CV) Maintenance Medications[1]

In mid-2015, the College of Pharmacy initiated the CMA program as an educational mailing which is processed quarterly and is sent to prescribers with members on chronic maintenance medications for DM, hypertension (HTN), and cholesterol. The purpose of the CMA mailing is to encourage medication adherence, reduce poor health outcome risk factors, and improve the quality of care for SoonerCare members receiving these medications. The CMA inclusion criteria for each biannual prescriber mailing cohort requires the prescriber to have ≥9 SoonerCare members taking DM, HTN, and cholesterol medications on a regular basis. The review period for each mailing is 1 year, and members are assigned to prescribers and included in the prescriber's patient list if they are the last prescriber of record for a maintenance medication as demonstrated in SoonerCare paid pharmacy claims.

Although criteria for inclusion, frequency of mailing, and types of mailings have changed slightly since program inception, the last substantial change was made in 2018. Since that time, the mailings have included both CV and DM medications in each mailing rather than alternating mailings. Cohort prescribers receive 4 letters per year to better inform them of their SoonerCare members using chronic maintenance medications and as a convenient way to track their members' adherence over time, including any improvements or changes. The consistent prescriber list is updated approximately once every 2 years to account for prescribers who have a change in their patient base or practice setting, move out of state, retire, or no longer contract with SoonerCare. The CMA prescriber list was most recently updated in August 2024.

Each mailing includes a prescriber summary report with a star rating based on the prescriber's overall percentage of members considered adherent to chronic maintenance medications. Adherence is estimated by measuring the proportion of days covered (PDC), or percentage of days in the past year covered by prescription claims. A member is considered adherent if their PDC is ≥80% and is considered non-adherent if their PDC is <80%. A higher prescriber percentage (and corresponding star rating) indicates that more of their SoonerCare members are adherent to chronic maintenance medications. Each mailing also includes a detailed patient list with each member's PDC, specific medication name and strength, total day supply, and

total study days. Prescribers also receive a list of medication adherence resources for patients in hopes they will utilize these methods to improve their patients' adherence.

Mailing Summaries

The following table outlines total letters mailed and total members included in each CMA mailing since February 2023 to the most recent mailing in May 2025:

Date Letter Processed	Total Letters Mailed to Prescribers	Total Members Included
February 2023	231	6,572
May 2023	226	6,304
August 2023	220	6,093
November 2023	217	5,940
February 2024	212	5,709
May 2024	206	5,451
August 2024*	238	6,400
November 2024	237	5,829
February 2025	230	5,765
May 2025	232	5,609

*CMA prescriber list updated

Star Ratings

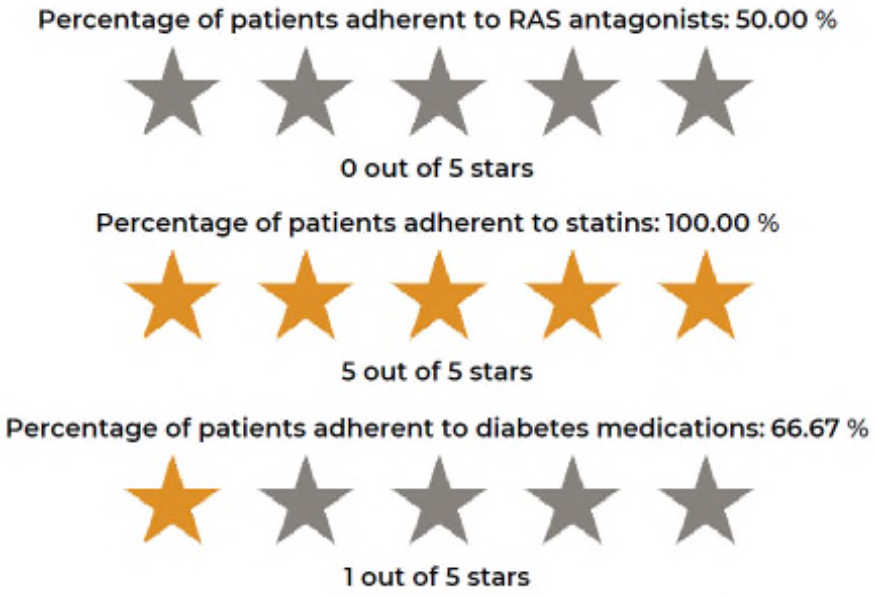
The star ratings for the percentage of SoonerCare members who are adherent to CV or DM chronic maintenance medications are based on the 2023-25 Medicare Star Ratings. However, a rating of 0 stars is exclusive to SoonerCare. The following descriptions illustrate the star ratings and adherence percentages for each star rating. It is important to note the threshold for each star rating has become increasingly higher with each annual update. Hence the provider star ratings may sometimes appear to show a trend towards worsening adherence with each February mailing, but this may actually reflect a more rigorous standard being applied. Adherence is shown in the Provider Summary Report as a percentage and corresponding star rating for each CV medication category and for the DM medications.

- **CV medications**
  - **RAS antagonists** [i.e., angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), direct renin inhibitors]
  - **Statins** [3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors]
- **DM medications**
  - Alpha-glucosidase inhibitors
  - Biguanides

- Dipeptidyl peptidase-4 (DPP-4) inhibitors
- Sodium-glucose transport protein 2 (SGLT-2) inhibitors
- Dopamine agonists (exclusively bromocriptine)
- Glinides (fasting insulin secretagogue)
- Glucagon-like peptide-1 (GLP-1) agonists and glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 agonists
- Sulfonylureas
- Thiazolidinediones

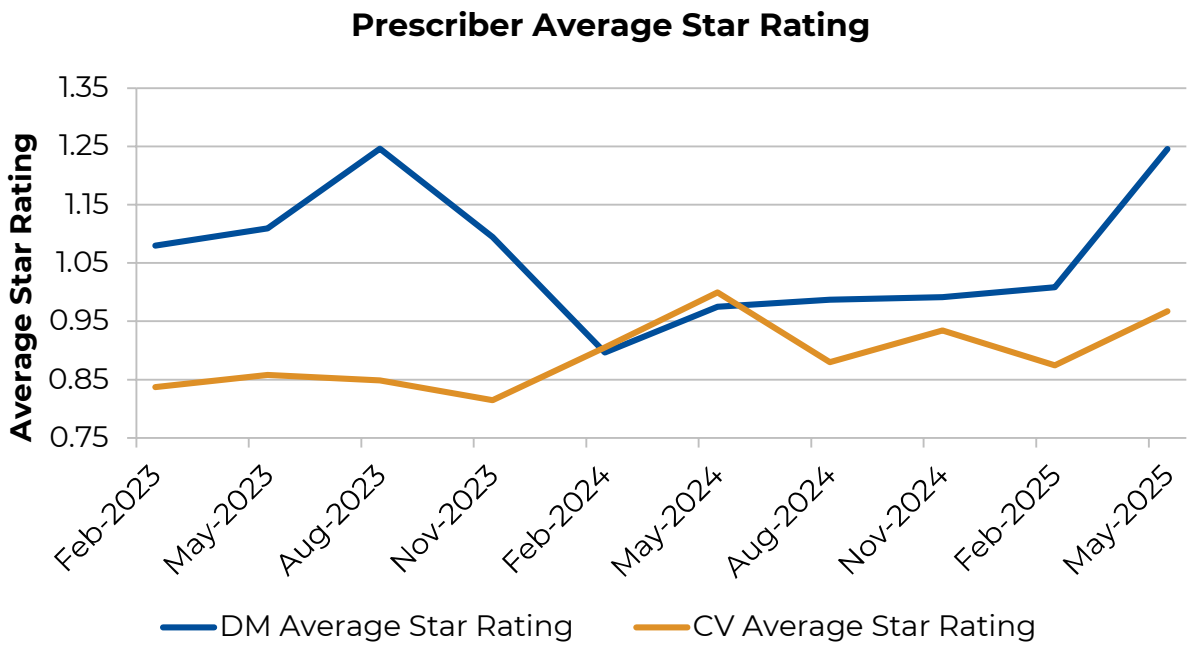
Provider Summary Report

Report date: <Report Date>
Provider: <Provider Name>
NPI: <Prescriber NPI>
SoonerCare Provider ID: <Provider ID>

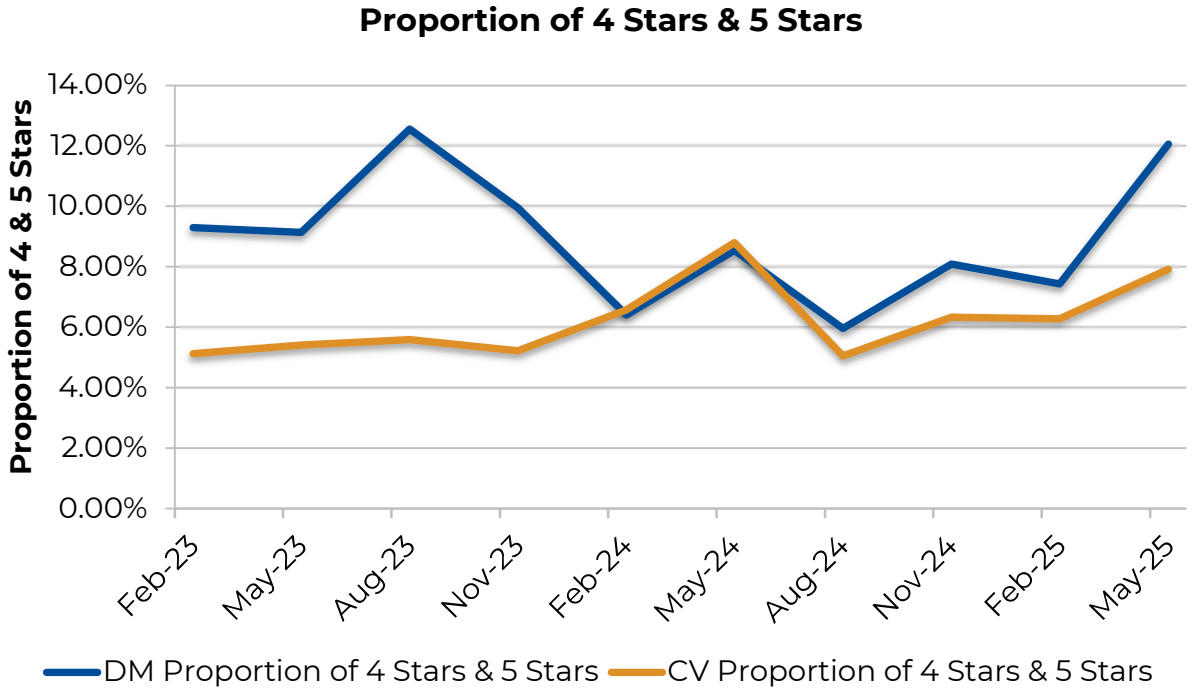


CMA Trends

The following line graph shows trends in the average star rating for prescribers included in the CMA mailing since February 2023. Please note, the vertical axis starts at 0.75 in order to reflect small changes. The mailing list is updated to include prescribers meeting the current CMA criteria and to remove prescribers no longer meeting the criteria. This graph is specific to those prescribers included in the mailings and differentiates between DM and CV (i.e., statins and RAS antagonists) modules. An overall improvement in the average star rating is seen during the analysis period. Since February, 2023, the DM star ratings have usually been higher than the CV star ratings during the same time period. Approximately 40-45% of the prescribers who received the CMA mailings in a given year continue receiving the CMA mailings when the list is updated. Despite overall favorable increases in the average star ratings, opportunities for further enhancements continue to exist.

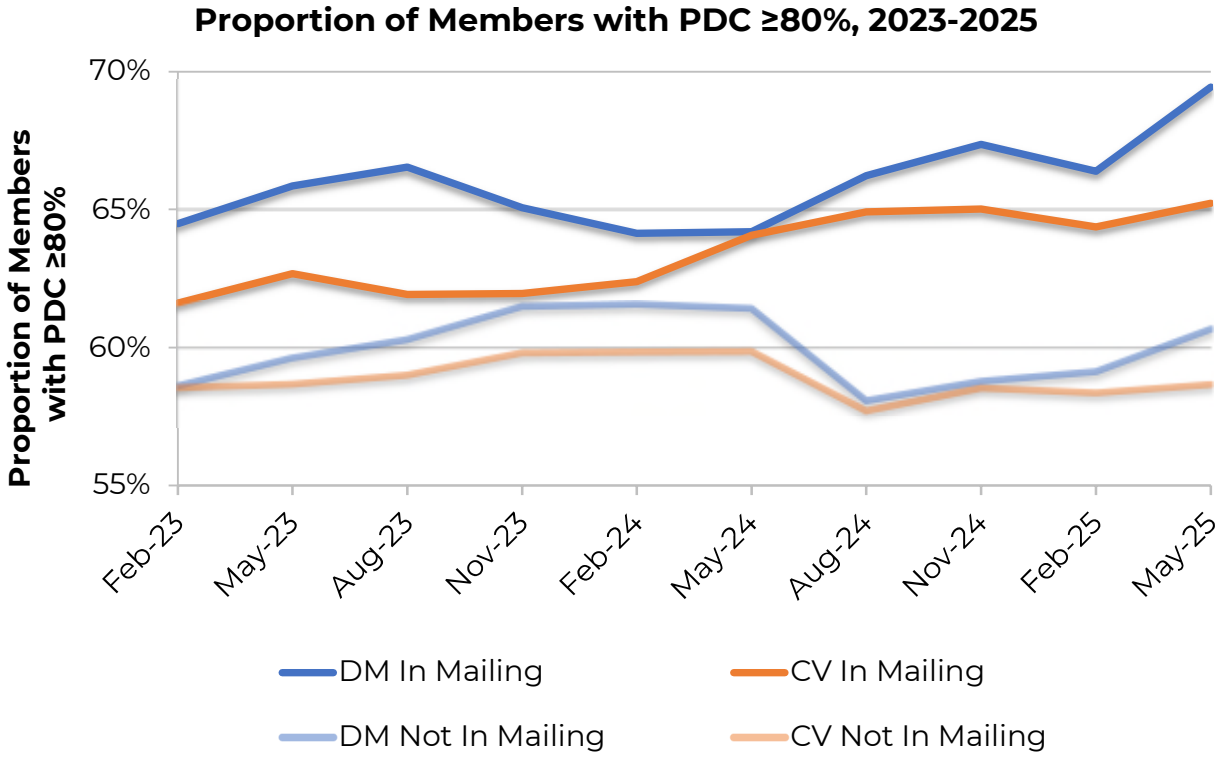


The following line graph shows trends in the proportion of prescribers with 4- and 5-star ratings included in the CMA mailing since February 2023. An overall increase in the proportion of 4 star and 5 star ratings was seen during the analysis period, similar to the average star ratings above. Also as above, overall favorable increases were seen, but opportunities for further enhancements continue to exist.



