OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
July 8, 2026
4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – July 8, 2026

DATE: July 1, 2026

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

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

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Enclosed are the following items related to the 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 Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection) and Update the Approval Criteria for the Anti-Emetic Medications – Appendix D

Action Item – Vote to Prior Authorize Bysanti™ (Milsaperidone) and Update the Approval Criteria for the Atypical Antipsychotic Medications – Appendix E

Action Item – Vote to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder), and Xofluza® (Baloxavir) and Update the Approval Criteria for the Antiviral Medications – Appendix F

Action Item – Vote to Prior Authorize Prior Authorize Loargys® (Pegzilarginase-nbln) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications – Appendix G

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

Action Item – Vote to Prior Authorize Inlexzo™ (Gemcitabine Intravesical System), Kyxata™ (Carboplatin), Lifyorli™ (Relacorilant), and Zusduri™ (Mitomycin Intravesical Solution) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications – Appendix I

Action Item – Annual Review of Anti-Ulcer Medications – Appendix J

Action Item – Annual Review of Epidermolysis Bullosa (EB) Medications – Appendix K

Annual Review of Colorectal Cancer (CRC) Medications and 30-Day Notice to Prior Authorize Jobevne™ (Bevacizumab-nwgd) – Appendix L

Annual Review of Anti-Diabetic Medications and Kerendia (Finerenone) and 30-Day Notice to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy) – Appendix M

Annual Review of Heart Failure Medications and 30-Day Notice to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten) – Appendix N

Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® Iqlik™ (Lecanemab-irmb) – Appendix O

Annual Review of Testosterone Products – Appendix P

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – July 8, 2026 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

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

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After registering, you will receive a confirmation email containing information about joining the webinar.

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 910 6408 1365
Passcode: 44589980

Public Comment for Meeting:

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

Items to be presented by Dr. Haymore, Chairman:

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

Items to be presented by Dr. Haymore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. June 10, 2026 DUR Board Meeting Minutes
   B. June 10, 2026 DUR Board Recommendations Memorandum

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 2026
   B. Medication Coverage Activity for June 2026

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

5. **Chronic Medication Adherence (CMA) Program Update – See Appendix C**
   A. CMA Prescriber Mailing Summary
   B. Mailing Summaries
   C. Star Ratings
   D. Provider Summary Report
   E. CMA Trends
   F. Conclusions

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

6. **Action Item – Vote to Prior Authorize Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection) and Update the Approval Criteria for the Anti-Emetic Medications – See Appendix D**
   A. Market News and Updates
   B. Nereus™ (Tradipitant) Product Summary
   C. Cost Comparison: Palonosetron Products
   D. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Bysanti™ (Milsaperidone) and Update the Approval Criteria for the Atypical Antipsychotic Medications – See Appendix E**
   A. Market News and Updates
   B. Bysanti™ (Milsaperidone) Product Summary
   C. Cost Comparison: Atypical Antipsychotics for Adjunct Treatment of MDD
   D. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder), and Xofluza® (Baloxavir) and Update the Approval Criteria for the Antiviral Medications – See Appendix F**
   A. Market News and Updates
   B. Hepcludex® (Bulevirtide-gmod) Product Summary
   C. Cost Comparison: Oral Influenza Antiviral Medications
   D. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Prior Authorize Loargys® (Pegzilarginase-nbln) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications – See Appendix G**
   A. Market News and Updates
   B. Loargys® (Pegzilarginase-nbln) Product Summary
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Cafergot® (Ergotamine/Caffeine Tablet), Desmoda™ (Desmopressin Oral Solution), Dicyclomine 40mg Tablet, Griseofulvin Ultramicrosize 165mg Tablet, Hydroxyzine Oral Solution Unit Dose Cups (UDCs), Khindivi™ (Hydrocortisone Oral Solution), Migergot® (Ergotamine/Caffeine Suppository), Ontralfy™ (Tizanidine Oral Solution), PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet,**

Quiofic™ (Folic Acid Oral Solution), Relgaabi™ (Gabapentin 200mg Capsule), and Vykoura™ (Leucovorin Injection) – See Appendix H

A. Introduction
B. Product Summaries
C. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Inlexzo™ (Gemcitabine Intravesical System), Kyxata™ (Carboplatin), Lifyorli™ (Relacorilant), and Zusduri™ (Mitomycin Intravesical Solution) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications – See Appendix I**

A. Market News and Updates
B. Product Summaries
C. Cost Comparison: Carboplatin Products
D. College of Pharmacy Recommendations

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

12. **Action Item – Annual Review of Anti-Ulcer Medications – See Appendix J**

A. Current Prior Authorization Criteria
B. Utilization of Anti-Ulcer Medications
C. Prior Authorization of Anti-Ulcer Medications
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Anti-Ulcer Medications

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

13. **Action Item – Annual Review of Epidermolysis Bullosa (EB) Medications – 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. College of Pharmacy Recommendations
F. Utilization Details of EB Medications

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

14. **Annual Review of Colorectal Cancer (CRC) Medications and 30-Day Notice to Prior Authorize Jobevne™ (Bevacizumab-nwgd) – See Appendix L**

A. Current Prior Authorization Criteria
B. Utilization of CRC Medications
C. Prior Authorization of CRC Medications
D. Market News and Updates
E. Cost Comparison: Bevacizumab Products
F. College of Pharmacy Recommendations
G. Utilization Details of CRC Medications

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

15. **Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy) – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Anti-Diabetic Medications and Kerendia® (Finerenone)
    C. Prior Authorization of Anti-Diabetic Medications and Kerendia® (Finerenone)
    D. Market News and Updates
    E. Awiqli® (Insulin Icodec-abae) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of Anti-Diabetic Medications and Kerendia® (Finerenone)

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

16. **Annual Review of Heart Failure (HF) Medications and 30-Day Notice to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten) – See Appendix N**
    A. Current Prior Authorization Criteria
    B. Utilization of HF Medications
    C. Prior Authorization of HF Medications
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of HF Medications

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

17. **Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® Iqlik™ (Lecanemab-irmb) – See Appendix O**
    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. College of Pharmacy Recommendations
    F. Utilization Details of Alzheimer's Disease Medications

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

18. **Annual Review of Testosterone Products – See Appendix P**
    A. Current Prior Authorization Criteria
    B. Utilization of Testosterone Products
    C. Prior Authorization of Testosterone Products
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Testosterone Products

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

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

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

20. **Future Business* (Upcoming Product and Class Reviews)**
    There is not a live DUR Board Meeting scheduled for August 2026. August 2026 will be a packet-only meeting.

A. Copper Metabolism Disorder Medications
B. Iron Chelating Agents
C. Iron Products
D. Miscellaneous Cancer Medications
E. Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications
F. Topical Corticosteroids
G. Various Systemic Antibiotics

*Future product and class reviews subject to change.

21. **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 10, 2026

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

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

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

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

OTHERS PRESENT:	
JJ Roth, Mirum Pharma	Scott Tabot, Agios Pharmaceuticals
Kenneth Berry, Alkermes	Jennifer Lauper, Bristol Myers Squibb
David Mendoza, Otsuka	Deidra Williams, Humana
Julie Vandaveer, Johnson & Johnson	Sarah Land, DO
Kellie Vazzanna, Alkermes	Bob Atkins, Biogen
Mark Kaiser, Otsuka	Lorenza Vasquez-Kirk, APRN-CNP
Scott Burns, Johnson & Johnson	Carrie Blumert, Mental Health Association of Oklahoma
Kristen Winters, Centene	Porsha Showers, Gilead
David Prather, Novo Nordisk	Audrey Rattan, Alexion
Brent Parker, Merck	Irene Chung, Aetna
Marc Parker, VS Health Group	Saurabh Patel, AbbVie
Michael Sullivan, Amgen	Jim Semans, SK Life Science
Dave Miley, Teva	Tina Hartmann, Arcutis
Ginger Papesh, Novo Nordisk	Gary Parenteau, Dexcom
Todd Dickerson, Jazz	Payal Tejani, Biogen
John Omick, Travere	Phillip Held, United Therapeutics
Shawn Akey, Concis Labs	Michelle Bice, Soleno
Lindsey Baker, Genentech	Eardie Curry, Genentech
Sergio Gomez, Concis Labs	Brad Zastrow, Axsome
Tim Melancon, Immedica	Rob Wilson Goehringer Ingelheim
Abby Hata, Immedica	Keely Larson Genmab
Mark DeClerk, Alkermes	Miranda Ryzenman, Artia Solutions
Rober Pearce, Bristol Myers Squibb	Brad Mullens, Bristol Myers Squibb
Janie Huff, Madrigal	Mariam Alboustani, Dyne Therapeutics

PRESENT FOR PUBLIC COMMENT:	
Andrew Delgado, Bristol Myers Squibb	Kenneth Berry, Alkermes
Lorenza Vasquez-Kirk, APRN-CNP	Julie Vandaveer, Johnson & Johnson
Sarah Land, DO	Carrie Blumert, Mental Health Asso. of OK

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. 17 ANDREW DELGADO
2B: AGENDA ITEM NO. 17 LORENZA VASQUEZ-KIRK
2C: AGENDA ITEM NO. 17 SARAH LAND
2D: AGENDA ITEM NO. 17 KENNETH BERRY
2E: AGENDA ITEM NO. 17 JULIE VANDAVEER
2F: AGENDA ITEM NO. 17 CARRIE BLUMERT
ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MEETING MINUTES
3A: APRIL 8, 2026 DUR MINUTES
Materials included in agenda packet; presented by Dr. Haymore
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT
4A: PHARMACY HELPDESK ACTIVITY FOR APRIL 2026
4B: MEDICATION COVERAGE ACTIVITY FOR APRIL 2026
4C: PHARMACY HELPDESK ACTIVITY FOR MAY 2026
4D: MEDICATION COVERAGE ACTIVITY FOR MAY 2026
Non-presentation item; materials included in agenda packet by Dr. DeRemer
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: EVALUATION OF PEDIATRIC OPIOID PRESCRIBING IN MEDICAID BENEFICIARIES
5A: INTRODUCTION
5B: CLINICAL PRACTICE GUIDANCE FOR PEDIATRIC OPIOID PRESCRIBING
5C: PROVIDER MAILING
5D: DATA ANALYSIS
5E: CONCLUSIONS
Materials included in agenda packet; presented by Dr. Dorsey
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE VOYXACT® (SIBEPRENLIMAB-SZSI) AND UPDATE THE APPROVAL CRITERIA FOR THE PRIMARY IMMUNOGLOBULIN A NEPHROPATHY (IgAN)
6A: MARKET NEWS AND UPDATES
6B: VOYXACT® (SIBEPRENLIMAB-SZSI) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE ARYNTA™ (LISDEXAMFETAMINE ORAL SOLUTION) AND ATONCY™ (ATOMOXETINE ORAL SOLUTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS
7A: MARKET NEWS AND UPDATES
7B: PRODUCT SUMMARIES
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. Ground

ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 8:</u> VOTE TO PRIOR AUTHORIZE ITVISMA® (ONASEMNOGENE ABEPARVOVEC-BRVE) AND UPDATE THE APPROVAL CRITERIA FOR THE SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS
8A: MARKET NEWS AND UPDATES
8B: ITVISMA® (ONASEMNOGENE ABEPARVOVEC-BRVE) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Patatanian moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> VOTE TO PRIOR AUTHORIZE JASCAYD® (NERANDOMILAST) AND UPDATE THE APPROVAL CRITERIA FOR THE INTERSTITIAL LUNG DISEASE (ILD) MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: JASCAYD® (NERANDOMILAST) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Grimes
Dr. Patatanian moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> VOTE TO PRIOR AUTHORIZE RETHYMIC® (ALLOGENEIC PROCESSED THYMUS TISSUE-AGDC)
10A: MARKET NEWS AND UPDATES
10B: RETHYMIC® (ALLOGENEIC PROCESSED THYMUS TISSUE-AGDC) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Dorsey
Dr. Holderread moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> VOTE TO PRIOR AUTHORIZE EYDENZELT® (AFLIBERCEPT-BOAV) AND UPDATE THE APPROVAL CRITERIA FOR THE AGE-RELATED MACULAR DEGENERATION (AMD) MEDICATIONS
11A: MARKET NEWS AND UPDATES
11B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Holderread moved to approve; seconded by Dr. Ground
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> VOTE TO PRIOR AUTHORIZE AVGEMSI™ (GEMCITABINE), EMRELIS™ (TELISOTUZUMAB VEDOTIN-TLLV), ENSACOVE™ (ENSARTINIB), HERNEXEOS® (ZONGERTINIB), HYRNUO® (SEVABERTINIB), IBTROZI™ (TALETRECTINIB), AND RYBREVANT FASPRO™ (AMIVANTAMAB/HYALURONIDASE-LPUJ) AND UPDATE THE APPROVAL CRITERIA FOR THE LUNG CANCER MEDICATIONS
12A: MARKET NEWS AND UPDATES
12B: PRODUCT SUMMARIES
12C: COST COMPARISON: GEMCITABINE PRODUCTS
12D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Patatanian moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF ZOKINVY® (LONAFARNIB)

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF ZOKINVY® (LONAFARNIB)
13C: PRIOR AUTHORIZATION OF ZOKINVY® (LONAFARNIB)
13D: MARKET NEWS AND UPDATES
13E: 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

AGENDA ITEM NO. 14: ANNUAL REVIEW OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE INLEXZO™ (GEMCITABINE INTRAVESICAL SYSTEM), KYXATA™ (CARBOPLATIN), LIFYORLI™ (RELACORILANT), AND ZUSDURI™ (MITOMYCIN INTRAVESICAL SOLUTION)

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
14C: PRIOR AUTHORIZATION OF GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: PRODUCT SUMMARIES
14F: COST COMPARISON: CARBOPLATIN PRODUCTS
14G: COLLEGE OF PHARMACY RECOMMENDATIONS
14H: 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

AGENDA ITEM NO. 15: ANNUAL REVIEW OF THE SOONERCARE PHARMACY BENEFIT

15A: SUMMARY
15B: MEDICAID DRUG REBATE PROGRAM
15C: ALTERNATIVE PAYMENT MODELS
15D: DRUG APPROVAL TRENDS
15E: TRADITIONAL VERSUS SPECIALTY PHARMACY PRODUCTS
15F: TOP 10 TRADITIONAL THERAPEUTIC CATEGORIES BY REIMBURSEMENT
15G: TOP 10 SPECIALTY THERAPEUTIC CATEGORIES BY REIMBURSEMENT
15H: TOP 10 MEDICATIONS BY REIMBURSEMENT
15I: COST PER CLAIM
15J: MARKET PROJECTIONS
15K: CONCLUSION
15L TOP 50 REIMBURSED DRUGS
15M: TOP 50 MEDICATIONS BY NUMBER OF CLAIMS
15N: FISCAL YEAR COMPARISONS

Materials included in agenda packet; presented by Dr. Dorsey
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: ANNUAL REVIEW OF ANTI-EMETIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE NEREUS™ (TRADIPITANT) AND POSFREA™ (PALONOSETRON INJECTION)

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF ANTI-EMETIC MEDICATIONS
16C: PRIOR AUTHORIZATION OF ANTI-EMETIC MEDICATIONS

16D: MARKET NEWS AND UPDATES
16E: NEREUS™ (TRADIPITANT) PRODUCT SUMMARY
16F: COST COMPARISON: PALONOSETRON PRODUCTS
16G: COLLEGE OF PHARMACY RECOMMENDATIONS
16H: UTILIZATION DETAILS OF ANTI-EMETIC MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

<u>AGENDA ITEM NO. 17:</u> ANNUAL REVIEW OF ATYPICAL ANTIPSYCHOTIC MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BYSANTI™ (MILSAPERIDONE)
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF ATYPICAL ANTIPSYCHOTICS
17C: PRIOR AUTHORIZATION OF ATYPICAL ANTIPSYCHOTICS
17D: OKLAHOMA RESOURCES
17E: MARKET NEWS AND UPDATES
17F: BYSANTI™ (MILSAPERIDONE) PRODUCT SUMMARY
17G: COST COMPARISON: ATYPICAL ANTIPSYCHOTICS FOR ADJUNCT TREATMENT OF MDD
17H: COLLEGE OF PHARMACY RECOMMENDATIONS
17I: UTILIZATION DETAILS OF ATYPICAL ANTIPSYCHOTICS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

<u>AGENDA ITEM NO. 18:</u> ANNUAL REVIEW OF ANTIVIRAL MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE HEPCLUDEX® (BULEVIRTIDE-GMOD), RELENZA® (ZANAMIVIR INHALATION POWDER) AND XOFLUZA® (BALOXAVIR)
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF ANTIVIRAL MEDICATIONS
18C: PRIOR AUTHORIZATION OF ANTIVIRAL MEDICATIONS
18D: MARKET NEWS AND UPDATES
18E: HEPCLUDEX® (BULEVIRTIDE-GMOD) PRODUCT SUMMARY
18F: COST COMPARISON: ORAL INFLUENZA ANTIVIRAL MEDICATIONS
18G: COLLEGE OF PHARMACY RECOMMENDATIONS
18H: UTILIZATION DETAILS OF ANTIVIRAL MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN JULY

<u>AGENDA ITEM NO. 19:</u> ANNUAL REVIEW OF UREA CYCLE DISORDER (UCD) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LOARGYS® (PEGZILARGINASE-NBLN)
19A: CURRENT PRIOR AUTHORIZATION CRITERIA
19B: UTILIZATION OF UCD MEDICATIONS
19C: PRIOR AUTHORIZATION OF UCD MEDICATIONS
19D: MARKET NEWS AND UPDATES
19E: LOARGYS® (PEGZILARGINASE-NBLN) PRODUCT SUMMARY
19F: COLLEGE OF PHARMACY RECOMMENDATIONS
19G: UTILIZATION DETAILS OF UCD MEDICATIONS
Materials included in agenda packet; presented by Dr. Grimes
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 AVERI™ (DESOGESTREL/ETHINYL ESTRADIOL/FERROUS BISGLYCINATE), CAFERGOT®

(ERGOTAMINE/CAFFEINE TABLET), DESMODA™ (DESMOPRESSIN ORAL SOLUTION), DICYCLOMINE 40MG TABLET, GRISEOFULVIN ULTRAMICROSIZE 165MG TABLET, HYDROXYZINE ORAL SOLUTION UNIT DOSE CUPS (UDCS), KHINDIVI™ (HYDROCORTISONE ORAL SOLUTION), MIGERGOT® (ERGOTAMINE/CAFFEINE SUPPOSITORY), ONTRALFY™ (TIZANIDINE ORAL SOLUTION), POKONZA™ (POTASSIUM CHLORIDE 10MEQ/15ML ORAL SOLUTION), POKONZA™ (POTASSIUM CHLORIDE 15MEQ PACKET), POTASSIUM CHLORIDE 40MEQ PACKET, QUIOFIC™ (FOLIC ACID ORAL SOLUTION), RELGAABI™ (GABAPENTIN 200MG CAPSULE), AND VYKOURA™ (LEUCOVORIN INJECTION)

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: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTRATION (DEA) UPDATES

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

AGENDA ITEM NO. 22: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)

22A: ALZHEIMER'S MEDICATIONS
22B: ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
22C: ANTI-ULCER MEDICATIONS
22D: COLORECTAL CANCER (CRC) MEDICATIONS
22E: EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS
22F: HEART FAILURE MEDICATIONS
22G: 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. 23: ADJOURNMENT

The meeting was adjourned at 6:15pm.

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

Memorandum

Date: June 12, 2026

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

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

Subject: DUR Board Recommendations from Meeting on June 10, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Evaluation of Pediatric Opioid Prescribing in SoonerCare Beneficiaries

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Voyxact® (Sibeprenlimab-szsi) 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 Voyxact® (sibeprenlimab-szsi) with the following criteria (shown in red):

Voyxact® (Sibeprenlimab-szsi) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); and

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

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

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

1. An FDA approved indication to reduce proteinuria in members with FSGS; and
2. Member must be 8 years of age or older; and
3. The diagnosis of FSGS must be confirmed by 1 of the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); or
   b. A genetic mutation known to cause FSGS (results of genetic testing must be submitted); and
4. Member must not have nephrotic syndrome; and
5. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
6. Member must have previously tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
7. Prescriber must verify the member will not use other renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) concurrently with Filspari®; and
8. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Filspari®; and
9. Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective

contraception during treatment and for 2 weeks after the last dose of Filspari®; and
10. Prescriber, pharmacy, and member must be enrolled in the Filspari® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
11. Quantity limits will apply as follows:
    a. 200mg tablets: A quantity limit of 30 tablets per 30 days will apply; and
    b. 400mg tablets: A quantity limit of 60 tablets per 30 days will apply.