The following line graph shows trends in the proportion of members with a PDC ≥80% for those members with prescribers included in the mailing

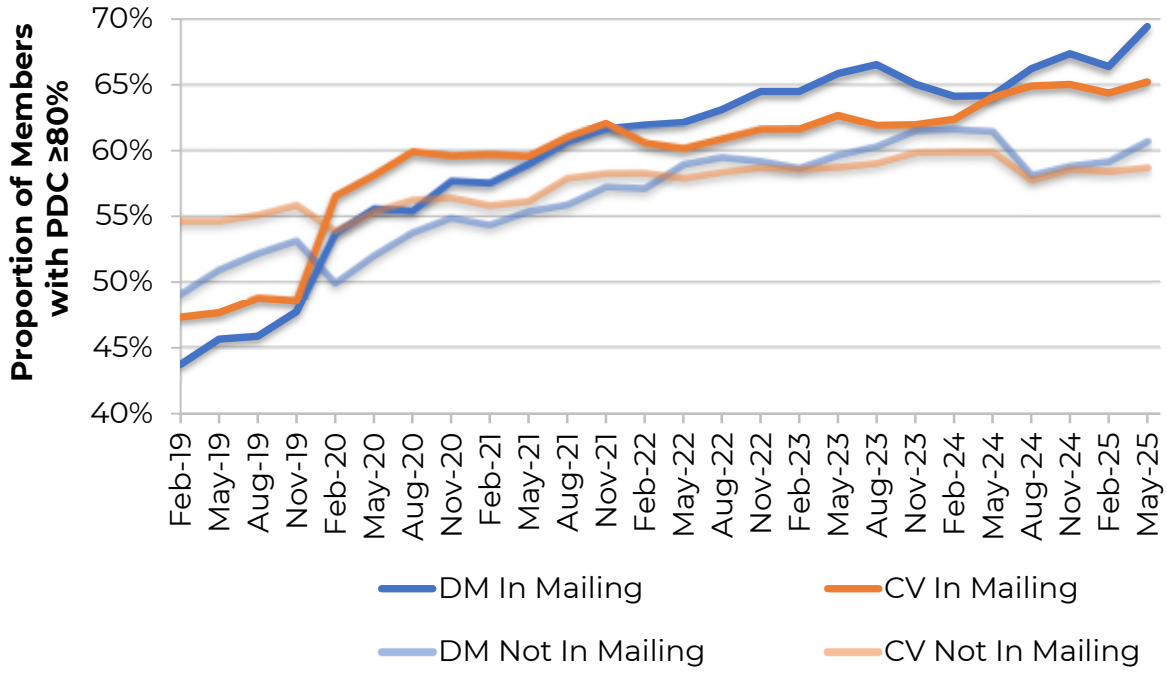
compared to those with prescribers not included in the mailing since February 2023. A member is considered adherent if their PDC is ≥80%. Please note, the vertical axis starts at 55% in order to reflect small changes.



Unlike prescribers included in the mailings, members included in the mailings are not consistent and may change during the calendar year due to medication discontinuations, gaining or losing SoonerCare eligibility, or changing to a prescriber not included in the mailing cohort. Despite member variability, an overall increase in the proportion of members with a PDC ≥80% was seen for both modules for those prescribers included in the recent mailing cohort. Notably, as of the May 2024 mailing, prescribers included in the mailing and prescribers not included in the mailing show a marked divergence in the proportion of members with PDC ≥80% for both DM and CV medications. This indicates prescriber mailings may have a positive impact on the proportion of members with PDC ≥80%.

The following graph shows the linear trends in the proportion of members with a PDC ≥80% for those members with prescribers included in the mailing compared to those with prescribers not included in the mailing since February 2019. Please note, the vertical axis starts at 40% in order to reflect small changes.

Proportion of Members with PDC ≥80%, 2019-2025



Since February 2019, members included in the CV mailings improved their rates of CV medication adherence by 238% compared to members not included in the CV mailings. During the same time period members included in the DM mailings improved their rates of DM medication adherence by 130% compared to members not included in the DM mailings.

Conclusions

Data specific to prescribers in the CMA mailing shows an overall trend toward higher average star ratings and an increase in the prescriber percentage of adherent members using chronic maintenance DM and CV medications. Trends in prescriber specific measures continue to show improvement, and while favorable increases were seen, opportunities for further enhancements continue to exist. The College of Pharmacy will continue to monitor SoonerCare member adherence with the goal of achieving a member PDC of ≥80% and a 5-star rating for the prescriber percentage of adherent members. New interventions will be implemented where appropriate, and results will be reported to the Drug Utilization Review (DUR) Board when available.

[1] Centers for Medicare and Medicaid Services (CMS): *Medicare 2024 Part C & D Star Rating Technical Notes*. Available online at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData. Last revised 04/09/2025. Last accessed 06/25/2025.

Appendix D

Vote to Prior Authorize Cobenfy™ (Xanomeline/ Trospium), Erzofri® [Paliperidone Palmitate Extended-Release (ER) Injection], and Opipza™ (Aripiprazole Oral Film) and Update the Approval Criteria for the Atypical Antipsychotic Medications

Oklahoma Health Care Authority
July 2025

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

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 of use 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.

Cobenfy™ (Xanomeline/Trospium) Product Summary[8,9,10]

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.

- <u>Key Inclusion Criteria:</u>
  - *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

- Positive and Negative Syndrome Scale (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	**$29.62**	**$1,777.20***	**$21,326.40**
Vraylar® (cariprazine) 6mg capsule	$48.47	$1,454.10α	$17,449.20
lurasidone 80mg tablet (generic)	$0.49	$29.40+	$352.80
risperidone 4mg tablet (generic)	$0.09	$10.80β	$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
αCost 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
βCost 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)	$3.74	$224.40	$2,692.80
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 palm) 234mg/1.5mL PFS	**$3,529.66**	**$45,885.58**
Invega Sustenna® (paliperidone palm) 234mg/1.5mL PFS	$3,427.83	$44,561.79

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).
palm = palmitate; PFS = pre-filled syringe; unit = each PFS
*Cost per year based on the maximum FDA approved dosing of 234mg once monthly

Recommendations[11]

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®)+

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
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®)ß
quetiapine (Seroquel®)		**paliperidone palmitate ER inj (Erzofri®)^∞**
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.
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) 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 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 meet 1 of the following:
    a. Member has a positive clinical response to olanzapine and experienced weight gain ≥7% from baseline body weight or other metabolic complications [e.g., increased waist circumference, increased metabolic parameters, worsening diabetes (i.e., increased A1c or glucose despite optimal adherent therapy for diabetes)] after starting olanzapine (baseline and current weight must be provided or documentation of metabolic complications); or
    b. Member has a trial of one Tier-1 and one Tier-2 medication with a lower weight gain or metabolic profile (e.g., aripiprazole, ziprasidone, lurasidone), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and
6. Member must not be taking opioids or undergoing acute opioid withdrawal; and
7. 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.

[1] U.S. Food and Drug Administration (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 06/17/2025.
[2] 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 06/17/2025.
[3] Erzofri® (Paliperidone Palmitate) – New Drug Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval_erzofri_2024-0729.pdf. Issued 07/28/2024. Last accessed 06/17/2025.
[4] 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 06/17/2025.
[5] 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 06/17/2025.
[6] 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 06/17/2025.
[7] 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 06/17/2025.
[8] 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 06/17/2025.
[9] 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.
[10] 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.
[11] 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 E

Vote 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) and Update the Approval Criteria for the Various Special Formulations

Oklahoma Health Care Authority
July 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.

Bucapsol™ (Buspirone Capsule) Product Summary and Recommendations[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 Unit	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).
Unit = capsule or tablet
*Cost per 30 days is based on an FDA approved dose of 30mg daily.

The College of Pharmacy recommends the prior authorization of Bucapsol™ (buspirone capsules) 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 Product Summary and Recommendations [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.

The College of Pharmacy recommends the prior authorization of carbamazepine 200mg chewable tablet with the following criteria (shown in red):

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.

Femlyv™ (Norethindrone Acetate/Ethinyl Estradiol ODT) Product Summary and Recommendations[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.

The College of Pharmacy recommends the prior authorization of Femlyv™ (norethindrone acetate/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/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.

Focinvez™ (Fosaprepitant Injection) Product Summary and Recommendations[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)	**$430.35**
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.

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.

Imkeldi (Imatinib Oral Solution) Product Summary and Recommendations[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)	$2.66	$159.60	$1,915.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days is based on an FDA approved maximum dose of 800mg per day.

The College of Pharmacy recommends the prior authorization of Imkeldi (imatinib oral solution) 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 Injection) Product Summary and Recommendations[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)	$108.03

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).

The College of Pharmacy recommends the prior authorization of IVRA (melphalan 90mg/mL) with the following criteria (shown in red):

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) Product Summary and Recommendations[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)	$1.73	$778.50	$9,342.00

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.

The College of Pharmacy recommends the prior authorization of Myhibbin™ (mycophenolate mofetil oral suspension) with the following criteria (shown in red):

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 ODT Product Summary and Recommendations[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.

The College of Pharmacy recommends the prior authorization of ondansetron 16mg ODT with the following criteria (shown in red):

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.

Tezruly™ (Terazosin Oral Solution) Product Summary and Recommendations[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)	$0.14	$8.40*	$100.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit= 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.

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.

Topiramate 50mg Sprinkle Capsule Product Summary and Recommendations[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)	$0.41	$196.80	$2,361.60
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.

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.

Veltassa® (Patiromer) 1g Powder Packet Product Summary and Recommendations[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.

The College of Pharmacy 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. For members 18 years of age and older, 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.

Vigafyde™ (Vigabatrin Oral Solution) Product Summary and Recommendations[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 pow 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).
pow = powder; sol = solution; unit = mL or packet
*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.

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.

Additional Recommendations

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.~~

[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 07/2024. 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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.

[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 06/12/2025.
[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 06/12/2025.
[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 06/12/2025.
[22] Veltassa® (Patiromer) Prescribing Information. Vifor Pharma, Inc. Available online at: https://www.veltassa.com/pi. Last revised 01/2025. Last accessed 06/12/2025.
[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 02/27/2025. Last accessed 06/12/2025.
[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 06/12/2025.

Appendix F

Vote to Prior Authorize Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications

Oklahoma Health Care Authority
July 2025

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

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[8]

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.

[1] U.S. Food and Drug Administration (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 06/24/2025.
[2] 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 06/24/2025.
[3] 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 06/24/2025.
[4] 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 06/24/2025.
[5] 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 06/24/2025.
[6] 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 06/24/2025.
[7] 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 06/24/2025.
[8] 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 06/24/2025.

Appendix G

Fiscal Year 2024 Annual Review of Colorectal Cancer (CRC) Medications

Oklahoma Health Care Authority
July 2025

Current Prior Authorization Criteria

Utilization data for Braftovi® (encorafenib), Keytruda® (pembrolizumab), Opdivo® (nivolumab), and Yervoy® (ipilimumab) and approval criteria for indications other than CRC can be found in the December 2024 Drug Utilization Review (DUR) packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Cyramza® (ramucirumab) and approval criteria for indications other than CRC can be found in the January 2025 DUR packet. This medication and criteria are reviewed annually with the gastrointestinal (GI) cancer medications. Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki), Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb), Perjeta® (pertuzumab), Trazimera® (trastuzumab-qyyp), Tukysa® (tucatinib), and Tykerb® (lapatinib) and approval criteria for indications other than CRC can be found in the September 2024 DUR packet. These medications and criteria are reviewed annually with the breast cancer medications. Utilization data for Krazati® (adagrasib) and Lumakras® (sotorasib) and approval criteria for indications other than CRC can be found in the May 2025 DUR packet. These medications and criteria are reviewed annually with the lung cancer medications.

Alymsys® (Bevacizumab-maly), Avzivi® (Bevacizumab-tnjn), and Vegzelma® (Bevacizumab-adcd) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Avastin® (bevacizumab), Mvasi® (bevacizumab-awwb), or Zirabev® (bevacizumab-bvzr), which are available without prior authorization, 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.

Braftovi® (Encorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic CRC; and
2. BRAF V600E mutation positive; and
3. Used in combination with cetuximab or panitumumab; and

a. Disease must have progressed following adjuvant therapy within 12 months; or
b. Used following progression of any line of metastatic therapy.

Cyramza® (Ramucirumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of CRC; and
2. Subsequent therapy for metastatic disease after progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine; and
3. Used in combination with an irinotecan-based regimen.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic disease; and
2. Disease has progressed on prior therapy; and
3. Human epidermal receptor type 2 (HER2)-amplified disease with immunohistochemistry (IHC) 3+; and
4. Used as a single agent.

Fruzaqla® (Fruquintinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic CRC; and
2. Previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previously treated with an anti-vascular endothelial growth factor (VEGF) therapy; and
4. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy.

Herceptin® (Trastuzumab), Hercessi™ (Trastuzumab-strf), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with pertuzumab, lapatinib, or tucatinib; and
4. Used in 1 of the following settings:
   a. If first-line therapy, patient should not be a candidate for intensive therapy; or
   b. For the treatment of advanced or metastatic disease following disease progression; and
5. Preferred trastuzumab products include Kanjinti® (trastuzumab-anns) and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred

trastuzumab products [Herceptin® (trastuzumab), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-pkrb), Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [Kanjinti® (trastuzumab-anns) or Trazimera® (trastuzumab-qyyp)]. 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.

Keytruda® (Pembrolizumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

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.

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic, recurrent, or unresectable CRC; and
2. Previously treated with a fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previously treated with an anti-vascular endothelial growth factor (VEGF) therapy; and
    a. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy; and
4. Used as monotherapy or in combination with bevacizumab.

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of metastatic gastric or GEJ adenocarcinoma; and
2. Previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, paclitaxel, docetaxel, or irinotecan; and
3. If human epidermal receptor type 2 (HER2)-positive disease, prior treatment should have included HER2 targeted therapy.

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.

Opdivo® (Nivolumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR).

Perjeta® (Pertuzumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with trastuzumab; and
4. Used in 1 of the following settings:
    a. If first-line therapy, member should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression.

Stivarga® (Regorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of metastatic, recurrent, or unresectable CRC; and
2. Previous treatment with a fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; and
3. Previous treatment with an anti-vascular endothelial growth factor (VEGF) therapy; and
    a. If RAS wild-type disease, previously treated with an anti-epidermal growth factor receptor (EGFR) therapy.

Stivarga® (Regorafenib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic GIST; and
2. Previously treated with imatinib and sunitinib.

Stivarga® (Regorafenib) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Previous treatment with sorafenib.

Stivarga® (Regorafenib) Approval Criteria [Osteosarcoma Diagnosis]:

1. Used for relapsed or refractory disease; and
2. Used in the second line or greater setting; and
3. Used as a single agent.

Tukysa® (Tucatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of RAS wild-type HER2-positive unresectable or metastatic CRC; and
2. Has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy; and
3. Used in combination with trastuzumab.

Tykerb® (Lapatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable, advanced, or metastatic disease; and
2. Member has human epidermal receptor 2 (HER2)-amplified disease; and
3. Member has wild-type RAS and BRAF disease; and
4. Member meets 1 of the following:
    a. Has tried at least 1 chemotherapy regimen; or
    b. Is not a candidate for intensive therapy, according to the prescriber; and
5. Used in combination with trastuzumab; and
6. Member has not been previously treated with a HER2-inhibitor.

Yervoy® (Ipilimumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and
3. Used in combination with nivolumab.