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

1. An FDA approved indication to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
    a. Kidney biopsy (can refer to a recent or historical biopsy); and
    b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent)~~, despite 3 months of maximal supportive care~~; and
6. ~~Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and~~
7. Member must have previously tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and
8. Prescriber must verify the member will ~~discontinue~~ not use ~~of~~ other renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs) ~~prior to initiating treatment~~ concurrently with Filspari®; and
9. ~~Member must not be taking strong CYP3A4 inhibitors (e.g., itraconazole) or strong CYP3A4 inducers (e.g., rifampin) concomitantly with Filspari®; and~~
10. ~~Member must not be taking H2 receptor blockers or proton pump inhibitors (PPIs) concomitantly with Filspari®; and~~
11. ~~If member is using antacids, they must agree to separate antacid and Filspari® administration by 2 hours; and~~

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

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

Vanrafia® (Atrasentan) Approval Criteria:

1. An FDA approved indication to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy (can refer to a recent or historical biopsy); and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day (or equivalent)~~, despite 3 months of maximal supportive care~~; and
6. ~~Member must be on a stable dose of a maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months, unless contraindicated or intolerant; and~~
7. Member must have previously tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) for at least 3 months alone, and member must agree to continue the use of an ACE or an ARB with Vanrafia™, unless contraindicated or intolerant; and
8. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Vanrafia®; and
9. Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 2 weeks after the last dose of Vanrafia®; and

10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

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

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

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

Recommendation 4: Vote to Prior Authorize Arynta™ (Lisdexamfetamine Oral Solution) and Atoncy™ (Atomoxetine Oral Solution) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications

MOTION CARRIED by unanimous approval.

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

1. Prior authorization of Arynta™ (lisdexamfetamine oral solution) and Atoncy™ (atomoxetine oral solution) and placement into the Special PA Tier with the additional criteria shown below; and

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

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine (Evekeo®)Δ amphetamine ODT (Evekeo ODT®)Δ amphetamine/ dextroamphetamine ER (Mydayis®)Δ dextroamphetamine (Dexedrine®)Δ dextroamphetamine soln (ProCentra®)Δ dextroamphetamine (Xelstrym®)Δ dextroamphetamine (Zenzedi®)Δ **lisdexamfetamine soln (Arynta™)Δ** methamphetamine (Desoxyn®)Δ methylphenidate ER 72mgΔ methylphenidate ER ODT (Cotempla XR-ODT®)Δ methylphenidate ER (Relexxii®)Δ methylphenidate chew tab (Methylin®)Δ methylphenidate ER chew tab (QuilliChew ER®)Δ
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®)	dextroamphetamine ER (Dexedrine Spansules®) lisdexamfetamine cap (Vyvanse®)+	amphetamine ER ODT (Adzenys XR-ODT®)Δ amphetamine ER susp and tab (Dyanavel® XR)Δ lisdexamfetamine chew tab (Vyvanse®)Δ	
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®)Δ methylphenidate (Ritalin®)			

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Long-Acting			
dexmethylphenidate ER (Focalin XR®) methylphenidate ER (Concerta®) methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) methylphenidate ER (Ritalin SR®)	methylphenidate ER (Aptensio XR®) ~~**methylphenidate ER (Daytrana®)Δ**~~ methylphenidate ER susp (Quillivant XR®)Δ methylphenidate ER (Ritalin LA®)	**methylphenidate ER (Daytrana®)Δ** methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)Δ	clonidine ER susp (Onyda™ XR)Δ	**atomoxetine soln (Atoncy™)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).
+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~~
4. For Quillivant XR®, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific,

clinically significant reason why a special formulation product is needed.

5. Kapvay® Approval Criteria:
   a. An FDA approved diagnosis; and
   b. A previously failed trial (within the last 180 days) with a long-acting Tier-1 stimulant or non-stimulant unless contraindicated, that did not yield adequate results.

~~6. Vyvanse® Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:~~
   ~~a. An FDA approved diagnosis of moderate-to-severe BED; and~~
   ~~b. Member must be 18 years of age or older; and~~
   ~~c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and~~
   ~~d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and~~
   ~~e. A quantity limit of 30 capsules per 30 days will apply; and~~
   ~~f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.~~

ADHD Medications Tier-3 Approval Criteria:

1. A covered diagnosis; and
2. A previously failed trial with at least 1 long-acting Tier-1 stimulant that resulted in an inadequate response; and
3. A previously failed trial with at least 1 long-acting Tier-2 stimulant that resulted in an inadequate response:
   a. Trials should have been within the last 365 days; and
   b. Trials should have been dosed up to maximum recommended dose or documented adverse effects at higher doses should be included; and
   c. If trials are not in member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the physician; and
4. For Adzenys XR-ODT® and Dyanavel® XR oral suspension, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
5. For Daytrana® patches, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
6. Onyda™ XR Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 years of age or older; and

c. Previously failed trials (within the last 180 days) with a long-acting Tier-1 stimulant, Intuniv®, and Strattera®, unless contraindicated, that did not yield adequate results; and
d. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use Kapvay® (clonidine ER tablet) must be provided.

7. ~~For~~ Vyvanse® Chewable Tablet Approval Criteria:
   a. For a diagnosis of binge eating disorder (BED), the member must meet the unique BED approval criteria; or
   b. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

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

medications that can be used for members who cannot swallow capsules or tablets must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Desoxyn®, Dexedrine®, Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Methylin® Chewable Tablets Approval Criteria:
   a. A covered diagnosis; and
   b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
   c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
6. Mydayis® Approval Criteria:
   a. A covered diagnosis; and
   b. Member must be 13 years of age or older; and
   c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
7. Qelbree® Approval Criteria:
   a. An FDA approved diagnosis; and
   b. Member must be 6 years of age or older; and
   c. Previously failed trial (within the last 180 days) with atomoxetine or any ADHD medication, unless contraindicated, that did not yield adequate results; and
      i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or any ADHD medications within the past 180 days of claims history; and
   ~~d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and~~
   ~~e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and~~
   f. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment; and
   g. Quantity limits will apply based on FDA-approved dosing.

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

1. An FDA approved diagnosis of moderate-to-severe BED; and
2. Member must be 18 years of age or older; and
3. ~~Vyvanse®~~ Lisdexamfetamine for the diagnosis of BED must be prescribed by a psychiatrist; and
4. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of ~~Vyvanse®~~ lisdexamfetamine for the treatment of obesity have not been established; and
5. For Vyvanse® chewable tablet:
    a. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
    b. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
6. For Arynta™:
    a. A patient-specific, clinically significant reason why the member cannot use Vyvanse® capsules (brand or generic), even when opened and mixed with yogurt, water, or orange juice must be provided; and
    b. A patient-specific, clinically significant reason why the member cannot use lisdexamfetamine chewable tablets must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
7. ~~A quantity limit of 30 capsules per 30 days will apply; and~~
8. A maximum dose of 70mg per day will apply; and
9. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of ~~Vyvanse®~~ lisdexamfetamine.

Recommendation 5: Vote to Prior Authorize Itvisma® (Onasemnogene Abeparvovec-brve) and Update the Approval Criteria for the Spinal Muscular Atrophy (SMA) Medications

MOTION CARRIED by unanimous approval.

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

Itvisma® (Onasemnogene Abeparvovec-brve) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and

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

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

Evrysdi® (Risdiplam) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA); and
2. Molecular genetic testing to confirm biallelic pathogenic variants in the *survival motor neuron 1 (SMN1)* gene (results of genetic testing must be submitted); and
3. Member is not currently dependent on permanent invasive ventilation (defined as ≥16 hours of respiratory assistance per day continuously for >21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Evrysdi® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and

5. For the tablet formulation, the member must be 2 years of age or older and weigh ≥20kg (recent weight measured within the last 3 months must be submitted); and
6. Prescriber must agree to evaluate member's liver function prior to initiating Evrysdi® and must verify the member does not have severe hepatic impairment (Child-Pugh C); and
7. Pharmacy must confirm Evrysdi® oral solution will be constituted by a pharmacist prior to dispensing and must confirm Evrysdi® oral solution will be shipped via cold chain supply to adhere to the storage and handling requirements in the package labeling; and
8. Prescriber must confirm the member or caregiver has been counseled on the proper storage of Evrysdi® and has been instructed on how to prepare the prescribed daily dose of Evrysdi® formulations prior to administration of the first dose; and
9. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
10. Female members of reproductive potential must be willing to use effective contraception during treatment with Evrysdi® and for at least 1 month after the last dose; and
11. Prescriber must verify male members of reproductive potential have been counseled on the potential effects on fertility and the potential of compromised male fertility is acceptable; and
12. Member will not be approved for concomitant treatment with Spinraza® (nusinersen); and
13. Member must not have previously received treatment with Itvisma® (onasemnogene abeparvovec-brve) or Zolgensma® (onasemnogene abeparvovec-xioi); and
14. A baseline assessment must be provided using a functionally appropriate exam [e.g., Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), Hammersmith Functional Motor Scale Expanded (HFMSE), Hammersmith Infant Neurological Exam (HINE), Upper Limb Module (ULM) Test]; and
15. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is compliant with Evrysdi® and responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pre-treatment baseline status using the same exam as performed at baseline assessment; and
16. Member's recent weight must be provided to ensure accurate dosing in accordance with package labeling; and
17. A quantity limit of 240mL per 36 days will apply.
18. For the oral solution, a quantity limit of 240mL per 36 days will apply and for the tablets, a quantity limit of 30 tablets per 30 days will apply.

Zolgensma® (Onasemnogene Abeparvovec-xioi) Approval Criteria:

1. An FDA approved diagnosis of spinal muscular atrophy (SMA) in pediatric members younger than 2 years of age; and

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

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

Spinraza® (Nusinersen) Approval Criteria:

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

>21 days in the absence of an acute, reversible illness or a perioperative state); and
4. Spinraza® must be prescribed by a neurologist or specialist with expertise in the treatment of SMA (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of SMA); and
5. Member must not have previously received treatment with Itvisma® (onasemnogene abeparvovec-brve) or Zolgensma® (onasemnogene abeparvovec-xioi); and
6. Member will not be approved for concomitant treatment with Evrysdi® (risdiplam); and
7. Prescriber must verify platelet count, coagulation laboratory testing, and quantitative spot urine protein testing have been assessed at baseline, levels are acceptable to the prescriber, and levels will be monitored prior to each dose; and
8. Spinraza® must be administered in a health care facility by a specialist experienced in performing lumbar punctures; and
    a. Spinraza® must be shipped to the facility where the member is scheduled to receive treatment; and
9. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. Hammersmith Infant Neurological Exam (HINE); or
    b. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); or
    c. Upper Limb Module (ULM) Test; or
    d. Hammersmith Functional Motor Scale Expanded (HFMSE); and
10. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment:
    a. HINE; or
    b. CHOP-INTEND; or
    c. ULM Test; or
    d. HFMSE; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. Only (1) 5mL vial of Spinraza® is to be dispensed prior to each scheduled procedure for administration.

Recommendation 6: Vote to Prior Authorize Jascayd® (Nerandomilast) and Update the Approval Criteria for the Interstitial Lung Disease (ILD) Medications

MOTION CARRIED by unanimous approval.