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 CRC Medications: Fiscal Year 2024

The following utilization data includes medications indicated for CRC; however, the data does not differentiate between CRC 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	23	71	$1,014,667.57	$14,291.09	$511.43	4,146	1,984
2023 Total	**23**	**71**	**$1,014,667.57**	**$14,291.09**	**$511.43**	**4,146**	**1,984**
Fiscal Year 2024							
FFS	23	71	$1,040,478.90	$14,654.63	$526.29	3,710	1,977
Aetna	2	3	$49,871.67	$16,623.89	$579.90	180	86
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**24**	**74**	**$1,090,350.57**	**$14,734.47**	**$528.53**	**3,890**	**2,063**
% Change	**4.30%**	**4.20%**	**7.50%**	**3.10%**	**3.30%**	**-6.20%**	**4.00%**
Change	**1**	**3**	**$75,683.00**	**$443.38**	**$17.10**	**-256**	**79**

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)

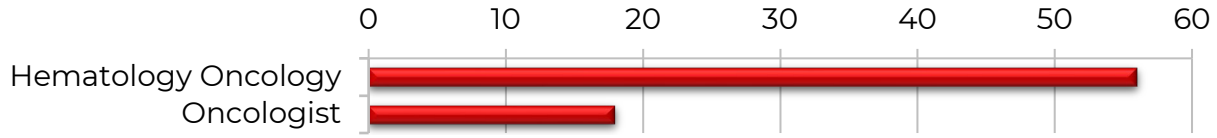
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	1,034	3,780	$3,101,326.20	$820.46	3.66
2023 Total	**1,034**	**3,780**	**$3,101,326.20**	**$820.46**	**3.66**
Fiscal Year 2024					
FFS	813	2,477	$2,556,988.28	$1,032.29	3.05
Aetna	17	33	$13,030.20	$394.85	1.94
Humana	28	43	$5,063.16	$117.75	1.54
OCH	25	36	$10,856.64	$301.57	1.44
2024 Total	**834**	**2,589**	**$2,585,938.28**	**$998.82**	**3.1**
% Change	**-19.34%**	**-31.51%**	**-16.62%**	**21.74%**	**-15.30%**
Change	**-200**	**-1,191**	**-$515,387.92**	**$178.36**	**-0.56**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 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 CRC Medications: Pharmacy Claims (All Plans)

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

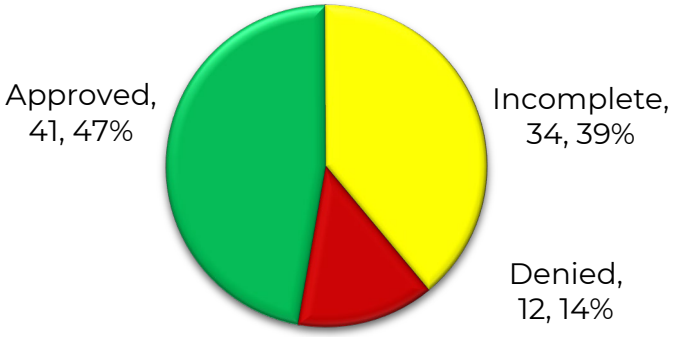
Top Prescriber Specialties of CRC Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of CRC Medications

There were 87 prior authorization requests submitted for CRC 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	38	48%	32	41%	9	11%	**79**
Aetna	1	33%	2	67%	0	0%	**3**
Humana	1	25%	0	0%	3	75%	**4**
OCH	1	100%	0	0%	0	0%	**1**
Total	**41**	**47%**	**34**	**39%**	**12**	**14%**	**87**

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]

Anticipated Patent Expirations

- Stivarga® (regorafenib): July 2032
- Fruzaqla® (fruquintinib): September 2035
- Lonsurf® (trifluridine/tipiracil): February 2037

Recommendations

The College of Pharmacy does not recommend any changes to the current CRC medications prior authorization criteria at this time.

Utilization Details of CRC Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRIFLURIDINE/TIPIRACIL PRODUCTS						
LONSURF TAB 20/8.19MG	30	14	$441,880.41	$14,729.35	2.14	40.53%
LONSURF TAB 15/6.14MG	22	8	$198,278.32	$9,012.65	2.75	18.18%
SUBTOTAL	**52**	**22**	**$640,158.73**	**$12,310.74**	**2.36**	**58.71%**
REGORAFENIB PRODUCTS						
STIVARGA TAB 40MG	16	10	$298,939.38	$18,683.71	1.6	27.42%
SUBTOTAL	**16**	**10**	**$298,939.38**	**$18,683.71**	**1.6**	**27.42%**
FRUQUINTINIB PRODUCTS						
FRUZAQLA CAP 5MG	6	3	$151,252.46	$25,208.74	2	13.87%
SUBTOTAL	**6**	**3**	**$151,252.46**	**$25,208.74**	**2**	**13.87%**
TOTAL	**74**	**24***	**$1,090,350.57**	**$14,734.47**	**3.08**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; 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
BEVACIZUMAB J9035 (AVASTIN)	1,936	751	$1,774,105.09	$916.38	2.58
BEVACIZUMAB-BVZR Q5118 (ZIRABEV)	598	79	$723,497.78	$1,209.86	7.57
BEVACIZUMAB-AWWB Q5107 (MVASI)	39	7	$30,607.71	$784.81	5.57
BEVACIZUMAB-ADCD Q5129 (VEGZELMA)	14	4	$51,669.70	$3,690.69	3.5
BEVACIZUMAB-MALY Q5126 (ALYMSYS)	2	1	$6,058.00	$3,029.00	2
TOTAL	**2,589**	**834**	**$2,585,938.28**	**$998.82**	**3.1**

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 06/2025. Last accessed 06/12/2025.

Appendix H

Fiscal Year 2024 Annual Review of Defencath® (Taurolidine/Heparin)

Oklahoma Health Care Authority
July 2025

Current Prior Authorization Criteria

Defencath® (Taurolidine/Heparin) Approval Criteria:

1. An FDA approved indication of reducing the incidence of catheter-related bloodstream infections (CRBSIs) in adult members with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC); and
2. Member must be 18 years of age or older; and
3. Must be used for prevention of CRBSIs; and
4. Prescriber must verify Defencath® is used only as a catheter lock solution (CLS) in CVCs and will not be administered systemically or used as a catheter lock flush product (i.e., it must be aspirated from the catheter and discarded prior to the next utilization of the CVC); and
5. Member must not have a known history of heparin-induced thrombocytopenia (HIT) or known hypersensitivity to pork products, taurolidine, heparin, or other components of Defencath®; and
6. A quantity limit of 2 vials per HD session or 24 vials per 28 days will apply; and
    a. For requests exceeding the quantity limit, supporting documentation (e.g., HD schedule, number of CVC lumens, CVC lumen volumes) must be provided for a quantity limit override; and
7. Approvals will be granted for 1 year.

Utilization of Defencath® (Taurolidine/Heparin): Fiscal Year 2024

There was no SoonerCare utilization of Defencath® (taurolidine/heparin) during fiscal year 2024 (07/01/2023 to 06/30/2024).

Prior Authorization of Defencath® (Taurolidine/Heparin)

There were no prior authorization requests submitted for Defencath® (taurolidine/heparin) during fiscal year 2024.

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Defencath® (taurolidine/heparin): April 2042

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

- **December 2024:** The package labeling for Defencath® (taurolidine/heparin) was updated to include additional instructions for administration. Per the updated labeling, if Defencath® cannot be aspirated from the central venous catheter (CVC) or if a catheter malfunction is suspected, standard of care measures should be utilized, including but not limited to flushing the lumen(s) with normal saline as appropriate.

Recommendations

The College of Pharmacy recommends the following changes to the Defencath® (taurolidine/heparin) approval criteria based on FDA approved updates to the package labeling (changes shown in red):

Defencath® (Taurolidine/Heparin) Approval Criteria:

1. An FDA approved indication of reducing the incidence of catheter-related bloodstream infections (CRBSIs) in adult members with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC); and
2. Member must be 18 years of age or older; and
3. Must be used for prevention of CRBSIs; and
4. Prescriber must verify Defencath® is used only as a catheter lock solution (CLS) in CVCs and will not be administered systemically or used as a catheter lock flush product (i.e., it ~~must~~ should be aspirated from the catheter and discarded prior to the next utilization of the CVC); and
5. Member must not have a known history of heparin-induced thrombocytopenia (HIT) or known hypersensitivity to pork products, taurolidine, heparin, or other components of Defencath®; and
6. A quantity limit of 2 vials per HD session or 24 vials per 28 days will apply; and
    a. For requests exceeding the quantity limit, supporting documentation (e.g., HD schedule, number of CVC lumens, CVC lumen volumes) must be provided for a quantity limit override; and
7. Approvals will be granted for 1 year.

[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 06/2025. Last accessed 06/24/2025.
[2] Defencath® (Taurolidine/Heparin) Prescribing Information. CorMedix. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/214520s003lbl.pdf. Last revised 12/19/2024. Last accessed 06/24/2025.

Appendix I

Fiscal Year 2024 Annual Review of Constipation and Diarrhea Medications

Oklahoma Health Care Authority
July 2025

Current Prior Authorization Criteria: Constipation Medications

Amitiza® (Lubiprostone) Approval Criteria [Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C) Diagnosis]:

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Linzess® (linaclotide) or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
8. A quantity limit of 60 capsules per 30 days will apply.

Amitiza® (Lubiprostone) Approval Criteria [Opioid-Induced Constipation (OIC) Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, except methadone, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
3. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
7. Amitiza® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 60 capsules per 30 days will apply.

Ibsrela® (Tenapanor) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or

    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 tablets per 30 days will apply.

Linzess® (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Chronic idiopathic constipation (CIC) in members 18 years of age or older; or
    b. Irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; or
    c. Functional constipation in members 6 to 17 years of age; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and

    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 capsules per 30 days will apply.

Motegrity® (Prucalopride) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 30 tablets per 30 days will apply.

Movantik® (Naloxegol) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and

2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Movantik® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 30 tablets per 30 days will apply.

Pizensy™ (Lactitol) Approval Criteria:

1. An FDA approved indication for treatment of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Member must not have a known contraindication to Pizensy™ (i.e., suspected gastrointestinal obstruction, galactosemia); and
3. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
4. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Member must not have known or suspected gastrointestinal obstruction; and
6. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be

within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
8. Use of the unit-dose packets will require a patient-specific, clinically significant reason why the member cannot use the multi-dose bottle; and
9. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
10. A quantity limit of 560 grams per 28 days will apply.

Relistor® (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Chronic Non-Cancer Pain Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
3. Member must have current use of opioid medications; and
4. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. Member must not have known or suspected gastrointestinal obstruction; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and

8. A patient-specific, clinically significant reason why the member cannot use the tablet formulation of Relistor® must be provided; and
9. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62kg; and/or
    b. Caregiver unable to draw up dose from vial; and
10. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
11. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
12. A quantity limit of 30 units per month will apply.

Relistor® (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Terminal Disease Diagnosis]:

1. An FDA approved diagnosis of OIC in members with severe terminal disease who are receiving only palliative care (life expectancy <6 months); and
2. Member must have current use of opioid medications; and
3. Documented treatment attempts with a minimum of 3 alternative products, excluding bulk forming laxatives; and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
4. Mechanical gastrointestinal obstruction has been ruled out; and
5. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62 kg; and/or
    b. Caregiver unable to draw up dose from vial; and
6. A quantity limit of 30 units per month will apply; and
7. Approvals will be for the duration of 16 weeks of therapy. Use of Relistor® beyond 4 months has not been studied in patients with severe terminal disease.

Relistor® (Methylnaltrexone) Tablets Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and

4. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different types of products that have failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 90 tablets per 30 days will apply.

Symproic® (Naldemedine) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be

within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Symproic® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 30 tablets per 30 days will apply.

Trulance® (Plecanatide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using 1 of the following methods (results must be submitted):
   a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
   b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners; and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. A quantity limit of 30 tablets per 30 days will apply.

Current Prior Authorization Criteria: Diarrhea Medications

Aemcolo® (Rifamycin) Approval Criteria:

1. An FDA approved diagnosis of traveler's diarrhea; and
2. Member must be 18 years of age or older; and

3. Traveler's diarrhea must be due to non-invasive strains of *Escherichia coli*; and
4. A patient-specific, clinically significant reason why the member cannot use Xifaxan® (rifaximin) oral tablets must be provided; and
5. A quantity limit of 12 tablets per 3 days will apply.

Motofen® (Difenoxin/Atropine) Approval Criteria:

1. An FDA approved diagnosis of acute nonspecific diarrhea or acute exacerbations of chronic functional diarrhea; and
2. Member must not be 2 years of age or younger;
3. Member must not have diarrhea associated with organisms that penetrate the intestinal mucosa (e.g., toxigenic *Escherichia coli*, *Salmonella* species, *Shigella*) or pseudomembranous colitis associated with broad spectrum antibiotics; and
4. A patient-specific, clinically significant reason why the member cannot use Lomotil® (diphenoxylate/atropine) and loperamide must be provided; and
5. A quantity limit of 16 tablets per 2 days will apply.

Mytesi® (Crofelemer) Approval Criteria:

1. An FDA approved diagnosis of non-infectious diarrhea in adult members with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) currently on anti-retroviral therapy; and
2. Duration of diarrhea has been ≥4 weeks; and
3. Dietary modifications have failed; and
4. Prescribers must verify that infectious diarrhea has been ruled out via confirmation of all of the following:
    a. CD4 count has been measured and possible opportunistic infections have been ruled out; and
    b. Member does not have fever; and
    c. Stool studies for pathogens are negative including:
        i. Bacterial cultures; and
        ii. Ova, parasite, cryptosporidium, and/or giardia; and
        iii. *Clostridium difficile* (*Clostridium difficile* testing should include a glutamate dehydrogenase screen and if positive, should be followed by a confirmatory test or nucleic acid amplification test in members with documented diarrhea; a toxin enzyme immunoassay should not be used as a stand-alone test); and
5. If stool study results are negative and the member has severe symptoms, particularly in the case of advanced immunodeficiency, an endoscopy with biopsy is recommended, at the prescriber's discretion, to rule out inflammatory bowel disease, cancer, cytomegalovirus (CMV)

infection, microsporidium, or mycobacterium avium complex (MAC); and
6. A quantity limit of 60 tablets per 30 days will apply. Initial approvals will be for 4 weeks of therapy. Subsequent approvals may be granted for 6 months if the prescriber documents the member is responding well to treatment.

Viberzi® (Eluxadoline) Approval Criteria:
1. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
2. Member must be 18 years of age or older; and
3. Member must not have any of the contraindications for use of Viberzi® (i.e., removed gallbladder; biliary duct obstruction or sphincter of Oddi disease or dysfunction; alcoholism, alcohol abuse, or alcohol addiction; history of pancreatitis or structural diseases of the pancreas; severe hepatic impairment; history of chronic or severe constipation; mechanical gastrointestinal obstruction); and
4. Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 tablets per 30 days will apply.

Xermelo® (Telotristat Ethyl) Approval Criteria:
1. An FDA approved diagnosis of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy; and
2. Member must be 18 years of age or older; and
3. Member must have been taking a stable dose of SSA therapy for the last 3 months and be inadequately controlled (4 or more bowel movements per day); and
4. Prescriber must verify member will continue taking SSA therapy in combination with Xermelo®; and
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
6. A quantity limit of 90 tablets per 30 days will apply.

Xifaxan® (Rifaximin) 200mg Approval Criteria:
1. An FDA approved diagnosis of traveler's diarrhea; and

2. Member must be 12 years of age or older; and
3. Traveler's diarrhea must be due to noninvasive strains of *Escherichia coli*; and
4. A quantity limit of 9 tablets per 3 days will apply.

Xifaxan® (Rifaximin) 550mg Approval Criteria:

1. An FDA approved indication for the reduction in risk of overt hepatic encephalopathy (HE) recurrence; or
2. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
   a. For the diagnosis of IBS-D: Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
   b. For the diagnosis of IBS-D: Member must be 18 years of age or older; and
3. A quantity limit of 60 tablets per 30 days will apply. Patients with the diagnosis of IBS-D needing 42 tablets for a 14-day treatment regimen (550mg 3 times daily for 14 days) will be approved for a quantity limit override upon meeting Xifaxan® approval criteria. Patients with IBS-D who experience a recurrence of symptoms can be retreated up to 2 times with the same 14-day treatment regimen (550mg 3 times daily for 14 days).