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

Jascayd® (Nerandomilast) Approval Criteria:

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

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

Ofev® (Nintedanib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of idiopathic pulmonary fibrosis (IPF); or
   b. Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype; or
   c. To slow the rate of decline in pulmonary function in members with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Ofev® treatment, at regular intervals during the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
4. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for at least 3 months after therapy completion; and
5. Medication must be prescribed by, or in consultation with, a pulmonologist, ~~or~~ pulmonary specialist, or rheumatologist (or an advanced care practitioner with a supervising physician who is a pulmonologist, ~~or~~ pulmonary specialist, or rheumatologist); and
6. A patient-specific, clinically significant reason why the member cannot use generic pirfenidone must be provided; and

7. A quantity limit of 60 capsules per 30 days will apply

Recommendation 7: Vote to Prior Authorize Rethymic® (Allogeneic Processed Thymus Tissue–agdc)

MOTION CARRIED by unanimous approval.

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

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

1. An FDA approved indication for immune reconstitution in pediatric patients with congenital athymia (CA). Diagnosis must be confirmed by the following (supporting documentation must be submitted):
   a. Flow cytometry documenting <50 naïve T-cells/mm^3 (CD45RA+, CD62L+) in the peripheral blood or <5% of total T-cells being naïve in phenotype; and
   b. Clinical, genetic, and/or immunologic findings, including evaluation to exclude severe combined immunodeficiency (SCID); and
2. Member must be younger than 18 years of age; and
3. Member must not have SCID; and
4. Member must not have a pre-existing cytomegalovirus (CMV) infection or pre-existing renal impairment; and
5. Rethymic® must be prescribed by a specialist with expertise in CA and in the administration of Rethymic®; and
6. Prescriber must attest that the member will not receive immunizations until immune function is established; and
7. Documentation of anti-human leukocyte antigen (HLA) antibody screening; and
   a. If the member is positive for anti-HLA antibodies, prescriber must verify the member will receive Rethymic® from a donor who does not express those HLA alleles; and
8. If the member has received a hematopoietic cell transplant (HCT) or a solid organ transplant, the following will be required:
   a. HLA matching; and
   b. Member will receive Rethymic® HLA matched to recipient alleles that were not expressed in the HCT donor to minimize the risk of graft-versus-host disease (GVHD); and
9. Verification that the member will be monitored and the member and/or caregiver will be counseled on all the following after treatment with Rethymic®, as per package labeling:
   a. Lymphoproliferative disorders; and
   b. Transmission of infectious disease; and
   c. Development of autoimmune disorders; and
   d. Development of GVHD; and
   e. Infection control measures and immune prophylaxis; and

10. Prescriber attestation that Rethymic® will be prescribed with immunosuppressive therapy based on disease phenotype and phytohemagglutinin levels; and
11. Member has no history of receiving a previous thymus tissue implantation in their lifetime; and
12. Approval will be for 1 treatment per member per lifetime.

Recommendation 8: Vote to Prior Authorize Eydenzelt® (Aflibercept-boav) 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 Eydenzelt® (aflibercept-boav) with the same criteria as the other aflibercept biosimilar products (changes shown in red):

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

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

Recommendation 9: Vote to Prior Authorize Avgemsi™ (Gemcitabine), Emrelis™ (Telisotuzumab Vedotin-tllv), Ensacove™ (Ensartinib), Hernexeos® (Zongertinib), Hyrnuo® (Sevabertinib), Ibtrozi™ (Taletrectinib), and Rybrevant Faspro™ (Amivantamab/Hyaluronidase-lpuj) and Update the Approval Criteria for the Lung Cancer Medications

MOTION CARRIED by unanimous approval.

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

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

1. Diagnosis of recurrent, advanced, or metastatic non-squamous NSCLC; and
2. Disease with high c-Met/MET protein overexpression, defined as ≥50% of tumor cells with strong staining [immunohistochemistry (IHC) 3+]; and
3. Epidermal growth factor receptor (EGFR) wild-type; and

4. Member has received prior systemic therapy; and
5. ECOG performance status of 0-2; and
6. Used as a single agent; and
7. Member must be 18 years of age or older.

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

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Anaplastic lymphoma kinase (ALK) positive; and
3. Used as a single agent; and
4. Member has not previous received an ALK inhibitor.

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

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

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

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

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

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

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

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

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Tumor exhibits epidermal growth factor receptor (EGFR) exon 20 insertion mutations; and
    a. As first-line therapy in combination with carboplatin and pemetrexed; or

b. As a single agent in disease that has progressed on or after platinum-based chemotherapy; or

3. Tumor exhibits EGFR exon 19 deletion or exon 21 L858R mutations; and
   a. As first-line therapy in combination with lazertinib; or
   b. As subsequent therapy in combination with carboplatin and pemetrexed after progression on an EGFR tyrosine kinase inhibitor.

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

Avgemsi™ (Gemcitabine; J9184) Approval Criteria:

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

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

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

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

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

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

5. Member is 18 years of age or older.

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

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

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

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

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

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

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

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

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

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

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

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

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

Recommendation 10: Fiscal Year 2025 Annual Review of Zokinvy® (Lonafarnib)

MOTION CARRIED by unanimous approval.

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

Zokinvy® (Lonafarnib) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. To reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS); or
   b. Treatment of processing-deficient Progeroid Laminopathies (PL) with either:
      i. Heterozygous *LMNA* mutation with progerin-like protein accumulation; or
      ii. Homozygous or compound heterozygous *ZMPSTE24* mutations; and
2. Member must have confirmatory mutational analysis showing mutation in the *LMNA* and/or *ZMPSTE24* gene (results of the genetic testing must be submitted); and
3. Zokinvy® will not be approved for other progeroid syndromes or processing-proficient PL (based upon its mechanism of action, Zokinvy® would not be effective in these populations); and
4. Member must be 1 year of age or older; and

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

Recommendation 11: Fiscal Year 2025 Annual Review of Genitourinary and Gynecologic Cancer Medications and 30-Day Notice to Prior Authorize Inlexzo™ (Gemcitabine Intravesical System), Kyxata™ (Carboplatin), Lifyorli™ (Relacorilant), and Zusduri™ (Mitomycin Intravesical Solution)

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

Recommendation 12: Fiscal Year 2025 Annual Review of the SoonerCare Pharmacy Benefit

NO ACTION REQUIRED

Recommendation 13: Fiscal Year 2025 Annual Review of Anti-Emetic Medications and 30-Day Notice to Prior Authorize Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection)

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

Recommendation 14: Fiscal Year 2025 Annual Review of Atypical Antipsychotic Medications and 30-Day Notice to Prior Authorize Bysanti™ (Milsaperidone)

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

Recommendation 15: Fiscal Year 2025 Annual Review of Antiviral Medications and 30-Day Notice to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder), and Xofluza® (Baloxavir)

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

Recommendation 16: Fiscal Year 2025 Annual Review of Urea Cycle Disorder (UCD) Medications and 30-Day Notice to Prior Authorize Loargys® (Pegzilarginase-nbln)

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

Recommendation 17: Fiscal Year 2025 Annual Review of Various Special Formulations and 30-Day Notice to Prior Authorize Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Cafergot® (Ergotamine/Caffeine Tablet), Desmoda™ (Desmopressin Oral Solution), Dicyclomine 40mg Tablet, Griseofulvin Ultramicrosize 165mg Tablet, Hydroxyzine Oral Solution Unit Dose Cups (UDCs), Khindivi™ (Hydrocortisone Oral Solution), Migergot® (Ergotamine/Caffeine Suppository), Ontralfy™ (Tizanidine Oral Solution), PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet, Quiofic™ (Folic Acid Oral Solution), Relgaabi™ (Gabapentin 200mg Capsule), and Vykoura™ (Leucovorin Injection)

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

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

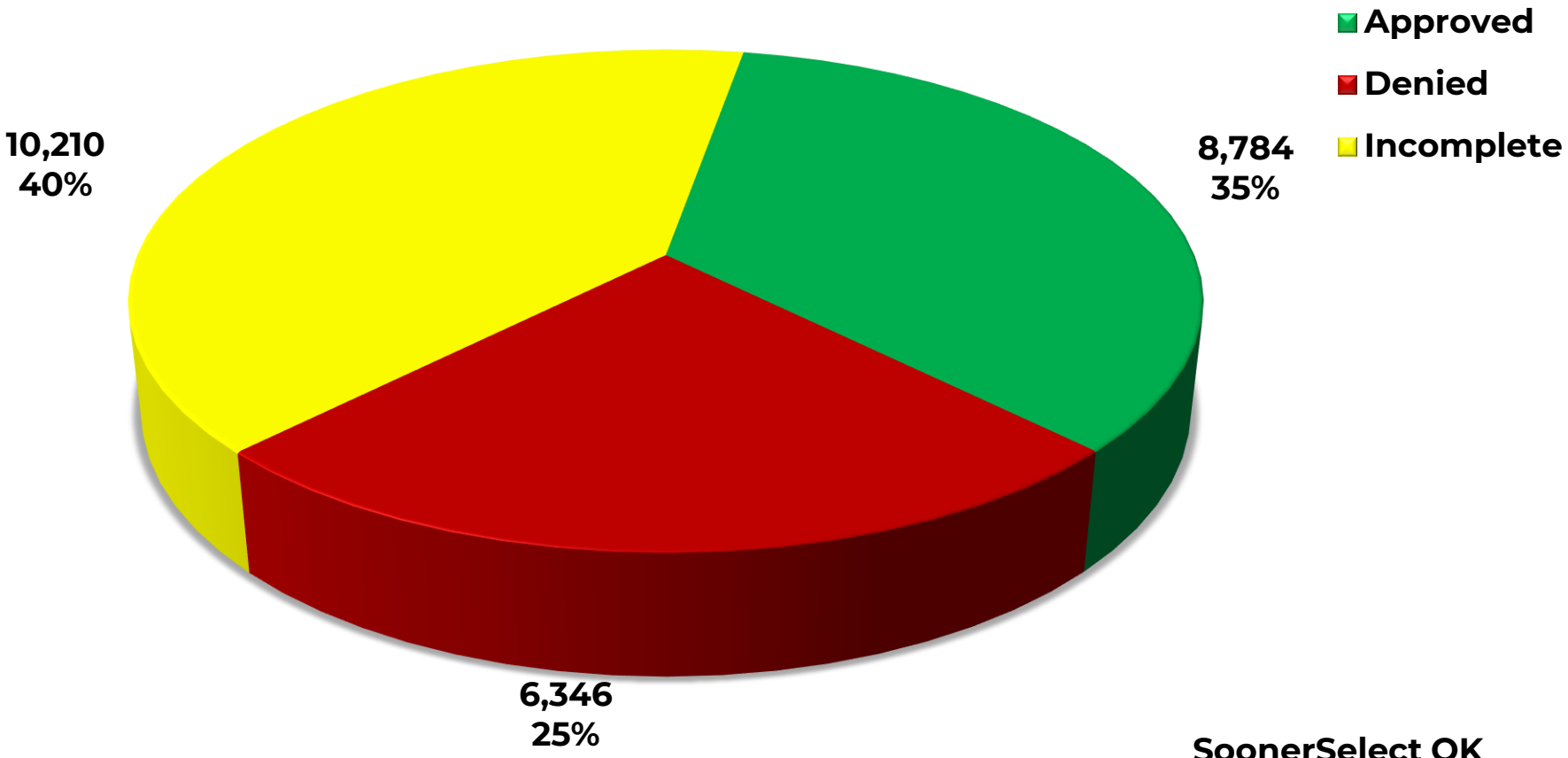
NO ACTION REQUIRED.