Utilization of Constipation and Diarrhea Medications: Fiscal Year 2024

Comparison of Fiscal Years: Constipation Medications: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	451	1,988	$901,055.34	$453.25	$14.96	65,924	60,228
2023 Total	**451**	**1,988**	**$901,055.34**	**$453.25**	**$14.96**	**65,924**	**60,228**
Fiscal Year 2024							
FFS	602	2,392	$1,125,918.60	$470.70	$15.62	77,561	72,082
Aetna	164	258	$125,922.88	$488.07	$16.33	8,140	7,710
Humana	233	403	$202,534.46	$502.57	$16.89	13,359	11,989
OCH	215	342	$179,269.16	$524.18	$17.52	10,861	10,231
2024 Total	**1,057**	**3,395**	**$1,633,645.10**	**$481.19**	**$16.01**	**109,921**	**102,012**
% Change	**134.40%**	**70.80%**	**81.30%**	**6.20%**	**7.00%**	**66.70%**	**69.40%**
Change	**606**	**1,407**	**$732,589.76**	**$27.94**	**$1.05**	**43,997**	**41,784**

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 SoonerSelect plans.

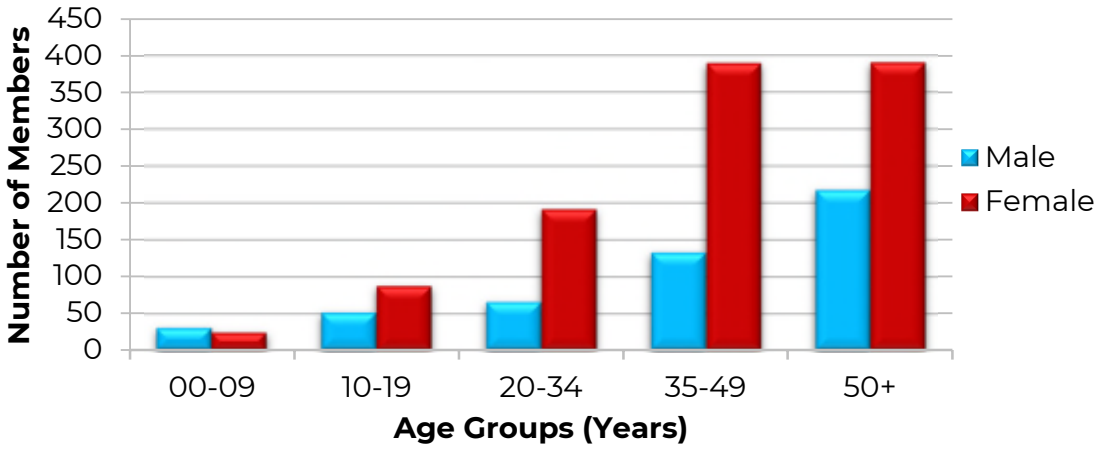
Comparison of Fiscal Years: Diarrhea Medications: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	459	1,971	$5,565,027.20	$2,823.45	$97.19	113,996	57,258
2023 Total	**459**	**1,971**	**$5,565,027.20**	**$2,823.45**	**$97.19**	**113,996**	**57,258**
Fiscal Year 2024							
FFS	462	1,936	$5,673,300.35	$2,930.42	$101.46	118,188	55,919
Aetna	42	78	$221,034.28	$2,833.77	$106.57	4,230	2,074
Humana	63	123	$364,132.34	$2,960.43	$105.48	7,010	3,452
OCH	53	88	$260,061.91	$2,955.25	$102.83	5,070	2,529
2024 Total	**523**	**2,225**	**$6,518,528.88**	**$2,929.68**	**$101.89**	**134,498**	**63,974**
% Change	**13.90%**	**12.90%**	**17.10%**	**3.80%**	**4.80%**	**18.00%**	**11.70%**
Change	**64**	**254**	**$953,501.68**	**$106.23**	**$4.70**	**20,502**	**6,716**

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 SoonerSelect plans.
The above table includes Xifaxan® (rifaximin), which was first approved by the FDA in 2004 and has a significant federal rebate. Please note, the majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

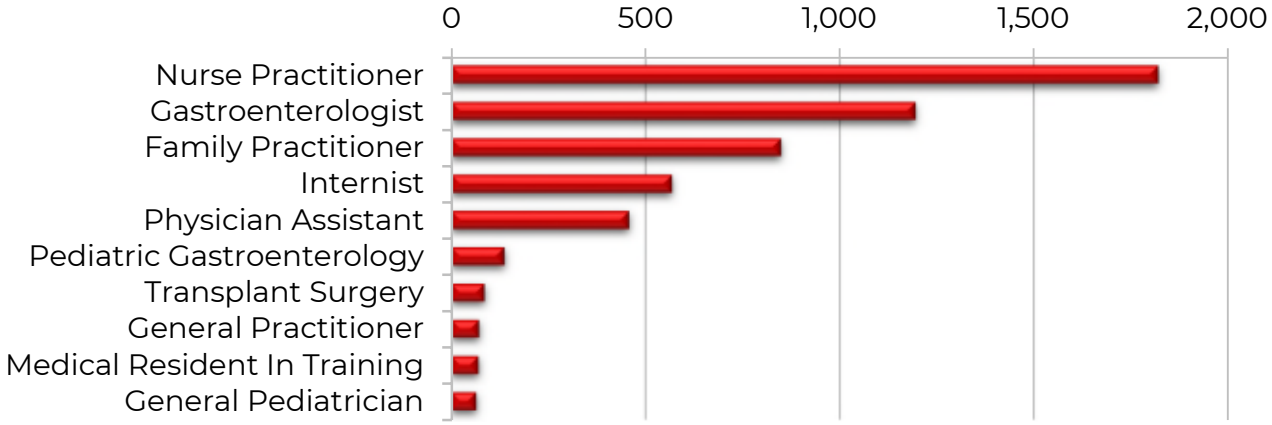
- Aggregate drug rebates collected during fiscal year 2024 for the constipation and diarrhea medications totaled $7,120,705.77.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Constipation and Diarrhea 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 Constipation and Diarrhea Medications by Number of Claims (All Plans)



Prior Authorization of Constipation and Diarrhea Medications

There were 4,789 prior authorization requests submitted for constipation and diarrhea medications during fiscal year 2024. Please note: The status of petitions below includes prior authorization requests for Xifaxan® (rifaximin) 550mg for the reduction in risk of overt hepatic encephalopathy (HE) recurrence. 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	1,040	23%	2,357	51%	1,184	26%	**4,581**
Aetna	49	45%	4	4%	56	51%	**109**
Humana	32	52%	0	0%	30	48%	**62**
OCH	15	41%	0	0%	22	59%	**37**
Total	**1,136**	**24%**	**2,361**	**49%**	**1,292**	**27%**	**4,789**

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

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

Anticipated Patent Expiration(s):

- Amitiza® (lubiprostone): October 2027
- Xifaxan® (rifaximin): October 2029
- Ibsrela® (tenapanor): August 2033
- Relistor® (methylnaltrexone injection): December 2030
- Xermelo® (telotristat ethyl): February 2031
- Relistor® (methylnaltrexone tablet): March 2031
- Mytesi® (crofelemer): October 2031
- Movantik® (naloxegol): April 2032
- Viberzi® (eluxadoline): March 2033
- Symproic® (naldemedine): May 2033
- Linzess® (linaclotide): August 2033
- Pizensy™ (lactitol): May 2037

Pipeline:

- **Crofelemer:** Crofelemer, which is currently U.S. Food and Drug Administration (FDA) approved as Mytesi® to treat diarrhea in patients with human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) who are on antiretroviral therapy (ART), is currently being evaluated for additional indications. A Phase 3 trial is recruiting participants to evaluate the efficacy of crofelemer for irritable bowel syndrome with diarrhea (IBS-D). Additionally, results of a global Phase 3 trial, OnTarget, evaluating crofelemer for cancer therapy-related diarrhea did not reach its primary endpoint in adult patients with solid tumors treated with targeted cancer therapy regimens; however, a subgroup analysis of patients with breast cancer achieved statistically significant results. Jaguar Health plans to continue to evaluate crofelemer for this indication. Lastly, Jaguar Health announced that preliminary results of pilot trials suggest that crofelemer may have utility in the treatment of functional diarrhea and chronic idiopathic diarrhea. The full results of the pilot trials are not yet published.

Recommendations[5,6,7,8,9,10]

The College of Pharmacy recommends the following changes to the current constipation medications approval criteria based on colorectal cancer screening guidelines published by the American College of Physicians (ACP), American Cancer Society (ACS), American College of Gastroenterology (ACG), American Gastroenterological Association (AGA), and the U.S. Preventative Services Task Force (USPSTF) (changes shown in red):

Amitiza® (Lubiprostone) Approval Criteria [Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C) Diagnosis]:

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Linzess® (linaclotide) or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
8. A quantity limit of 60 capsules per 30 days will apply.

Amitiza® (Lubiprostone) Approval Criteria [Opioid-Induced Constipation (OIC) Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, except methadone, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and

~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~

4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
7. Amitiza® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 60 capsules per 30 days will apply.

Ibsrela® (Tenapanor) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and

6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 tablets per 30 days will apply.

Linzess® (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Chronic idiopathic constipation (CIC) in members 18 years of age or older; or
   b. Irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; or
   c. Functional constipation in members 6 to 17 years of age; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 capsules per 30 days will apply.

Motegrity® (Prucalopride) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) in members 18 years of age or older; and

2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 30 tablets per 30 days will apply.

Movantik® (Naloxegol) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~

5. depending on risk factors and/or previous screening results); and
6. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Movantik® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 30 tablets per 30 days will apply.

Pizensy™ (Lactitol) Approval Criteria:

1. An FDA approved indication for treatment of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Member must not have a known contraindication to Pizensy™ (i.e., suspected gastrointestinal obstruction, galactosemia); and
3. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
    ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
    ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
5. Member must not have known or suspected gastrointestinal obstruction; and
6. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and

8. Use of the unit-dose packets will require a patient-specific, clinically significant reason why the member cannot use the multi-dose bottle; and
9. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
10. A quantity limit of 560 grams per 28 days will apply.

Relistor® (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Chronic Non-Cancer Pain Diagnosis]:

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
3. Member must have current use of opioid medications; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
5. Documentation of hydration attempts and trials of at least 3 different products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. Member must not have known or suspected gastrointestinal obstruction; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use the tablet formulation of Relistor® must be provided; and
9. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
   a. Weight range of 38kg to 62kg; and/or
   b. Caregiver unable to draw up dose from vial; and

10. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
11. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
12. A quantity limit of 30 units per month will apply.

Relistor® (Methylnaltrexone) Tablets Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
5. Documentation of hydration attempts and trials of at least 3 different types of products that have failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 90 tablets per 30 days will apply.

Symproic® (Naldemedine) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who

are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Symproic® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 30 tablets per 30 days will apply.

Trulance® (Plecanatide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members 45 years of age or older using an appropriate screening strategy ~~1 of the following methods~~ (results must be submitted)~~:~~; and
   ~~a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or~~
   ~~b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and~~
4. Member must not have known or suspected gastrointestinal obstruction; and

5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners; and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. A quantity limit of 30 tablets per 30 days will apply.

The College of Pharmacy also recommends the following changes to the Motofen® (difenoxin/atropine) criteria for clarity and to be consistent with FDA-approved package labeling (changes shown in red):

Motofen® (Difenoxin/Atropine) Approval Criteria:

1. An FDA approved diagnosis of acute nonspecific diarrhea or acute exacerbations of chronic functional diarrhea; and
2. Member must ~~not~~ be 2 years of age or ~~younger;~~ older. Use is contraindicated in pediatric patients younger than 2 years of age; and
3. Member must not have diarrhea associated with organisms that penetrate the intestinal mucosa (e.g., toxigenic *Escherichia coli*, *Salmonella* species, *Shigella*) or pseudomembranous colitis associated with broad spectrum antibiotics; and
4. A patient-specific, clinically significant reason why the member cannot use Lomotil® (diphenoxylate/atropine) and loperamide must be provided; and
5. A quantity limit of 16 tablets per 2 days will apply.

Utilization Details of Constipation Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LINACLOTIDE PRODUCTS						
LINZESS CAP 145MCG	945	309	$484,751.53	$512.96	3.06	29.67%
LINZESS CAP 290MCG	717	295	$373,146.06	$520.43	2.43	22.84%
LINZESS CAP 72MCG	671	175	$338,615.49	$504.64	3.83	20.73%
SUBTOTAL	**2,333**	**779**	**$1,196,513.08**	**$512.86**	**2.99**	**73.24%**
PLECANATIDE PRODUCTS						
TRULANCE TAB 3MG	497	169	$265,208.00	$533.62	2.94	16.23%
SUBTOTAL	**497**	**169**	**$265,208.00**	**$533.62**	**2.94**	**16.23%**
LUBIPROSTONE PRODUCTS						
LUBIPROSTONE CAP 24MCG	215	83	$16,632.44	$77.36	2.59	1.02%
LUBIPROSTONE CAP 8MCG	58	26	$4,615.15	$79.57	2.23	0.28%
AMITIZA CAP 24MCG	20	6	$5,416.21	$270.81	3.33	0.33%
AMITIZA CAP 8MCG	1	1	$362.48	$362.48	1	0.02%
SUBTOTAL	**294**	**116**	**$27,026.28**	**$91.93**	**2.53**	**1.65%**
NALOXEGOL PRODUCTS						
MOVANTIK TAB 25MG	115	46	$42,825.83	$372.40	2.5	2.62%
MOVANTIK TAB 12.5MG	35	15	$14,062.15	$401.78	2.33	0.86%
SUBTOTAL	**150**	**61**	**$56,887.98**	**$379.25**	**2.46**	**3.48%**
PRUCALOPRIDE PRODUCTS						
MOTEGRITY TAB 2MG	66	17	$33,632.08	$509.58	3.88	2.06%
MOTEGRITY TAB 1MG	14	3	$6,890.25	$492.16	4.67	0.42%
SUBTOTAL	**80**	**20**	**$40,522.33**	**$506.53**	**4**	**2.48%**
NALDEMEDINE PRODUCTS						
SYMPROIC TAB 0.2MG	18	5	$8,082.63	$1,665.61	3.6	0.49%
SUBTOTAL	**18**	**5**	**$8,082.63**	**$1,665.61**	**3.6**	**0.49%**
METHYLNALTREXONE PRODUCTS						
RELISTOR TAB 150MG	14	14	$24,414.31	$1,743.88	1	1.49%
SUBTOTAL	**14**	**14**	**$24,414.31**	**$1,743.88**	**1**	**1.49%**
TENAPANOR PRODUCTS						
IBSRELA TAB 50MG	9	3	$14,990.49	$449.04	3	0.92%
SUBTOTAL	**9**	**3**	**$14,990.49**	**$449.04**	**3**	**0.92%**
TOTAL	**3,395**	**1,057***	**$1,633,645.10**	**$481.19**	**3.21**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; 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.