Recommendation 19: Future Business

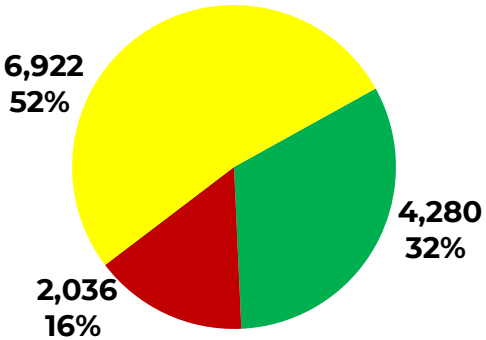
NO ACTION REQUIRED.

Appendix B

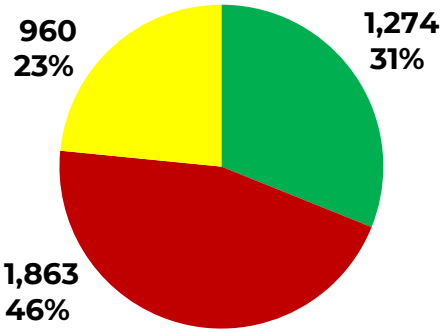
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JUNE 2026



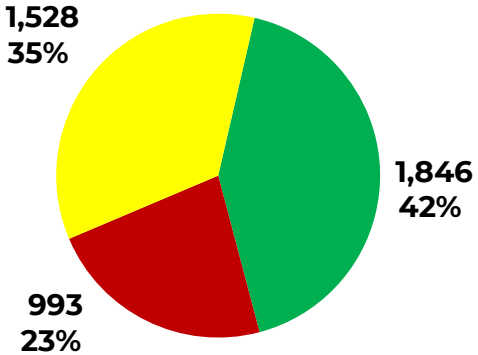
SoonerCare FFS



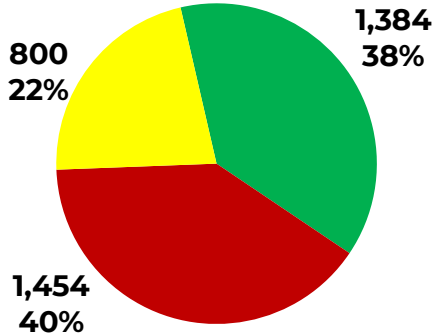
SoonerSelect Aetna



SoonerSelect Humana

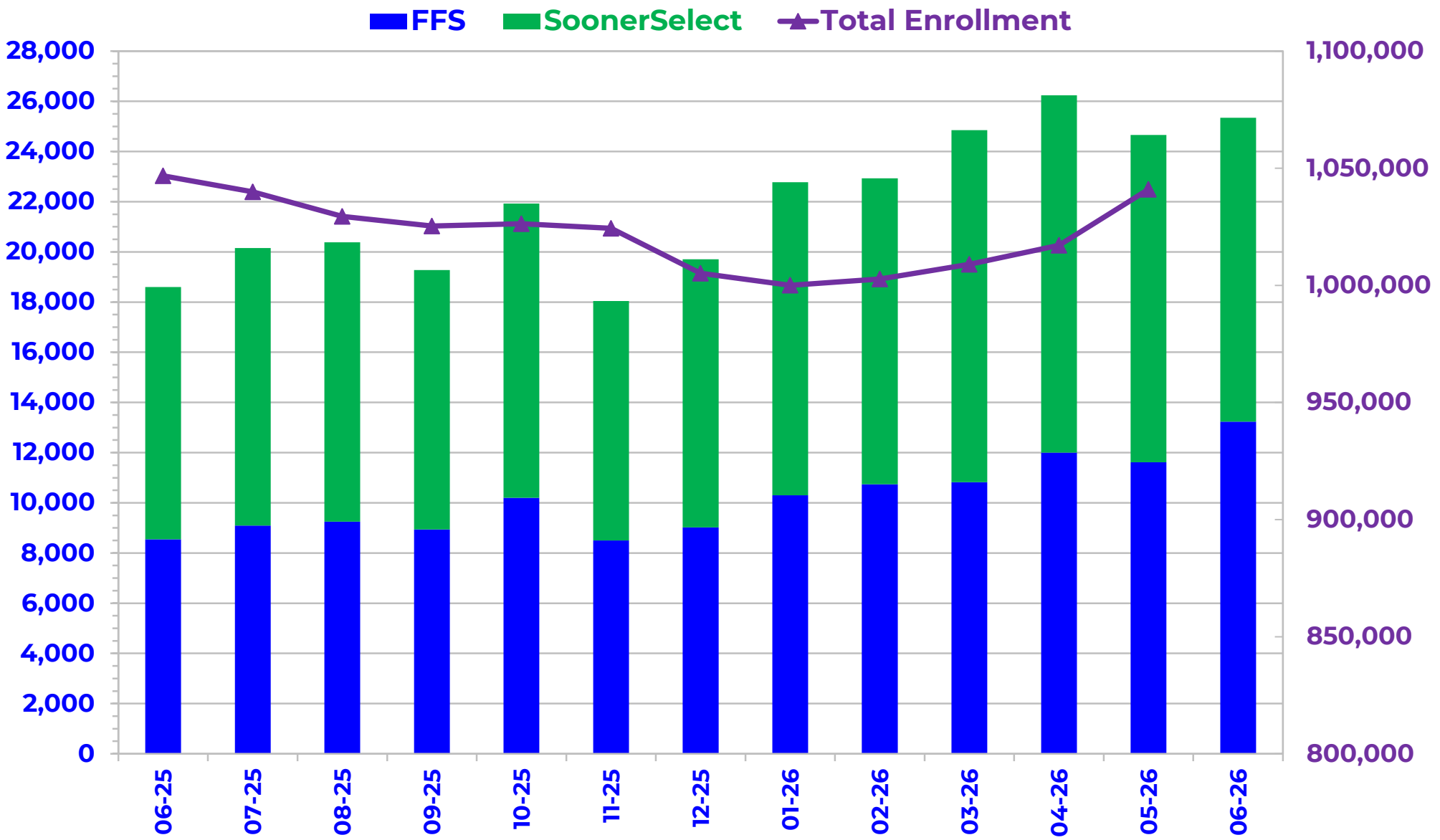


SoonerSelect OK Complete Health



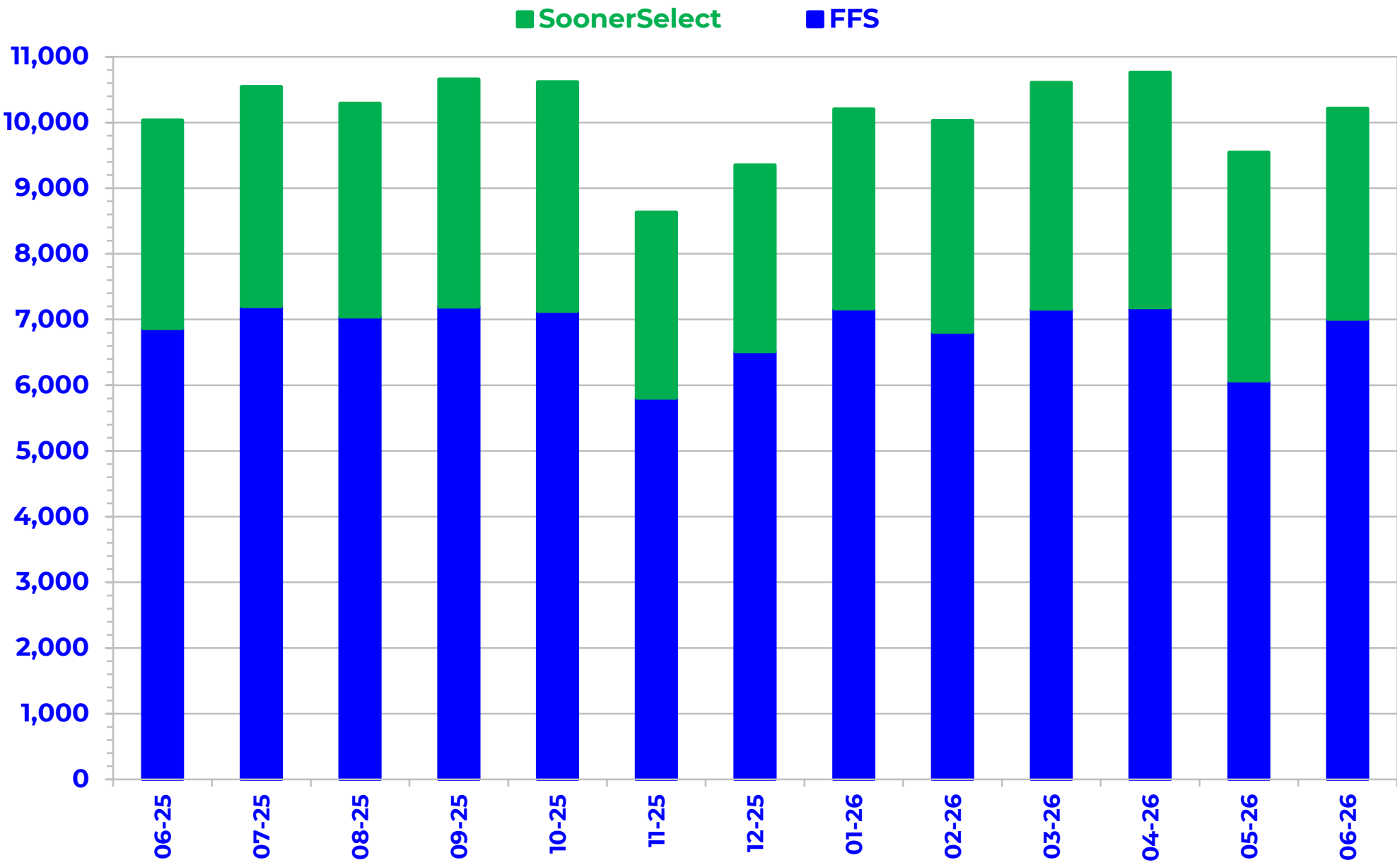
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JUNE 2025 – JUNE 2026