Utilization Details of Diarrhea Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RIFAXIMIN PRODUCTS						
XIFAXAN TAB 550MG	2,192	511	$6,472,747.15	$2,952.90	4.29	99.30%
XIFAXAN TAB 200MG	4	2	$1,707.76	$426.94	2	0.03%
SUBTOTAL	**2,196**	**513**	**$6,474,454.91**	**$2,948.29**	**4.28**	**99.32%**
ELUXADOLINE PRODUCTS						
VIBERZI TAB 100MG	18	3	$26,958.15	$1,497.68	6	0.47%
VIBERZI TAB 75MG	10	6	$14,623.01	$1,462.30	1.33	0.11%
SUBTOTAL	**28**	**9**	**$41,581.16**	**$1,485.04**	**3.11**	**0.64%**
CROFELEMER PRODUCTS						
MYTESI TAB 125MG	1	1	$2,492.81	$2,492.81	1	0.04%
SUBTOTAL	**1**	**1**	**$2,492.81**	**$2,492.81**	**1**	**0.04%**
TOTAL	**2,225**	**523***	**$6,518,528.88**	**$2.10**	**4.25**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
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.
Xifaxan® (rifaximin) was first FDA approved in 2004 and has a significant federal rebate. Please note, the majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

[1] U.S. Food and Drug Administration (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 06/2025. Last accessed 06/13/2025.
[2] Napo Pharmaceuticals. Pipeline. Available online at: https://napopharma.com/pipeline/. Last accessed 06/13/2025.
[3] Jaguar Health, Inc. Jaguar Health Provides Update on Meeting with FDA Discussing Statistically Significant Results of Responder Analysis of Breast Cancer Patients in Phase 3 OnTarget Trial and Potential Approval Pathway for Crofelemer. *BioSpace*. Available online at: https://www.biospace.com/press-releases/jaguar-health-provides-update-on-meeting-with-fda-discussing-statistically-significant-results-of-responder-analysis-of-breast-cancer-patients-in-phase-3-ontarget-trial-and-potential-approval-pathway-for-crofelemer. Issued 06/09/2025. Last accessed 06/13/2025.
[4] Jaguar Health, Inc. Significant Positive Results with Jaguar Health's Crofelemer for Chronic Refractory Diarrhea in IBS-D, Presented at American College of Gastroenterology Annual Meeting. Available online at: https://jaguarhealth.gcs-web.com/news-releases/news-release-details/significant-positive-results-jaguar-healths-crofelemer-chronic. Issued 10/29/2024. Last accessed 06/13/2025.
[5] Qaseem A, Harrod CS, Crandall CJ, et al. Screening for Colorectal Cancer in Asymptomatic Average-Risk Adults: A Guidance Statement from the American College of Physicians (Version 2). *Ann Intern Med*. 2023;176(8):1092-1100. doi: 10.7326/M23-0779.
[6] Wolf AMD, Fontham ETH, Church TR, et al. Colorectal Cancer Screening for Average-Risk Adults: 2018 Guideline Update from The American Cancer Society. *CA Cancer J Clin*. 2018;68(4):250-281. doi: 10.3322/caac.21457.
[7] Shaukat A, Kahi CJ, Burke Carol. ACG Clinical Guidelines: Colorectal Cancer Screening 2021. *Am J Gastroenterol*. 2021;116(3):458-479. doi: 10.14309/ajg.0000000000001122.
[8] Issaka RB, Chan AT, Gupta S. AGA Clinical Practice Update on Risk Stratification for Colorectal Cancer Screening and Post-Polypectomy Surveillance: Expert Review. *Gastroenterology*. 2023;165:1280-1291. doi: 10.1053/j.gastro.2023.06.033.
[9] U.S. Preventative Services Task Force. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021;325(19):1965-1977. doi: 10.1001/jama.2021.6238.
[10] Motofen® (Difenoxin/Atropine Sulfate) Prescribing Information. Sebela Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017744s026lbl.pdf. Last revised 03/28/2017. Last accessed 06/24/2025.

Appendix J

Fiscal Year 2024 Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Azmiro™ (Testosterone Cypionate) and Undecatrex™ (Testosterone Undecanoate)

Oklahoma Health Care Authority
July 2025

Current Prior Authorization Criteria

Testosterone Products		
Tier-1	**Tier-2**	**Special PA**
testosterone cypionate IM inj (Depo Testosterone®)	testosterone enanthate sub-Q auto-injector (Xyosted®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone topical gel 1%, 1.62% packet (Androgel®)	testosterone nasal gel (Natesto®)
testosterone topical gel 1% packet, tube (Testim®, Vogelxo®)	testosterone topical gel 1% pump (Vogelxo®)	testosterone pellets (Testopel®)
testosterone topical gel 1.62% pump (Androgel®)	testosterone topical gel 2% pump (Fortesta®)	testosterone undecanoate IM inj (Aveed®)
testosterone topical solution (Axiron®)		testosterone undecanoate oral cap (Jatenzo®, Kyzatrex®, Tlando®)

cap = capsule; IM = intramuscular; inj = injection; PA = prior authorization; sub-Q = subcutaneous; tab = tablet

Initial Approval Criteria for All Testosterone Products:

1. An FDA approved diagnosis of 1 of the following:
   a. Testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchiectomy; or
   b. Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation; or
   c. Delayed puberty; or
   d. Advanced inoperable metastatic mammary cancer in females 1 to 5 years postmenopausal, or premenopausal females with breast cancer benefitting from oophorectomy and have been determined to have a hormone-responsive tumor; and
2. The prescriber must verify the member has been evaluated for the presence of a pituitary tumor as the potential cause of low testosterone

and the member will receive appropriate follow-up and/or treatment as necessary; and
3. Must include 2 labs showing pre-medication, morning testosterone (total testosterone) levels <300ng/dL; and
4. Must include 1 lab showing abnormal gonadotropins and/or other information necessary to demonstrate diagnosis; or
5. Testosterone and gonadotropin labs are not required for authorization of testosterone therapy if documentation is provided for established hypothalamic pituitary or gonadal disease, if the pituitary gland or testes has/have been removed, or for postmenopausal females with advanced inoperable metastatic mammary cancer or premenopausal females with breast cancer benefitting from oophorectomy and that have been determined to have a hormone-responsive tumor.

Testosterone Products Tier-2 Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. Member must have a trial of at least 2 Tier-1 products (must include at least 1 injectable and 1 topical formulation) at least 12 weeks in duration; or
3. A patient-specific, clinically significant reason why member cannot use all available Tier-1 products must be provided; or
4. Prior stabilization on a Tier-2 product (within the past 180 days); and
5. Approvals will be for the duration of 1 year; and
6. For Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]:
    a. Member must be trained by a health care professional on sub-Q administration and storage of Xyosted® sub-Q auto-injector.

Testosterone Products Special Prior Authorization (PA) Approval Criteria:

1. All diagnoses and laboratory requirements listed in the initial approval criteria for all testosterone products must be met; and
2. A patient-specific, clinically significant reason why member cannot use all other available formulations of testosterone must be provided; and
3. Approvals will be for the duration of 1 year.

Utilization of Testosterone Products: 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	524	2,278	$294,772.34	$129.40	$3.74	41,016	78,908
2023 Total	**524**	**2,278**	**$294,772.34**	**$129.40**	**$3.74**	**41,016**	**78,908**
Fiscal Year 2024							
FFS	484	1,621	$114,750.33	$70.79	$2.00	32,033	57,233
Aetna	243	339	$16,132.19	$47.59	$1.80	4,353	8,940
Humana	378	625	$25,364.97	$40.58	$1.43	3,882	17,773
OCH	320	495	$20,955.74	$42.33	$1.49	4,174	14,036
2024 Total	**1,258**	**3,080**	**$177,203.23**	**$57.53**	**$1.81**	**44,442**	**97,982**
% Change	**140.10%**	**35.20%**	**-39.90%**	**-55.50%**	**-51.60%**	**8.40%**	**24.20%**
Change	**734**	**802**	**-$117,569.11**	**-$71.87**	**-$1.93**	**3,426**	**19,074**

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	13	57	$202.20	$3.55	4.38
2023 Total	**13**	**57**	**$202.20**	**$3.55**	**4.38**
Fiscal Year 2024					
FFS	14	41	$92.81	$2.26	2.93
Aetna	9	13	$10.04	$0.77	1.44
Humana	4	14	$0.12	$0.01	3.5
OCH	8	14	$15.29	$1.09	1.75
2024 Total	**34**	**82**	**$118.26**	**$1.44**	**2.41**
% Change	**161.54%**	**43.86%**	**-41.51%**	**-59.44%**	**-44.98%**
Change	**21**	**25**	**-$83.94**	**-$2.11**	**-1.97**

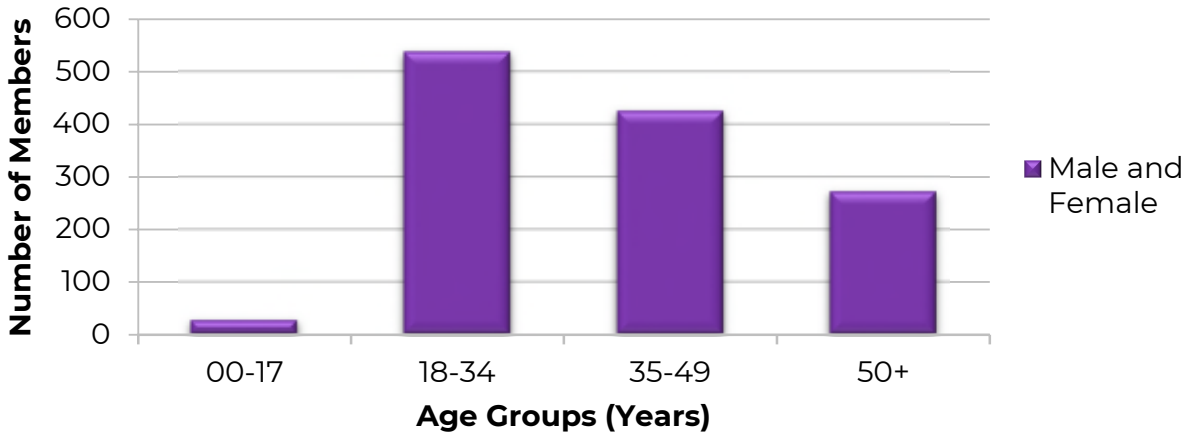
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data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

- Aggregate drug rebates collected during fiscal year 2024 for testosterone products totaled $53,365.72[Δ]. Rebates are collected after

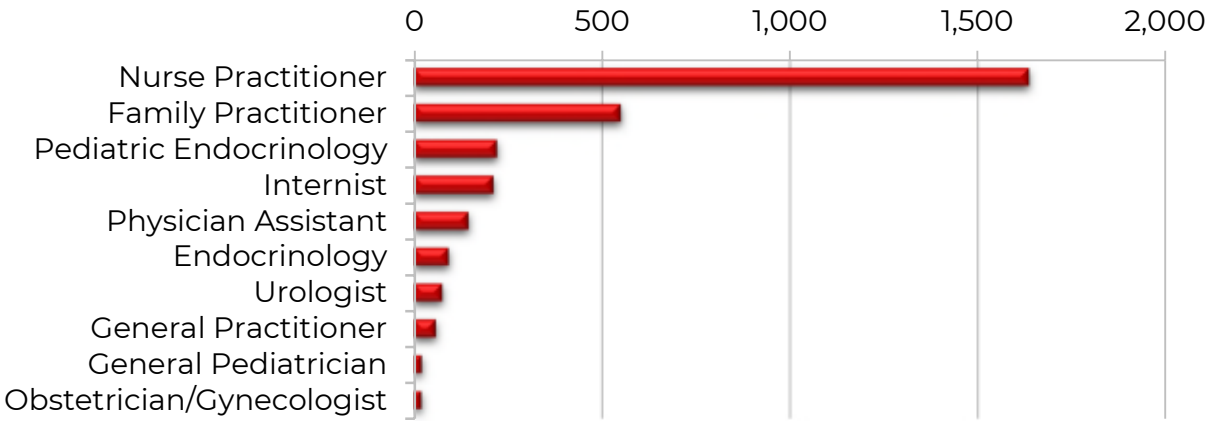
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

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 Testosterone Products: Pharmacy Claims (All Plans)



Top Prescriber Specialties of Testosterone Products by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Testosterone Products

There were 2,404 prior authorization requests submitted for testosterone products during fiscal year 2024. All testosterone products require prior authorization regardless of tier status in order to evaluate diagnosis and submitted labs. 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	521	24%	1,106	51%	544	25%	**2,171**
Aetna	39	31%	2	2%	83	67%	**124**
Humana	20	24%	1	1%	62	75%	**83**
OCH	10	38%	0	0%	16	62%	**26**
Total	**590**	**25%**	**1,109**	**46%**	**705**	**29%**	**2,404**

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]

Anticipated Patent Expiration(s):

- Aveed® [testosterone undecanoate intramuscular (IM) injection]: May 2027
- Natesto® (testosterone nasal gel): March 2034
- Xyosted® [testosterone enanthate subcutaneous (sub-Q) auto-injector]: August 2038
- Azmiro™ (testosterone cypionate IM injection): March 2039
- Jatenzo® (testosterone undecanoate oral capsule): April 2039
- Tlando® (testosterone undecanoate oral capsule): April 2041

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

- **June 2022:** The FDA approved a new drug application (NDA) for a new formulation of testosterone cypionate for IM injection through the 505(b)(2) approval pathway. Subsequently, in February 2024 the FDA approved a supplemental NDA (sNDA) allowing for the addition of the proprietary name, Azmiro™, to the package labeling. According to the FDA's National Drug Code (NDC) Directory, the marketing start date for Azmiro™ was in October 2024.

News:

- **September 2024:** Undecatrex™ (testosterone undecanoate) is an NDA authorized generic of Kyzatrex® (testosterone undecanoate). According

to the FDA's NDC Directory, the marketing start date for Undecatrex™ was in September 2024.

Azmiro™ (Testosterone Cypionate) Product Summary[5]

Therapeutic Class: Androgen

Indication(s): Testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): Testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins [follicle stimulating hormone (FSH), luteinizing hormone (LH)] above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.
- **Limitation(s) of Use:**
  - Safety and efficacy of Azmiro™ in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
  - Safety and effectiveness in pediatric patients younger than 12 years of age have not been established.

How Supplied: 200mg/mL solution in a single-dose vial or single-dose prefilled syringe

Dosing and Administration:

- The recommended dosage is 50mg to 400mg administered every 2-4 weeks as a deep IM injection in the gluteal muscle.
- The dose and schedule should be individualized based on the patient's age, diagnosis, response to treatment, and the appearance of adverse reactions.
- The prefilled syringe should be administered as an IM injection by a health care professional only.

Undecatrex™ (Testosterone Undecanoate) Product Summary[6]

Therapeutic Class: Androgen

Indication(s): Testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): Testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): Gonadotropin or LHRH deficiency, pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.
- **Limitation(s) of Use:**
  - Safety and effectiveness in males younger than 18 years of age have not been established.

How Supplied: 100mg, 150mg, and 200mg oral capsules

Dosing and Administration:

- The recommended starting dose is 200mg twice daily with food.
- Serum testosterone should be measured 7 days after initiation (or after dosage adjustment), and dose should be adjusted as necessary.
- The minimum recommended dose is 100mg once daily in the morning.
- The maximum recommended dose is 400mg twice daily.
- See the full *Prescribing Information* for specific dosage adjustment recommendations, based on serum testosterone concentrations.

Cost Comparison: Testosterone Products

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Azmiro™ (testost cyp) 200mg/mL syr	**$250.00**	**$1,000.00***	**$13,000.00**
Undecatrex™ (testost undec) 200mg cap	**$15.78**	**$1,893.60[Δ]**	**$22,723.20**
testosterone 1% gel 5g tube (generic)	$0.74	$222.00[¥]	$2,664.00
testosterone 1% gel 5g packet (generic)	$0.71	$213.00[¥]	$2,556.00
testosterone 30mg/1.5mL solution (generic)	$0.74	$133.20[€]	$1,598.40
testosterone 1.62% gel pump (generic)	$0.46	$69.00[§]	$828.00
testosterone cyp 200mg/mL vial (generic)	$12.76[+]	$51.04*	$663.52

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 max FDA approved dose of 400mg every 2 weeks.
[Δ]Cost per month based on the max FDA approved dose of 400mg twice daily.
[¥]Cost per month based on the max FDA approved dose of 100mg (10g of gel) once daily.
[€]Cost per month based on the max FDA approved dose of 120mg (6mL of solution) once daily.
[§]Cost per month based on the max FDA approved dose of 81mg (5g of gel) once daily.
[+]Cost varies by NDC
Unit = each capsule, gram, or milliliter
cap = capsule; cyp = cypionate; syr = syringe; testost = testosterone; undec = undecanoate

Recommendations

The College of Pharmacy recommends the following changes to the Testosterone Products Product Based Prior Authorization (PBPA) category based on current product availability and net costs (changes shown in red in the following Tier chart):

1. Prior authorization of Azmiro™ (testosterone cypionate) and Undecatrex™ (testosterone undecanoate) and placement into the Special Prior Authorization (PA) Tier based on net costs; and
2. Moving testosterone topical gel 1% packet and tube (Testim®, Vogelxo®) and testosterone topical solution (Axiron®) from Tier-1 to Tier-2 based on net cost.