SoonerCare FFS Prior Authorization Activity

6/1/2026 Through 6/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	4	0	3	1	0
Amphetamines	991	558	61	372	357
Analgesics - Anti-Inflammatory	274	90	32	152	336
Analgesics - Nonnarcotic	11	0	2	9	0
Analgesics - Opioid	553	222	43	288	123
Androgens - Anabolic	117	5	44	68	323
Anorectal and Related Products	6	0	0	6	0
Anorexiants Non-Amphetamine	3	0	2	1	0
Anthelmintics	36	2	8	26	4
Anti-Infective Agents - Misc.	34	9	3	22	63
Anti-Obesity Agents	521	85	226	210	80
Antianginal Agents	3	1	0	2	1,091
Antianxiety Agents	48	4	6	38	255
Antiasthmatic and Bronchodilator Agents	751	117	121	513	435
Antibiotics	36	11	4	21	118
Anticoagulants	17	1	3	13	360
Anticonvulsants	364	131	18	215	349
Antidepressants	357	63	49	245	668
Antidiabetics	1,945	532	330	1,083	370
Antidotes and Specific Antagonists	6	3	0	3	359
Antiemetics	41	2	8	31	191
Antifungals	21	7	3	11	51
Antihistamines	35	13	6	16	258
Antihyperlipidemics	103	19	20	64	268
Antihypertensives	66	14	7	45	596
Antineoplastics and Adjunctive Therapies	242	141	10	91	178
Antiparkinson and Related Therapy Agents	14	2	1	11	1,091
Antipsychotics/Antimanic Agents	467	156	39	272	379
Antivirals	29	9	3	17	89
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	309	188	27	94	1,004
Beta Blockers	19	6	0	13	1,091
Calcium Channel Blockers	13	5	1	7	941
Cardiovascular Agents - Misc.	165	64	11	90	435
Chemicals	1	0	1	0	0
Contraceptives	63	29	4	30	380
Corticosteroids	15	4	3	8	287
Cough/Cold/Allergy	4	0	4	0	0
Dermatologicals	761	188	179	394	250
Diagnostic Products	59	22	2	35	168
Digestive Aids	17	13	0	4	326
Diuretics	23	10	2	11	754
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	5	0	0	5	0
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	231	72	41	118	265
Estrogens	23	2	7	14	331
Gastrointestinal Agents - Misc.	492	108	112	272	274
Genitourinary Agents - Misc.	7	2	0	5	361

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gout Agents	17	2	2	13	359
Hematological Agents - Misc.	29	8	1	20	316
Hematopoietic Agents	53	12	15	26	170
Histamine H3-receptor Antagonist/Inverse Agonists	11	2	3	6	187
Hypnotics/Sedatives/Sleep Disorder Agents	70	6	12	52	213
Laxatives	23	7	1	15	169
Medical Devices and Supplies	472	75	108	289	297
Migraine Products	661	155	159	347	245
Minerals and Electrolytes	19	5	2	12	76
Miscellaneous Therapeutic Classes	90	31	8	51	324
Multivitamins	3	0	1	2	0
Musculoskeletal Therapy Agents	93	5	11	77	292
Nasal Agents - Systemic and Topical	17	1	4	12	87
Neuromuscular Agents	144	50	32	62	339
Nutrients	5	2	1	2	223
Ophthalmic Agents	114	18	12	84	392
Other*	66	21	3	42	261
Otic Agents	81	30	6	45	15
Passive Immunizing and Treatment Agents	45	19	1	25	294
Pharmaceutical Adjuvants	1	1	0	0	356
Progestins	17	3	1	13	248
Psychotherapeutic and Neurological Agents - Misc.	299	97	37	165	281
Respiratory Agents - Misc.	47	25	1	21	269
Stimulants - Misc.	215	105	16	94	357
Thyroid Agents	7	1	1	5	1,091
Ulcer Drugs/Antispasmodics/Anticholinergics	147	23	4	120	631
Urinary Antispasmodics	64	4	11	49	542
Vaginal and Related Products	14	0	2	12	0
Vasopressors	3	0	1	2	0
Vitamins	95	7	69	19	274
Total	**12,224**	**3,625**	**1,971**	**6,628**	

Overrides					
Brand	28	15	2	11	344
Compound	43	24	3	16	14
Diabetic Supplies	1	0	1	0	0
Dosage Change	168	140	1	27	17
High Dose	3	1	0	2	5
IHS-Brand	1	1	0	0	25
Ingredient Duplication	3	1	0	2	30
Lost/Broken Rx	43	31	5	7	27
MAT Override	14	8	0	6	87
NDC vs Age	119	77	16	26	572
NDC vs Sex	12	8	1	3	354
Nursing Home Issue	65	60	2	3	18
Opioid MME Limit	59	16	1	42	142
Opioid Quantity	26	15	6	5	177
Other	46	34	3	9	28
Prescriber Temp Unlock	1	1	0	0	1,091
Quantity vs Days Supply	300	184	15	101	298

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
STBS/STBSM	22	8	5	9	127
Step Therapy Exception	9	3	3	3	247
Stolen	6	5	1	0	21
Third Brand Request	45	23	0	22	15
Overrides Total	**1,014**	**655**	**65**	**294**	
Total Regular PAs + Overrides	**13,238**	**4,280**	**2,036**	**6,922**	

Denial Reasons	
Unable to verify required trials.	6,479
Does not meet established criteria.	2,096
Lack required information to process request.	601
Other PA Activity	
Duplicate Requests	1,862
Letters	62,672
No Process	3
Helpdesk Initiated Prior Authorizations	381
PAs Missing Information	431
Pharmacotherapy	86
Changes to Existing PAs	736

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

SoonerSelect Aetna Prior Authorization Activity

6/1/2026 Through 6/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	301	205	83	13	360
Analgesics - Anti-Inflammatory	123	79	17	27	362
Analgesics - Nonnarcotic	7	1	5	1	365
Analgesics - Opioid	132	62	45	25	124
Androgens - Anabolic	69	6	63	0	365
Anorectal and Related Products	5	0	4	1	0
Anthelmintics	2	0	2	0	0
Antianginal Agents	6	0	0	6	0
Antianxiety Agents	50	5	9	36	268
Antiasthmatic and Bronchodilator Agents	184	33	100	51	308
Antibiotics	30	2	7	21	61
Anticoagulants	9	1	2	6	365
Anticonvulsants	70	17	22	31	303
Antidepressants	251	37	102	112	284
Antidiabetics	569	168	285	116	306
Antidiarrheal/Probiotic Agents	1	0	1	0	0
Antidotes and Specific Antagonists	1	1	0	0	365
Antiemetics	21	1	15	5	365
Antifungals	1	0	1	0	0
Antihistamines	30	9	19	2	426
Antihyperlipidemics	45	12	15	18	304
Antihypertensives	34	5	4	25	365
Anti-Infective Agents - Misc.	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	36	13	2	21	185
Anti-Obesity Agents	310	51	244	15	83
Antiparkinson and Related Therapy Agents	6	0	4	2	0
Antipsychotics/Antimanic Agents	156	42	63	51	333
Antivirals	11	6	3	2	74
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	68	47	16	5	825
Beta Blockers	17	0	1	16	0
Calcium Channel Blockers	14	2	0	12	365
Cardiovascular Agents - Misc.	53	20	22	11	346
Contraceptives	22	4	17	1	365
Corticosteroids	4	2	1	1	365
Dermatologicals	356	127	166	63	257
Diagnostic Products	42	17	15	10	402
Dietary Products/Dietary Management Products	2	0	0	2	0
Digestive Aids	5	1	0	4	365
Diuretics	30	2	2	26	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	1	0	0	365
Endocrine and Metabolic Agents - Misc.	34	20	8	6	248
Estrogens	29	3	8	18	365
Gastrointestinal Agents - Misc.	101	35	56	10	234
Genitourinary Agents - Misc.	1	0	1	0	0
Gout Agents	6	0	3	3	0

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hematological Agents - Misc.	9	4	0	5	365
Hematopoietic Agents	10	1	7	2	365
Hypnotics/Sedatives/Sleep Disorder Agents	39	3	16	20	244
Laxatives	14	0	5	9	0
Medical Devices and Supplies	87	22	49	16	365
Migraine Products	207	68	124	15	226
Minerals and Electrolytes	13	1	1	11	365
Miscellaneous Therapeutic Classes	13	8	2	3	297
Mouth/Throat/Dental Agents	1	0	0	1	0
Multivitamins	3	1	2	0	365
Musculoskeletal Therapy Agents	69	6	26	37	269
Nasal Agents - Systemic and Topical	15	1	12	2	92
Neuromuscular Agents	2	0	2	0	0
Ophthalmic Agents	35	8	18	9	191
Other	6	1	2	3	365
Otic Agents	27	2	21	4	61
Passive Immunizing and Treatment Agents	10	5	5	0	320
Progestins	3	0	3	0	0
Psychotherapeutic and Neurological Agents - Misc.	28	11	15	2	274
Respiratory Agents - Misc.	4	2	1	1	365
Stimulants - Misc.	98	71	22	5	360
Thyroid Agents	3	2	0	1	274
Ulcer Drugs/Antispasmodics/Anticholinergics	55	5	21	29	304
Urinary Antispasmodics	27	6	16	5	365
Vaccines	2	1	1	0	30
Vaginal and Related Products	5	0	4	1	0
Vitamins	65	8	54	3	276
****Total**	**4,097**	**1,274**	**1,863**	**960**	

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

Overrides					
Other	960	0	0	960	0
Quantity Level Limit	28	28	0	0	224
Step Therapy Met	1	1	0	0	30
Vacation Override	2	2	0	0	30
Overrides Total	**991**	**31**	**0**	**960**	

Denial Reason	
Benefit	179
Experimental/Investigational	145
Lack Required Infomation to Process Request	136
Medical Necessity	1,396
Other	7
Other PA Activity	
Duplicate Requests	39
Letters	5,104
No Process	313
Changes to existing PAs	0
PAs missing info	12

*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

6/1/2026 Through 6/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	0	1	0
Amphetamines	7	2	1	4	365
Analgesics - Anti-Inflammatory	72	51	2	19	328
Analgesics - Nonnarcotic	2	2	0	0	365
Analgesics - Opioid	94	39	28	27	235
Androgens - Anabolic	79	19	45	15	203
Anorectal and Related Products	5	0	0	5	0
Anthelmintics	4	2	0	2	243
Antianxiety Agents	3	1	0	2	122
Antiasthmatic and Bronchodilator Agents	147	68	40	39	325
Antibiotics	6	0	0	6	0
Anticoagulants	6	0	0	6	0
Anticonvulsants	21	8	6	7	339
Antidepressants	60	23	14	23	548
Antidiabetics	436	139	183	114	219
Antidotes and Specific Antagonists	1	0	0	1	0
Antiemetics	9	1	3	5	183
Antihistamines	1	0	0	1	0
Antihyperlipidemics	32	16	9	7	187
Anti-Infective Agents - Misc.	2	2	0	0	365
Antimalarials	1	0	0	1	0
Antimyasthenic/Cholinergic Agents	1	1	0	0	365
Antineoplastics and Adjunctive Therapies	56	36	1	19	243
Anti-Obesity Agents	278	73	99	106	119
Antiparkinson and Related Therapy Agents	3	1	0	2	365
Antipsychotics/Antimanic Agents	4	1	0	3	365
Antivirals	7	4	1	2	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	20	10	0	10	460
Beta Blockers	3	1	0	2	365
Calcium Channel Blockers	1	1	0	0	365
Cardiovascular Agents - Misc.	42	22	3	17	470
Chemicals	2	0	0	2	0
Contraceptives	29	5	18	6	79
Corticosteroids	9	2	1	6	88
Dermatologicals	236	141	40	55	249
Diagnostic Products	12	10	1	1	320
Digestive Aids	1	0	0	1	0
Diuretics	3	0	0	3	0
Endocrine and Metabolic Agents - Misc.	50	31	6	13	266
Estrogens	8	0	3	5	0
Gastrointestinal Agents - Misc.	118	45	41	32	158
Genitourinary Agents - Misc.	1	1	0	0	365
Gout Agents	11	2	1	8	320
Hematological Agents - Misc.	5	1	0	4	152