Testosterone Products		
Tier-1	**Tier-2**	**Special PA**
testosterone cypionate IM inj (Depo Testosterone®)	testosterone enanthate sub-Q auto-injector (Xyosted®)	methyltestosterone oral tab/cap (Android®, Methitest®, Testred®)
testosterone enanthate IM inj (Delatestryl®)	testosterone topical gel 1%, 1.62% packet**, tube** (Androgel®, **Testim®, Vogelxo®**)	**testosterone cypionate IM inj (Azmiro™)**
~~**testosterone topical gel 1% packet, tube (Testim®, Vogelxo®)**~~	testosterone topical gel 1% pump (Vogelxo®)	testosterone nasal gel (Natesto®)
testosterone topical gel 1.62% pump (Androgel®)	testosterone topical gel 2% pump (Fortesta®)	testosterone pellets (Testopel®)
~~**testosterone topical solution (Axiron®)**~~	**testosterone topical solution (Axiron®)**	testosterone undecanoate IM inj (Aveed®)
		testosterone undecanoate oral cap (Jatenzo®, Kyzatrex®, Tlando®**, Undecatrex™**)

cap = capsule; IM = intramuscular; inj = injection; PA = prior authorization; sub-Q = subcutaneous; tab = tablet

Utilization Details of Testosterone Products: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TESTOSTERONE INJECTABLE PRODUCTS						
TESTOST CYP INJ 200MG/ML	2,719	1,134	$108,509.71	$39.91	2.4	61.23%
TESTOST CYP INJ 100MG/ML	44	31	$2,360.66	$53.65	1.42	1.33%
TESTOST ENAN INJ 200MG/ML	31	20	$2,536.43	$81.82	1.55	1.43%
DEPO-TESTOST INJ 200MG/ML	17	11	$721.70	$42.45	1.55	0.41%
DEPO-TESTOST INJ 100MG/ML	2	2	$117.18	$58.59	1	0.07%
SUBTOTAL	**2,813**	**1,198**	**$114,245.68**	**$40.61**	**2.35**	**64.47%**
TESTOSTERONE TOPICAL PRODUCTS						
TESTOSTERONE GEL 1% (50MG)	127	43	$18,954.16	$149.25	2.95	10.70%
TESTOSTERONE GEL 1.62% PUMP	76	41	$3,442.12	$45.29	1.85	1.94%
ANDROGEL GEL 1.62% PUMP	39	20	$30,171.97	$773.64	1.95	17.03%
TESTIM GEL 1% (50MG)	7	2	$4,011.40	$573.06	3.5	2.26%
TESTOSTERONE GEL 1% (25MG)	4	3	$376.16	$94.04	1.33	0.21%
TESTOSTERONE SOL 30MG/ACT	3	2	$569.77	$189.92	1.5	0.32%
TESTOSTERONE GEL 1.62% (40.5MG)	2	2	$345.50	$172.75	1	0.19%
TESTOSTERONE GEL 1.62% (20.25MG)	2	1	$302.17	$151.09	2	0.17%
TESTOSTERONE GEL 10MG/ACT PUMP	1	1	$253.94	$253.94	1	0.14%
SUBTOTAL	**261**	**115**	**$58,427.19**	**$223.86**	**2.27**	**32.97%**
TESTOSTERONE ORAL PRODUCTS						
TLANDO CAP 112.5MG	6	1	$4,530.36	$755.06	6	2.56%
SUBTOTAL	**6**	**1**	**$4,530.36**	**$755.06**	**6**	**2.56%**
TOTAL	**3,080**	**1,258***	**$177,203.23**	**$57.53**	**2.45**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; CAP = capsule; CYP = cypionate; ENAN = enanthate; INJ = injection; SOL = solution; TESTOST = testosterone
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
TESTOSTERONE CYPIONATE INJ J1071	82	34	$118.26	$1.44	2.41
TOTAL	**82**	**34**	**$118.26**	**$1.44**	**2.41**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*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] 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 06/2025. Last Accessed 06/16/2025.
[2] U.S. FDA. NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/216318Orig1s000ltr.pdf. Issued 06/02/2022. Last accessed 06/17/2025.
[3] U.S. FDA. Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/216318Orig1s002ltr.pdf. Issued 02/01/2024. Last accessed 06/17/2025.
[4] U.S. FDA. National Drug Code Directory. Available online at: https://dps.fda.gov/ndc. Last revised 06/17/2025. Last accessed 06/17/2025.
[5] Azmiro™ (Testosterone Cypionate) Prescribing Information. Azurity Pharmaceuticals, Inc. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=235b5625-570d-3fba-e063-6394a90aa2d1. Last revised 05/2024. Last accessed 06/16/2025.
[6] Undecatrex™ (Testosterone Undecanoate) Prescribing Information. Trifluent Pharma. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0828e67d-8b53-4297-aab8-196ded3dba1f. Last revised 09/2022. Last accessed 06/16/2025.

Appendix K

Fiscal Year 2024 Annual Review of Epidermolysis Bullosa (EB) Medications and 30-Day Notice to Prior Authorize Zevaskyn™ (Prademagene Zamikeracel)

Oklahoma Health Care Authority
July 2025

Current Prior Authorization Criteria

Filsuvez® (Birch Triterpenes 10% Topical Gel) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members 6 months of age and older with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB); and
2. Diagnosis must be confirmed by a pathogenic variant in the *COL7A1* gene for DEB or biallelic pathogenic variants in the *COL17A1*, *ITGA3*, *ITGA6*, *ITGB4*, *LAMA3*, *LAMB3*, or *LAMC2* genes for JEB (results of genetic testing must be submitted); and
3. Filsuvez® must be prescribed by a dermatologist or other specialist with expertise in the treatment of DEB or JEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB or JEB); and
4. Member must have the presence of open partial-thickness wounds associated with DEB or JEB for ≥21 days; and
5. Filsuvez® must be applied to open partial-thickness wounds at dressing changes at least once every 4 days or up to once daily; and
6. Prescriber must attest that member and/or caregiver has been counseled on the appropriate administration and storage of Filsuvez® based on package labeling including that each sterile tube is for one-time use only; and
7. Member and/or caregiver has been advised on possible hypersensitivity reactions with Filsuvez® and to discontinue use and contact the prescriber if symptoms of a hypersensitivity reaction develop; and
8. Filsuvez® will not be approved for concomitant use with Vyjuvek® (beremagene geperpavec-svdt); and
9. A maximum approval quantity of 1 tube (23.4 grams) per day or 702 grams per 30 days will apply; and
    a. A quantity limit override will be considered for approval of quantities greater than 1 tube per day if the provider documents the number and size of wounds being treated to justify the need for a larger quantity; and
10. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is

responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Filsuvez® will not be applied to closed wounds.

Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members 6 months of age and older with dystrophic epidermolysis bullosa (DEB); and
2. Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of genetic testing must be submitted); and
3. Vyjuvek® must be prescribed by a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and
4. Pharmacy or prescriber must confirm Vyjuvek® will be prepared by a pharmacist trained in the preparation of Vyjuvek® prior to dispensing and must confirm Vyjuvek® will be shipped to the administering provider via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek® package labeling; and
5. Vyjuvek® must be administered by a health care professional (HCP) trained in the administration of Vyjuvek®. Approvals will not be granted for self-administration. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health); and
6. Prescriber must attest that Vyjuvek® gel will be dosed per package labeling and applied to the same wound(s) until closed before selecting new wound(s) to treat, and that they will prioritize weekly treatment to previously treated wounds if they re-open; and
7. Prescriber must attest member or caregiver(s) have been counseled on the precautions prior to and during treatment with Vyjuvek® that are listed in the package labeling, including avoiding direct contact with treated wounds and dressings for 24 hours following administration; and
8. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy; and
9. Vyjuvek® will not be approved for concomitant use with Filsuvez® (birch triterpenes 10% topical gel); and
10. A maximum approval quantity of 1 carton (2.5mL) per week will apply; and
11. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is

responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Vyjuvek® will not be applied to closed wounds.

Utilization of EB Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

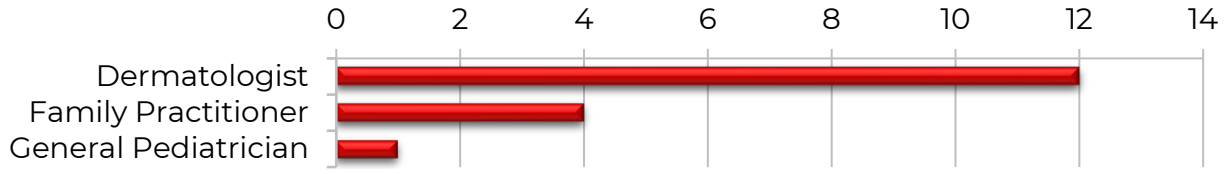
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	3	17	$536,427.97	$31,554.59	$3,030.67	404	177
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**3**	**17**	**$536,427.97**	**$31,554.59**	**$3,030.67**	**404**	**177**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.
Please note: There were no paid pharmacy claims during fiscal year 2023 (07/01/2022 to 06/30/2023) to allow for a fiscal year comparison. Vyjuvek® (beremagene geperpavec-svdt) and Filsuvez® (birch triterpenes 10% topical gel) were first FDA approved 05/2023 and 12/2023, respectively.

Demographics of Members Utilizing EB Medications: Pharmacy Claims (All Plans)

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

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



Prior Authorization of EB Medications

There were 24 prior authorization requests submitted for EB 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	7	30%	13	57%	3	13%	**23**
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%	1	100%	**1**
Total	**7**	**29%**	**13**	**54%**	**4**	**17%**	**24**

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]

Anticipated Patent Expiration(s):

- Filsuvez® (birch triterpenes 10% topical gel): January 2039

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

- **April 2025:** The FDA approved Zevaskyn™ (prademagene zamikeracel) for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa (RDEB).

Pipeline:

- **Allo-APZ2-OTS:** Allo-APZ2-OTS is an intravenous therapy comprised of allogeneic dermal ABCB5-positive mesenchymal stromal cells (ABCB5+ MSCs). It is being studied for the treatment of patients with RDEB, and this would be the first systemic treatment for EB. A Phase 3 trial is currently ongoing with study completion expected in December 2025.
- **Dabocemagene Autoficel (D-Fi):** D-Fi is an intradermal injection that is composed of fibroblasts isolated from the patient's own skin biopsies which are genetically corrected with the full-length collagen type VII alpha 1 chain (*COL7A1*) gene. It is being studied to treat wounds associated with DEB in patients 2 years of age or older. A Phase 3 trial is currently ongoing with primary completion expected in September 2027.

Zevaskyn™ (Prademagene Zamikeracel) Product Summary[6,7]

Therapeutic Class: Autologous cell sheet-based gene therapy

Indication(s): Treatment of wounds in adults and pediatric patients with RDEB

How Supplied: Zevaskyn™ is supplied as a single-dose of up to 12 cellular sheets each measuring 41.25cm^2 (5.5cm x 7.5cm) and consisting of the patient's own, viable, gene-modified cells that contain functional copies of the *COL7A1* gene, which express collagen 7 protein.

Dosing and Administration:

- For autologous topical application on wounds only.
- The recommended dose of Zevaskyn™ is based on the surface area of the wound(s). One sheet of Zevaskyn™ covers an area of 41.25cm^2.
- Up to 12 Zevaskyn™ sheets may be manufactured from the patient biopsies and supplied for potential use.
- Verify the patient's identity prior to Zevaskyn™ application.
- See full *Prescribing Information* for Zevaskyn™ preparation, and administration instructions.

Efficacy: The safety and efficacy of Zevaskyn™ were evaluated in a multi-center, randomized, intrapatient-controlled study called VIITAL.

- Key Inclusion Criteria:
  - ≥6 years of age
  - Clinical diagnosis of RDEB
  - 2 confirmed mutations in the *COL7A1* gene with recessive inheritance patterns (or confirmation that the parents do not have any evidence of dominant disease)
  - 1 pair of matched, large (at least 1 wound ≥20cm^2 for treatment and at least 1 wound ≥20cm^2 for control), stage 2 (partial thickness), chronic wounds (≥6 months) associated with RDEB
- Intervention: Matched wound pairs were randomized in a 1:1 ratio to receive either Zevaskyn™ (up to 6 sheets) or control treatment (standard of care wound dressing)
- Primary Outcome(s):
  - Proportion of randomized wound pairs ≥50% healing at 6 months with confirmation of wound healing 2 weeks later as assessed using baseline digital photography
  - Pain reduction as assessed by the mean differences in patient-reported pain scores using the Wong-Baker FACES scale between randomized wound pairs at 6 months

- Secondary Outcome(s):
  - Proportion of randomized wound pairs with complete wound healing defined as reepithelialization with no drainage or erosion and presence of only minor crusting from baseline at 3 months and 6 months with confirmation of wound healing 2 weeks later
- Results:
  - Proportion of randomized wound pairs healed ≥50% from baseline at 6 months: 35 (81%) in the Zevaskyn™ treated wounds vs. 7 (16%) in the control wounds (P<0.0001)
  - Mean pain reduction from baseline at 6 months [standard deviation (SD)]: -3.07 (3.19) in the Zevaskyn™ treated wounds vs. -0.90 (2.73) in the control wounds (P=0.0002)
  - Proportion of randomized wound pairs completely healed from baselined at 3 months: 6 (14%) in the Zevaskyn™ treated wounds vs. 0 (0%) in the control groups (P=0.0316)
  - Proportion of randomized wound pairs completely healed from baseline at 6 months: 7 (16%) in the Zevaskyn™ treated wounds vs. 0 (0%) in the control groups (P=0.0160)

Cost Comparison: EB Medications

Product	Cost
Zevaskyn™ (prademagene zamikeracel)	**$3,100,000.00‡**
Vyjuvek® (beremagene geperpavec-svdt)	$1,311,960.00*
Filsuvez® (birch triterpenes 10% topical gel)	$655,173.79α

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 per treatment cycle for Zevaskyn™. Depending on the size and number of wounds, patients may need more than 1 cycle.
*Cost is per year for Vyjuvek® and is based on the FDA maximum recommended weekly dose, which would require 1 carton (2.5mL) per week regardless of dose.
αCost is per year for Filsuvez® and is based on the use of 1 tube (23.4g) daily.

Recommendations

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

Zevaskyn™ (Prademagene Zamikeracel) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members with recessive dystrophic epidermolysis bullous (RDEB); and
2. Diagnosis must be confirmed by biallelic pathogenic variants in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of the genetic testing must be submitted); and
3. Zevaskyn™ must be prescribed by a dermatologist at a qualified treatment center with expertise in the treatment of RDEB; and

4. Member must have the presence of partial-thickness RDEB wounds open chronically for ≥6 months; and
5. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the wounds that will be treated; and
6. If member is currently using Vyjuvek® or Filsuvez®, the prescriber must verify the products will be discontinued before the application of Zevaskyn™. Vyjuvek® and Filsuvez® cannot be used on wounds treated or designated to be treated with Zevaskyn™; and
7. Zevaskyn™ must be administered at a Zevaskyn™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zevaskyn™ from receipt to storage to administration; and
8. Approval will be granted for 1 year for 1 treatment cycle; and
9. A new prior authorization may be considered for any previously untreated wounds. For consideration, the prescriber must attest Zevaskyn™ will not be used on wounds previously treated by Zevaskyn™ and the member responded well to treatment with Zevaskyn™ as indicated by the presence of wound healing; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's response to therapy and ongoing treatment plan.

The College of Pharmacy recommends updating the approval criteria for Filsuvez® (birch triterpenes 10% topical gel) and Vyjuvek® (beremagene geperpavec-svdt) based on the recent FDA approval of Zevaskyn™ (prademagene zamikeracel) and to be consistent with clinical practice (changes shown in red):

Filsuvez® (Birch Triterpenes 10% Topical Gel) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members 6 months of age and older with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB); and
2. Diagnosis must be confirmed by a pathogenic variant in the *COL7A1* gene for DEB or biallelic pathogenic variants in the *COL17A1*, *ITGA3*, *ITGA6*, *ITGB4*, *LAMA3*, *LAMB3*, or *LAMC2* genes for JEB (results of genetic testing must be submitted); and
3. Filsuvez® must be prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB or JEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB or JEB); and
4. Member must have the presence of open partial-thickness wounds associated with DEB or JEB for ≥21 days; and

5. Filsuvez® must be applied to open partial-thickness wounds at dressing changes at least once every 4 days or up to once daily; and
6. Prescriber must attest that member and/or caregiver has been counseled on the appropriate administration and storage of Filsuvez® based on package labeling including that each sterile tube is for one-time use only; and
7. Member and/or caregiver has been advised on possible hypersensitivity reactions with Filsuvez® and to discontinue use and contact the prescriber if symptoms of a hypersensitivity reaction develop; and
8. Filsuvez® will not be approved for concomitant use with Vyjuvek® (beremagene geperpavec-svdt) or for use on wounds treated with Zevaskyn™ (prademagene zamikeracel); and
9. A maximum approval quantity of 1 tube (23.4 grams) per day or 702 grams per 30 days will apply; and
    a. A quantity limit override will be considered for approval of quantities greater than 1 tube per day if the provider documents the number and size of wounds being treated to justify the need for a larger quantity; and
10. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Filsuvez® will not be applied to closed wounds; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with every request documenting the member's response to treatment and ongoing treatment plan.

Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB); and
2. Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of genetic testing must be submitted); and
3. Vyjuvek® must be prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and
4. Pharmacy or prescriber must confirm Vyjuvek® will be prepared by a pharmacist trained in the preparation of Vyjuvek® prior to dispensing and must confirm Vyjuvek® will be shipped to the administering provider via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek® package labeling; and

5. Vyjuvek® must be administered by a health care professional (HCP) trained in the administration of Vyjuvek®. Approvals will not be granted for self-administration. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health); and
6. Prescriber must attest that Vyjuvek® gel will be dosed per package labeling and applied to the same wound(s) until closed before selecting new wound(s) to treat, and that they will prioritize weekly treatment to previously treated wounds if they re-open; and
7. Prescriber must attest member or caregiver(s) have been counseled on the precautions prior to and during treatment with Vyjuvek® that are listed in the package labeling, including avoiding direct contact with treated wounds and dressings for 24 hours following administration; and
8. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy; and
9. Vyjuvek® will not be approved for concomitant use with Filsuvez® (birch triterpenes 10% topical gel) or for use on wounds treated with Zevaskyn™ (prademagene zamikeracel); and
10. A maximum approval quantity of 1 carton (2.5mL) per week will apply; and
11. Initial approvals will be for 3 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Vyjuvek® will not be applied to closed wounds; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with every request documenting the member's response to treatment and ongoing treatment plan.

Utilization Details of EB Medications: Fiscal Year 2024

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VYJUVEK GEL	16	3	$509,416.56	$31,838.54	5.33	94.96%
FILSUVEZ GEL 10%	1	1	$27,011.41	$27,011.41	1	5.04%
TOTAL	**17**	**3***	**$536,427.97**	**$31,554.59**	**5.67**	**100%**

Costs do not reflect rebated prices or net costs.
*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 06/2025. Last accessed 06/11/2025.
[2] Abeona Therapeutics. U.S. FDA Approves Zevaskyn™ (Prademagene Zamikeracel), the First and Only Cell-Based Gene Therapy for Patients with Recessive Dystrophic Epidermolysis Bullosa (RDEB). Available online at: https://investors.abeonatherapeutics.com/press-releases/detail/303/u-s-fda-approves-zevaskyn-prademagene-zamikeracel. Issued 04/29/2025. Last accessed 06/11/2025.
[3] Allogeneic ABCB5-positive Dermal Mesenchymal Stromal Cells for Treatment of Epidermolysis Bullosa (Phase III). *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT05838092. Last revised 10/30/2023. Last accessed 06/16/2025.
[4] RHEACELL®. Epidermolysis Bullosa (EB). Available online at: https://www.rheacell.com/en/eb-trial/. Last accessed 06/16/2025.
[5] Evaluation of D-Fi for the Treatment of Wounds Due to DEB. *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT06892639. Last revised 06/11/2025. Last accessed 06/16/2025.
[6] Zevaskyn™ (Prademagene Zamikeracel) Prescribing Information. Abeona Therapeutics Inc. Available online at: https://d1io3yog0oux5.cloudfront.net/_97c62242a52d17e584a3147d26ed2790/abeonatherapeutics/files/ZEVASKYN_Final_Label_30Apr2025.pdf. Last revised 04/2025. Last accessed 06/11/2025.
[7] Phase 3, Open-label Clinical Trial of EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB). *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT04227106. Last revised 12/05/2022. Last accessed 06/11/2025.

Appendix L

Fiscal Year 2024 Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Zunveyl® (Benzgalantamine)

Oklahoma Health Care Authority
July 2025

Current Prior Authorization Criteria

Alzheimer's Disease Medications Approval Criteria:

1. Special formulation products including oral solutions, transdermal patches, and other convenience formulations require prior authorization with the following approval criteria:
    a. A patient-specific, clinically significant reason why the special formulation is necessary in place of the standard formulation.
2. An age restriction for ages 0 to 50 years applies to all Alzheimer's medications. Members older than 50 years of age can receive formulations without prior authorization. Members younger than 50 years of age will require prior authorization with the following criteria:
    a. An FDA approved diagnosis; or
    b. Other patient-specific, clinically significant information supporting the use of the medication.

Aduhelm® (Aducanumab-avwa) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 24 and 30; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Aduhelm® must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. 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

5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin 325mg per day or less, and the prescriber must attest that the increased safety risks for developing ARIA with the concomitant use have been discussed and are acceptable to the member prior to initiating Aduhelm®; and
8. Member must not have had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have any pre-treatment localized superficial siderosis, ≥10 brain microhemorrhages, or a brain hemorrhage >1cm within 1 year of treatment initiation as safety with Aduhelm® has not been established in patients with these conditions; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Aduhelm® and prior to the 7th infusion (1st dose of 10mg/kg) and 12th infusion (6th dose of 10mg/kg); and
12. The prescriber must confirm that the member will be monitored for ARIA during the first 8 doses of treatment with Aduhelm®, particularly during titration, and also throughout treatment; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H); and
14. Aduhelm® 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; and
    a. Aduhelm® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. A patient-specific, clinically significant reason why the member cannot use Leqembi® (lecanemab-irmb) must be provided; and

17. Initial approvals will be for 6 months. Confirmation that MRI has been completed and is acceptable to the provider prior to 7th infusion is required for continuation; and
18. Subsequent approvals will be for 6 months and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy; and
19. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
20. The maximum dose approvable is 10mg/kg per 28 days; and
21. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Kisunla™ (Donanemab-azbt) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 20 and 38; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Kisunla™ must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. 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
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing ARIA with the concomitant use have been discussed and are acceptable to the member prior to initiating Kisunla™; and

8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or
    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Kisunla™ and prior to the 2nd, 3rd, 4th, and 7th infusions; and
12. Prescriber must confirm that the member will be monitored for ARIA during the first 12 weeks and throughout treatment with Kisunla™; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Kisunla™ 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; and
    a. Kisunla™ must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 2nd, 3rd, 4th, and 7th infusions is required for continuation; and
16. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and
17. Approval quantities will be dependent on dosing based on package labeling; and

18. The maximum dose approvable is 1,400mg per 28 days; and
19. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Leqembi® (Lecanemab-irmb) Approval Criteria:

1. An FDA approved diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease [stage 3 or stage 4 Alzheimer's disease based on the Global Deterioration Scale (GDS)]. Diagnosis must be confirmed by at least 2 of the following:
    a. Mini-Mental State Exam (MMSE) score between 22 and 30; or
    b. Clinical Dementia Rating Global Score (CDR-GS) equal to 0.5 or 1; or
    c. Montreal Cognitive Assessment (MoCA) score ≥19; or
    d. Quick Dementia Rating System (QDRS) score ≤5; and
2. Member must have presence of amyloid pathology confirmed by a positive amyloid positron emission tomography (PET) scan or cerebral spinal fluid (CSF) test; and
3. Leqembi® must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. 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
5. Member must not have brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities that increase the risk of hemorrhage; and
6. Prescriber must verify member and/or caregiver has been counseled on the risks of amyloid related imaging abnormalities (ARIA) that may occur and testing for ApoE ε4 status has been completed if appropriate; and
7. Member must not be taking anticoagulant or antiplatelet agents except for aspirin or clopidogrel, and the prescriber must attest that the increased safety risks for developing intracerebral hemorrhage with the concomitant use have been discussed and are acceptable to the member prior to initiating Leqembi®; and
8. Member must not have had a stroke, transient ischemic attack (TIA), or unexplained loss of consciousness in the past year; and
9. Member must not have any contraindications to brain magnetic resonance imaging (MRI) or PET scans; and
10. Member must not have risk factors for intracerebral hemorrhage, including the following:
    a. Prior cerebral hemorrhage >1cm in greatest diameter; or
    b. >4 microhemorrhages; or
    c. An area of superficial siderosis; or
    d. Evidence of vasogenic edema; or

    e. Evidence of cerebral contusion, aneurysms, vascular malformations, or infective lesions; or
    f. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease; and
11. Member must have a recent (within 1 year) brain MRI prior to initiating treatment with Leqembi® and prior to the 5th, 7th, and 14th infusions; and
12. Prescriber must confirm that the member will be monitored for ARIA during the first 14 weeks and throughout treatment with Leqembi®; and
13. If ≥10 new incident microhemorrhages or >2 focal areas of superficial siderosis [radiographic severe amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H)] are observed on MRI, prescriber must confirm that treatment will be continued with caution and only after a clinical evaluation confirming resolution of symptoms, if present, and a follow-up MRI demonstrating radiographic stabilization (i.e., no increase in size or number of ARIA-H) have been completed; and
14. Leqembi® 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; and
    a. Leqembi® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment and stored in the refrigerator; and
15. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. Initial approvals will be for 6 months. Confirmation that MRIs have been completed and were acceptable to the provider prior to the 5th and 7th infusions is required for continuation; and
17. Subsequent approvals will be for 6 months, and prescriber must document that the member has responded well to therapy compared to pretreatment baseline status as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment using the same baseline test(s) performed at initiation of therapy for each subsequent approval; and
18. Approval quantities will be dependent on the member's weight and dosing based on package labeling; and
19. The maximum dose approvable is 10mg/kg per 14 days; and
20. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Namenda XR® [Memantine Extended-Release (ER) Capsules] Approval Criteria:

1. An FDA approved diagnosis for the treatment of moderate-to-severe Alzheimer's type dementia; and
2. A patient-specific, clinically significant reason why the member cannot use memantine immediate-release tablets must be provided.

Namzaric® [Memantine Extended-Release (ER)/Donepezil] Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe Alzheimer's type dementia; and
2. Member must have a patient-specific, clinically significant reason why the separate immediate-release products which do not require prior authorization cannot be used over this combination product; and
3. A quantity limit of 30 capsules per 30 days will apply.

Utilization of Alzheimer's Disease 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	905	5,946	$87,876.68	$14.78	$0.41	320,017	214,750
2023 Total	**905**	**5,946**	**$87,876.68**	**$14.78**	**$0.41**	**320,017**	**214,750**
Fiscal Year 2024							
FFS	918	5,897	$88,142.76	$14.95	$0.41	320,432	214,482
Aetna	32	72	$1,591.85	$22.11	$0.52	5,026	3,051
Humana	45	78	$1,211.94	$15.54	$0.33	5,431	3,711
OCH	32	42	$644.50	$15.35	$0.30	2,772	2,162
2024 Total	**950**	**6,089**	**$91,591.05**	**$15.04**	**$0.41**	**333,661**	**223,406**
% Change	**5.00%**	**2.40%**	**4.20%**	**1.80%**	**0.00%**	**4.30%**	**4.00%**
Change	**45**	**143**	**$3,714.37**	**$0.26**	**$0.00**	**13,644**	**8,656**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = OK 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.

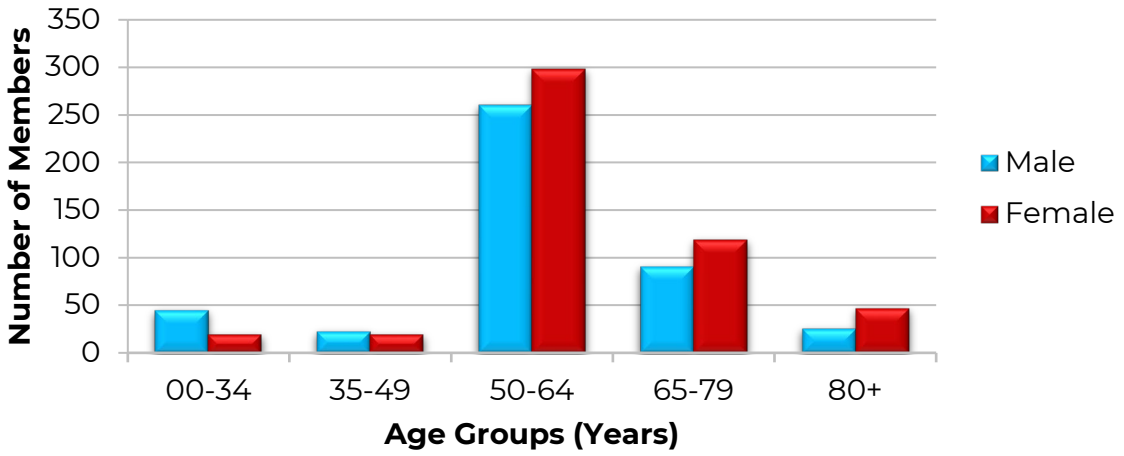
Fiscal Year 2024 Utilization: Medical Claims (All Plans)

Plan Type	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	1	22	$29,576.00	$1,344.36	22
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**1**	**22**	**$29,576.00**	**$1,344.36**	**22**

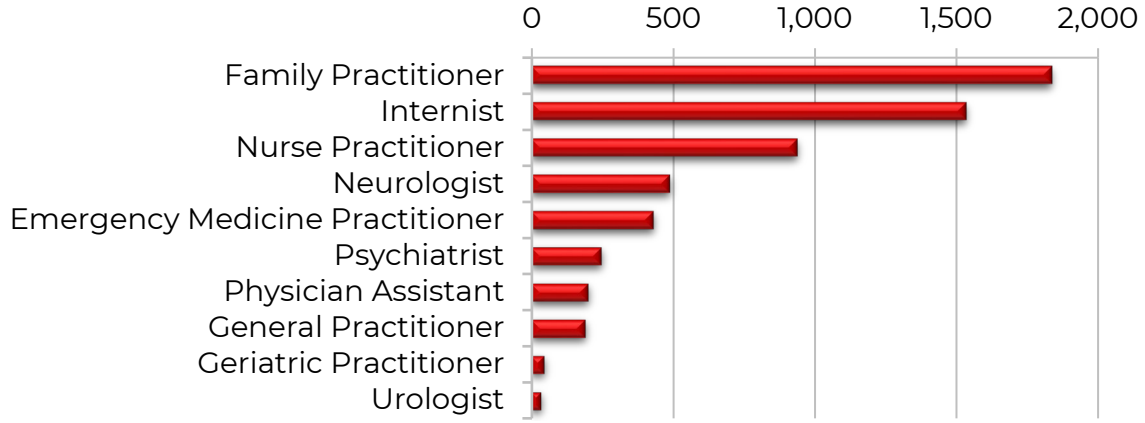
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = OK Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.
Please note: There were no paid medical claims during fiscal year 2023 to allow for a fiscal year comparison.