*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	19	9	0	10	239
Hypnotics/Sedatives/Sleep Disorder Agents	7	3	4	0	365
Laxatives	4	1	2	1	365
Medical Devices and Supplies	18	9	2	7	841
Migraine Products	167	110	44	13	186
Minerals and Electrolytes	4	0	0	4	0
Miscellaneous Therapeutic Classes	13	8	0	5	315
Mouth/Throat/Dental Agents	1	0	0	1	0
Multivitamins	2	2	0	0	319
Musculoskeletal Therapy Agents	29	13	4	12	342
Nasal Agents - Systemic and Topical	8	1	4	3	61
Neuromuscular Agents	23	12	3	8	220
Ophthalmic Agents	31	8	6	17	309
Otic Agents	5	0	1	4	0
Passive Immunizing and Treatment Agents	3	3	0	0	304
Psychotherapeutic and Neurological Agents - Misc.	39	23	4	12	251
Respiratory Agents - Misc.	9	6	0	3	304
Stimulants - Misc.	14	10	2	2	322
Thyroid Agents	1	1	0	0	365
Ulcer Drugs/Antispasmodics/Anticholinergics	18	6	5	7	235
Urinary Antispasmodics	15	3	7	5	588
Vaginal and Related Products	2	0	1	1	0
Vasopressors	2	0	0	2	0
Vitamins	80	8	1	71	47
Total	**2,403**	**997**	**636**	**770**	
Overrides					
Dosage Change	132	55	63	14	140
Ingredient Duplication	130	69	42	19	155
NDC vs Age	419	281	20	118	245
NDC vs Sex	6	4	0	2	243
Opioid MME Limit	5	5	0	0	329
Opioid Quantity	5	4	0	1	291
Other	214	71	77	67	116
Quantity vs Days Supply	253	171	32	50	252
STBS/STBSM	593	61	78	454	37
Step Therapy Exception	205	128	44	33	229
Third Brand Request	1	0	1	0	0
Overrides Total	**1,963**	**849**	**357**	**758**	
Total Regular PAs + Overrides	**4,366**	**1,846**	**993**	**1,528**	
Denial Reasons					
Alternatives Not Met					268
Medical Necessity					725

*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

6/1/2026 Through 6/30/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	200	103	77	20	1,062
Analgesics - Anti-Inflammatory	94	41	28	25	811
Analgesics - Nonnarcotic	8	0	7	1	0
Analgesics - Opioid	262	85	111	66	245
Androgens - Anabolic	61	2	44	15	1,095
Anorectal and Related Products	5	1	4	0	365
Anorexiants Non-Amphetamine	3	0	0	3	0
Anthelmintics	12	2	9	1	366
Antianxiety Agents	27	7	17	3	640
Antiasthmatic and Bronchodilator Agents	188	65	81	42	584
Antibiotics	28	11	7	10	384
Anticonvulsants	71	27	31	13	978
Antidepressants	153	54	79	20	841
Antidiabetics	544	277	158	109	889
Antiemetics	19	8	8	3	216
Antifungals	2	1	1	0	206
Antihistamines	15	4	6	5	1,095
Antihyperlipidemics	28	6	18	4	915
Antihypertensives	5	1	2	2	1,095
Anti-Infective Agents - Misc.	7	1	3	3	365
Antineoplastics and Adjunctive Therapies	47	33	9	5	511
Anti-Obesity Agents	191	46	65	80	541
Antipsychotics/Antimanic Agents	140	56	52	32	915
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	66	37	19	10	1,045
Beta Blockers	5	2	3	0	208
Calcium Channel Blockers	5	3	2	0	557
Cardiovascular Agents - Misc.	33	11	12	10	849
Chemicals	1	0	0	1	0
Contraceptives	29	11	8	10	387
Corticosteroids	9	2	2	5	143
Cough/Cold/Allergy	2	1	0	1	210
Dermatologicals	322	107	145	70	547
Diagnostic Products	23	15	6	2	755
Dietary Products/Dietary Management Products	2	1	0	1	365
Digestive Aids	1	0	0	1	0
Diuretics	2	1	1	0	1,095
Endocrine and Metabolic Agents - Misc.	36	9	21	6	1,003
Estrogens	12	5	5	2	201
Gastrointestinal Agents - Misc.	78	27	40	11	723
Genitourinary Agents - Misc.	6	0	2	4	0
Gout Agents	8	2	3	3	1,095
Hematological Agents - Misc.	4	3	1	0	798
Hematopoietic Agents	26	6	10	10	398
Histamine H3-Receptor Antagonist/Inverse Agonists	1	1	0	0	1,095

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	24	4	14	6	272
Laxatives	16	9	4	3	359
Medical Devices and Supplies	118	56	27	35	947
Migraine Products	178	71	94	13	850
Minerals and Electrolytes	3	0	1	2	0
Miscellaneous Therapeutic Classes	12	6	3	3	730
Multivitamins	6	4	2	0	498
Musculoskeletal Therapy Agents	31	8	15	8	449
Nasal Agents - Systemic and Topical	11	6	4	1	555
Neuromuscular Agents	28	11	5	12	365
Ophthalmic Agents	56	19	26	11	323
Other	31	5	4	22	602
Otic Agents	62	18	30	14	250
Passive Immunizing and Treatment Agents	14	3	7	4	1,111
Psychotherapeutic and Neurological Agents - Misc.	44	14	15	15	912
Respiratory Agents - Misc.	9	3	2	4	1,095
Stimulants - Misc.	74	38	25	11	996
Thyroid Agents	8	5	0	3	383
Ulcer Drugs/Antispasmodics/Anticholinergics	27	6	15	6	499
Urinary Antispasmodics	30	10	16	4	467
Vaginal and Related Products	3	2	1	0	642
Vasopressors	1	1	0	0	197
Vitamins	70	10	46	14	851
****Total**	**3,638**	**1,384**	**1,454**	**800**	

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

Denial Reasons	
Medical Necessity	1,454

*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 2026

CMA Prescriber Mailing Summary[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 diabetes mellitus (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. To be included in the CMA prescriber mailing cohort, each prescriber must have a minimum of SoonerCare members taking CMA medications, with the inclusion criteria adjusted to achieve a mailing cohort of approximately 250-300 providers:

- February 2024-November 2024: at least 7 members
- February 2025-November 2025: at least 9 members
- February 2026: at least 12 members

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. Since August 2024, the CMA mailings have included data only for those members in the SoonerCare fee-for-service (FFS) population. Members covered by other health plans are excluded from all calculations and from the patient lists included in each mailing.

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 cardiovascular (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 February 2026.

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.

To maximize reach and engagement, previous mailings prioritized provider inclusion based on the number of members receiving CMA medications. More recent refinements instead target cohorts with the greatest unmet clinical need by focusing on providers whose members demonstrate lower PDC. In the absence of direct clinical indicators such as hemoglobin A1c (HbA1c), blood pressure, or lipid levels, PDC serves as a practical, evidence-based proxy for clinical risk and helps direct resources toward populations where adherence-focused interventions may have the greatest impact.

Mailing Summaries

The following table outlines total letters mailed and total members included in each CMA mailing since February 2024 to the most recent mailing in February 2026. Mailings are currently paused as efforts focus on consolidating CMA with additional recurrent mailings to streamline prescriber communications, reduce alert fatigue, and enhance clinical representation.

CMA Mailing (2024-2026)

Date Letter Mailed	Total Letters Mailed to Prescribers	Total Members Included
February 2024	212	5,709
May 2024	206	5,451
August 2024*	238	6,459
November 2024	237	6,056
February 2025*	230	5,954
May 2025	232	5,649
August 2025	235	5,960
November 2025	224	5,743
February 2026*	257	4,263

*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 2024-26 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 PDC threshold for each star rating often becomes increasingly higher with each annual update in January. Hence the prescriber 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. The following charts outline the minimum PDC thresholds required to achieve each associated star ratings for CMA medication classes from 2019 to 2026.

RAS Antagonists: Minimum PDC (%) Threshold (2019-2026)*

Number of Stars	2019	2020	2021	2022	2023	2024	2025	2026
5	89	90	90	91	96	94	92	93
4	87	88	88	88	91	91	90	91
3	86	85	86	86	89	89	89	90
2	84	83	84	82	86	87	87	88
1	60	60	60	60	60	60	60	60
0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
*RAS: Renin-Angiotensin System; N/A: Not applicable								

Statins: Minimum PDC (%) Threshold (2019-2026)

Number of Stars	2019	2020	2021	2022	2023	2024	2025	2026
5	88	88	88	90	90	93	92	92
4	84	86	86	88	88	89	89	90
3	82	83	81	86	87	87	88	89
2	80	79	78	82	84	84	86	85
1	60	60	60	60	60	60	60	60
0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
N/A: Not applicable								

DM Medications: Minimum PDC (%) Threshold (2019-2026)