- Aggregate drug rebates collected during fiscal year 2024 for Alzheimer's disease medications totaled $3,255.50.[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 Alzheimer's Disease Medications: Pharmacy Claims (All Plans)



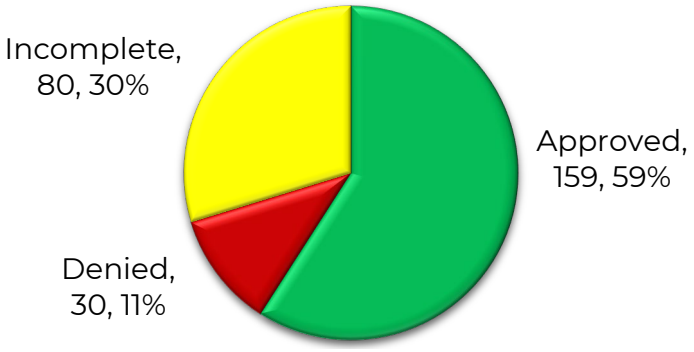
Top Prescriber Specialties of Alzheimer's Disease Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Alzheimer's Disease Medications

There were 269 prior authorization requests submitted for Alzheimer's disease 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	157	60%	78	30%	27	10%	**262**
Aetna	2	40%	2	40%	1	20%	**5**
Humana	0	0%	0	0%	1	100%	**1**
OCH	0	0%	0	0%	1	100%	**1**
Total	**159**	**59%**	**80**	**30%**	**30**	**11%**	**269**

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[1,2,3,4,5,6,7,8,9]

Anticipated Patent Expiration(s):

- Namzaric® [memantine extended-release (ER)/donepezil capsules]: December 2029
- Zunveyl® [benzgalantamine delayed release (DR) tablets]: February 2044

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

- **July 2024:** The FDA approved Zunveyl® (benzgalantamine) DR tablets for the treatment of mild to moderate dementia of the Alzheimer's type in adults. Zunveyl® is a prodrug of galantamine and is expected to release galantamine after bypassing the stomach. The efficacy of Zunveyl® was based on 3 bioavailability studies in healthy adults comparing Zunveyl® to galantamine immediate-release tablets and galantamine ER capsules where Zunveyl® was found to be bioequivalent to both formulations of galantamine. Zunveyl® is available as an oral DR tablet in 3 strengths (5mg, 10mg, and 15mg), and the recommended starting dose is 5mg twice daily for at least 4 weeks with a maximum recommended dose of 15mg twice daily. In March 2025, Alpha Cognition announced the launch of Zunveyl®.
- **January 2025:** Leqembi® (lecanemab-irmb) was approved for a supplemental Biologics License Application (sBLA) for a new intravenous (IV) maintenance dosing regimen of 10mg/kg every 4 weeks. The *Prescribing Information* has been updated to now include that after the initial 18 months, patients can continue 10mg/kg every 2 weeks or transition to 10mg/kg every 4 weeks for maintenance dosing. This label expansion is based on modeling of observed data from the Phase 2 trial and the Clarity AD trial and their respective long-term extension (LTE) trials. Data from the off-treatment period between the Phase 2 core trial and LTE trial showed that discontinuation of treatment is associated with reaccumulation of amyloid positron emission tomography (PET) and plasma and cerebrospinal fluid (CSF) biomarkers, and reversion to placebo rate of clinical decline. Over 3 years of treatment across the Clarity AD core trial and LTE trial, Leqembi® reduced cognitive decline on the Clinical Dementia Rating-Sum of Boxes (CDR-SB) by -0.95 relative to a matched natural history cohort, showing clinically meaningful benefit for early Alzheimer's disease patients and that ongoing treatment can slow disease progression and prolong the benefit of therapy. Modeling simulations predict that transitioning to every 4 weeks maintenance dosing after 18 months of every 2 weeks treatment will maintain clinical and biomarker benefits of therapy.

News:

- **January 2024:** Biogen announced that they will be discontinuing the development and commercialization of Aduhelm® (aducanumab-avwa) and stopping the ENVISION clinical trial which was required by the FDA for consideration of traditional approval for Aduhelm®. Biogen announced that the discontinuation of Aduhelm® was not due to any safety or efficacy concerns but, instead, was to be able to reprioritize their resources to advance Leqembi® and accelerate development of potential new treatment modalities. A marketing end date for Aduhelm® was issued for November 1, 2024.

Pipeline:

- **Leqembi® (Lecanemab-irmb) Subcutaneous (Sub-Q):** Leqembi® is being studied as a new sub-Q autoinjector formulation for weekly maintenance dosing for patients who have completed the biweekly IV initiation phase. A BLA was submitted to the FDA based on data from the Clarity AD open label extension (OLE) trial and modeling of observed data. Results from these trials showed that with continuous administration, Leqembi® clears highly toxic protofibrils which can continue to cause neuronal injury even after amyloid-beta plaque has been cleared from the brain. The BLA was accepted by the FDA and a Prescription Drug User Fee Act (PDUFA) date of 08/31/2025 has been set.
- **Kisunla™ (Donanemab-azbt):** Kisunla™ is being studied in the TRAILBLAZER-ALZ 6 trial to investigate different dosing regimens and their effect on amyloid-related imaging abnormalities with edema/effusion (ARIA-E) in adults with early symptomatic Alzheimer's disease. The trial included 4 treatment arms, 1 arm was the once-monthly standard dosing regimen used in the Phase 3 TRAILBLAZER-ALZ 2 trial and 3 arms using alternative dosing regimens with the same total drug administered. The primary end point of the trial was the proportion of patients with any occurrence of ARIA-E by week 24, and the results showed the incidence of ARIA-E was 14% in patients receiving the modified titration compared with 24% for those receiving the standard dosing regimen, a 41% lower relative risk. The largest ARIA-E reduction with the modified titration was seen in apolipoprotein E (ApoE ε4) homozygotes. In these patients, 19% had ARIA-E on the modified titration as compared to 57% on the standard dosing regimen, resulting in a 67% lower relative risk. Eli Lilly is planning to submit to the FDA for a label update for Kisunla™ based on these results.

Cost Comparison: Benzgalantamine and Galantamine Products

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Zunveyl® (benzgalantamine) DR 15mg tablet	**$12.48**	**$748.80***	**$8,985.60**
galantamine ER 24mg capsule (generic)	$0.96	$28.80⁺	$345.60
galantamine 12mg tablet (generic)	$0.60	$36.00⁺	$432.00

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).
DR = delayed-release; ER = extended-release; Unit = capsule or tablet
*Cost per month based on the maximum FDA approved dosing of 15mg twice daily.
⁺Cost per month based on the maximum FDA recommended dose of 24mg per day.

Recommendations

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

Zunveyl® (Benzgalantamine) Approval Criteria:

1. An FDA approved diagnosis of mild-to-moderate Alzheimer's type dementia; and
2. A patient-specific, clinically significant reason why the member cannot use galantamine immediate-release tablets, which are available without a prior authorization, and galantamine extended-release capsules must be provided; and
3. A quantity limit of 60 tablets per 30 days will apply.

Utilization Details of Alzheimer's Disease Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MEMANTINE PRODUCTS						
MEMANTINE TAB HCL 10MG	2,241	345	$33,509.32	$14.95	6.5	36.59%
MEMANTINE TAB HCL 5MG	849	240	$13,005.53	$15.32	3.54	14.20%
MEMANTINE TAB 10MG	373	118	$5,949.27	$15.95	3.16	6.50%
MEMANTINE HCL CAP 28MG ER	120	11	$3,499.75	$29.16	10.91	3.82%
MEMANTINE TAB 5MG	47	22	$683.95	$14.55	2.14	0.75%
MEMANTINE HCL CAP 7MG ER	6	1	$143.23	$23.87	6	0.16%
MEMANTINE HCL SOL 2MG/ML	5	1	$1,727.79	$345.56	5	1.89%
MEMANTINE TITRA PAK 5-10MG	3	3	$79.94	$26.65	1	0.09%
SUBTOTAL	**3,644**	**741**	**$58,598.78**	**$16.08**	**4.92**	**63.98%**
DONEPEZIL PRODUCTS						
DONEPEZIL TAB 10MG	1,303	297	$15,970.85	$12.26	4.39	17.44%
DONEPEZIL TAB 5MG	990	272	$11,500.63	$11.62	3.64	12.56%
DONEPEZIL TAB 23MG	7	2	$184.56	$26.37	3.5	0.20%
SUBTOTAL	**2,300**	**571**	**$27,656.04**	**$12.02**	**4.03**	**30.20%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GALANTAMINE PRODUCTS						
GALANTAMINE TAB 4MG	38	5	$769.21	$20.24	7.6	0.84%
GALANTAMINE TAB 8MG	26	4	$688.17	$26.47	6.5	0.75%
GALANTAMINE CAP 8MG ER	5	1	$186.34	$37.27	5	0.20%
GALANTAMINE CAP 16MG ER	4	1	$172.08	$43.02	4	0.19%
SUBTOTAL	**73**	**11**	**$1,815.80**	**$24.87**	**6.64**	**1.98%**
RIVASTIGMINE PRODUCTS						
RIVASTIGMINE CAP 3MG	24	6	$572.66	$23.86	4	0.63%
RIVASTIGMINE CAP 1.5MG	17	7	$373.74	$21.98	2.43	0.41%
RIVASTIGMINE PATCH 9.5MG/24HR	13	3	$878.65	$67.59	4.33	0.96%
RIVASTIGMINE PATCH 4.6MG/24HR	11	6	$728.52	$66.23	1.83	0.80%
RIVASTIGMINE PATCH 13.3MG/24HR	4	2	$220.14	$55.04	2	0.24%
RIVASTIGMINE CAP 4.5MG	2	2	$49.31	$24.66	1	0.05%
EXELON PATCH 13.3MG/24HR	1	1	$697.41	$697.41	1	0.76%
SUBTOTAL	**72**	**27**	**$3,520.43**	**$48.89**	**2.67**	**3.84%**
TOTAL	**6,089**	**950***	**$91,591.05**	**$15.04**	**6.41**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ER = extended-release; HCL = hydrochloride; HR = hour; TAB = tablet; TITRA = titration
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.

Medical Claims (All Plans)

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LECANEMAB-IRMB INJ J0174	22	1	$29,576.00	$1,344.36	22
TOTAL	**22**	**1**	**$29,576.00**	**$1,344.36**	**22**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
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.

[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 06/2025. Last accessed 06/17/2025.
[2] Zunveyl® (Benzgalantamine) – New drug approval. *OptumRx*®. Available online at: https://professionals.optumrx.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval_zunveyl_2024-0729.pdf. Issued 07/29/2024. Last accessed 06/17/2025.
[3] U.S. FDA. Zunveyl® (Benzgalantamine) Summary Review. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218549Orig1s000SumR.pdf. Issued 07/25/2024. Last accessed 06/17/2025.
[4] Alpha Cognition. Alpha Cognition Announces the Commercial Launch of Zunveyl® (Benzgalantamine) for the Treatment of Mild to Moderate Alzheimer's Disease. *Businesswire*. Available online at: https://www.businesswire.com/news/home/20250319665873/en/Alpha-Cognition-Announces-the-Commercial-Launch-of-ZUNVEYL-Benzgalantamine-for-the-Treatment-of-Mild-to-Moderate-Alzheimers-Disease. Issued 03/18/2025. Last accessed 06/17/2025.
[5] Eisai. FDA Approves Leqembi® (Lecanemab-irmb) IV Maintenance Dosing for the Treatment of Early Alzheimer's Disease. Available online at: https://media-us.eisai.com/2025-01-26-FDA-Approves-LEQEMBI-R-lecanemab-irmb-IV-Maintenance-Dosing-for-the-Treatment-of-Early-Alzheimers-Disease. Issued 01/26/2025. Last accessed 06/17/2025.
[6] Biogen. Biogen to Realign Resources for Alzheimer's Disease Franchise. Available online at: https://investors.biogen.com/news-releases/news-release-details/biogen-realign-resources-alzheimers-disease-franchise. Issued 01/31/2024. Last accessed 06/17/2025.
[7] Aduhelm® (Aducanumab-avwa) Prescribing Information. Biogen. Available online at: https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=842203. Last revised 08/2023. Last accessed 06/24/2025.
[8] Eisai. FDA Accepts Leqembi® (Lecanemab-irmb) Biologics License Application for Subcutaneous Maintenance Dosing for the Treatment of Early Alzheimer's Disease. Available online at: https://media-us.eisai.com/2025-01-13-FDA-Accepts-LEQEMBI-R-lecanemab-irmb-Biologics-License-Application-for-Subcutaneous-Maintenance-Dosing-for-the-Treatment-of-Early-Alzheimers-Disease. Issued 01/13/2025. Last accessed 06/17/2025.
[9] Eli Lilly. Modified Titration of Donanemab Demonstrated Reduction of ARIA-E in Early Symptomatic Alzheimer's Disease Patients in Phase 3b study. Available online at: https://investor.lilly.com/news-releases/news-release-details/modified-titration-donanemab-demonstrated-reduction-aria-e-early. Issued 10/29/2024. Last accessed 06/17/2025.

Appendix M

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: June 27, 2025

FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor CAR T-cell Immunotherapies

The FDA announced that it has eliminated the REMS for currently approved B-cell Maturation Antigen (BCMA)- and CD19-directed autologous chimeric antigen receptor (CAR) T-cell immunotherapies. These products are gene therapies that are currently approved to treat blood cancers, such as multiple myeloma and certain types of leukemia and lymphoma.

A REMS is a safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The FDA determined that the approved REMS for the following products should be eliminated because a REMS is no longer necessary to ensure that the benefits of the autologous CAR T-cell immunotherapies outweigh their risks.

- Abecma® (idecabtagene vicleucel)
- Breyanzi® (lisocabtagene maraleucel)
- Carvykti® (ciltacabtagene autoleucel)
- Kymriah® (tisagenlecleucel)
- Tecartus® (brexucabtagene autoleucel)
- Yescarta® (axicabtagene ciloleucel)

The elimination of REMS for the above products removes the requirements that hospitals and their associated clinics that dispense products must be specially certified and have on-site, immediate access to tocilizumab. The information regarding the risks for these CAR T-cell immunotherapies can be conveyed adequately via the current product labeling, which includes a boxed warning for the risks of cytokine release syndrome and neurological toxicities, and medication guides. These products will continue to be subject to safety monitoring, through adverse event reporting requirements in accordance with regulations. The elimination of the REMS for these products does not change FDA requirements for manufacturers to conduct post marketing observational safety studies to assess the risk of secondary malignancies and long-term safety with follow up of patients for 15 years after product administration.

Current Drug Shortages Index (as of June 30, 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***