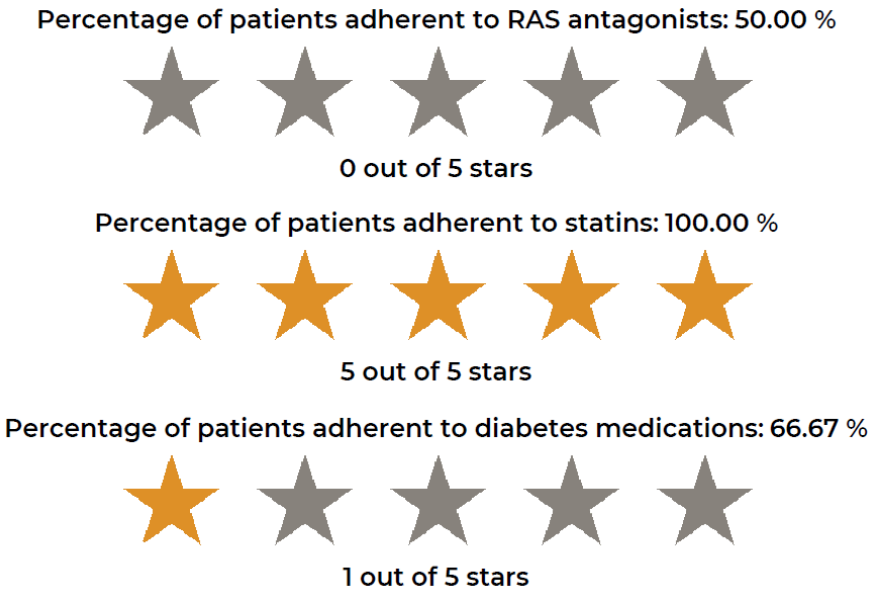
Number of Stars	2019	2020	2021	2022	2023	2024	2025	2026
5	88	88	87	90	90	93	93	92
4	86	85	85	88	88	89	89	89
3	84	83	82	86	86	87	87	87
2	82	79	79	84	84	84	85	85
1	60	60	60	60	60	60	60	60
0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
N/A: Not applicable								

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:** 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 cotransporter 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

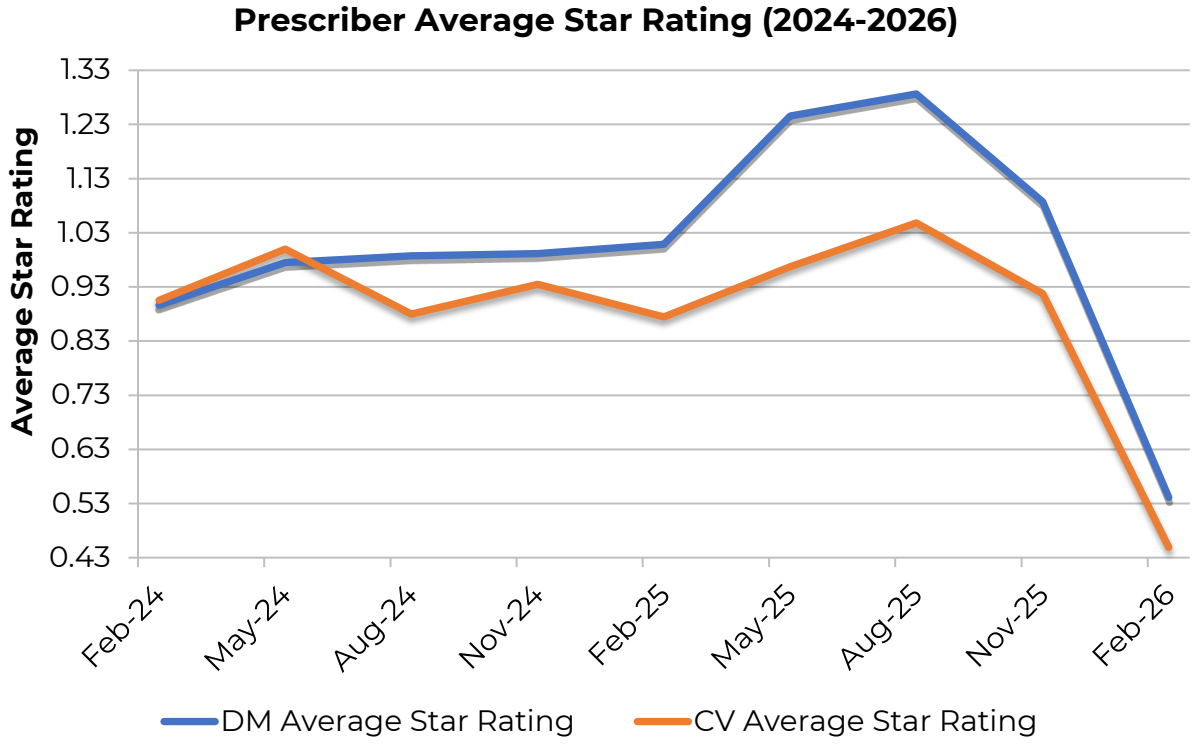
Report date: <Report Date>
Provider: <Provider Name>
NPI: <Prescriber NPI>
SoonerCare Provider ID: <Provider ID>



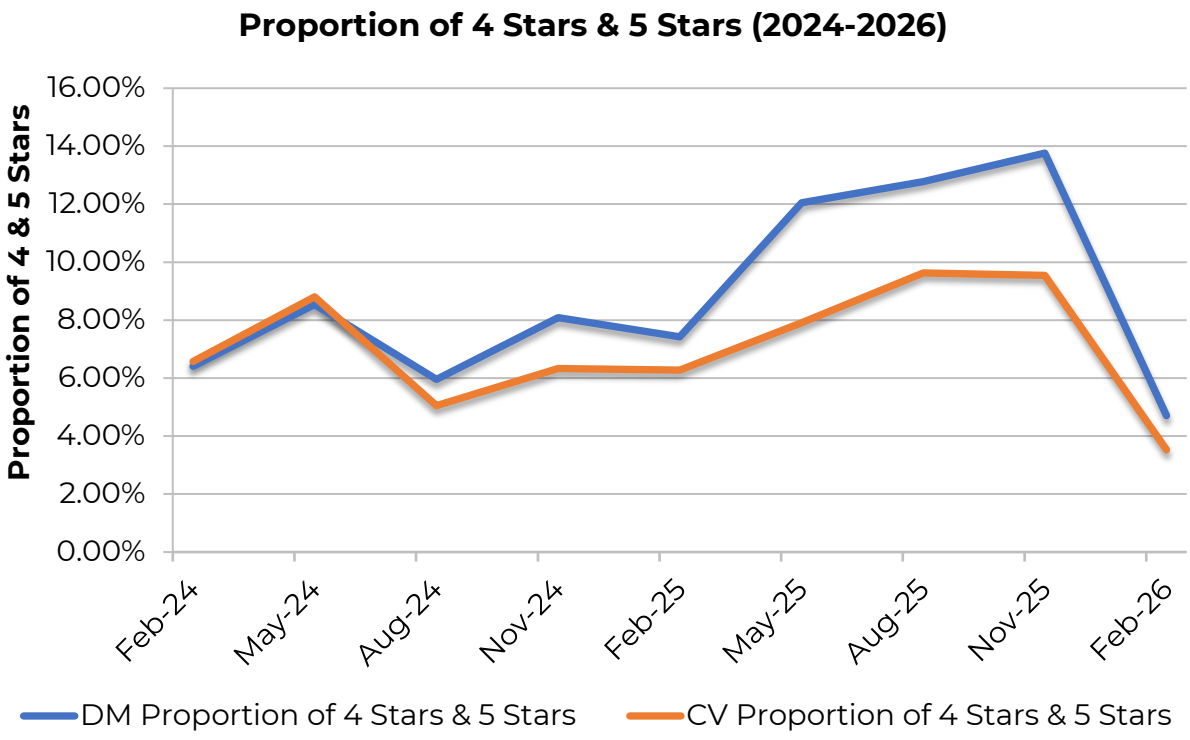
CMA Trends

The following line graph shows trends in the average star rating for prescribers included in the CMA mailing since February 2024. Please note, the vertical axis starts at 0.43 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

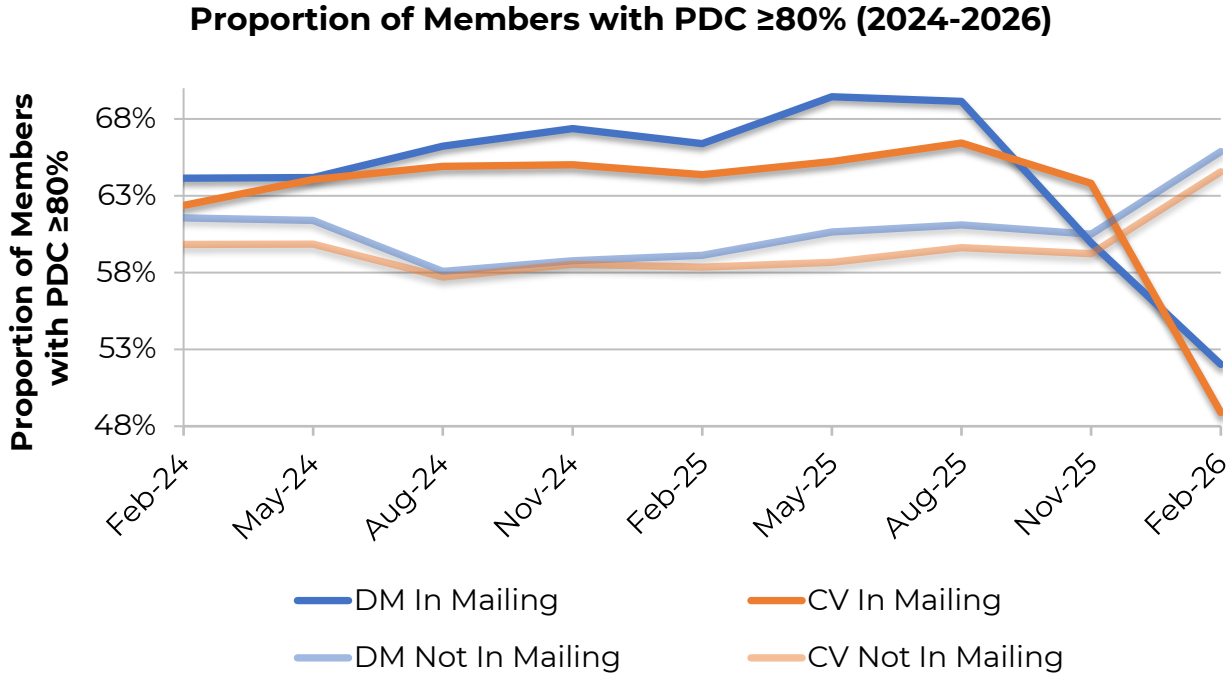
and CV modules. An overall mild improvement in the DM average star rating is seen during most of the analysis period. Since February 2024, the DM star ratings have usually been higher than the CV star ratings during the same time period. Historically, approximately 40-45% of the prescribers who received the CMA mailings in a given year continue receiving the CMA mailings when the list is updated. However, the 2026 update represents a significant change in that trend. Increasing the number of members required for 2026 cohort inclusion, updating the medications evaluated for adherence, and prioritizing members with lower PDC have the combined effect of dramatically changing the prescribers included. So, only 20% of the prescribers in the 2024 cohort continued to receive mailings in 2026. Even with the increased number of members per provider, the total number of members included in February 2026 is nearly 27% lower than the average of the previous 8 years.



The following line graph shows trends in the proportion of prescribers with 4- and 5-star ratings included in the CMA mailing since February 2024. 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, with the same variation seen in February 2026, and with the same contributing factors. Also as above, overall favorable increases were seen, but opportunities for further enhancements continue to exist.



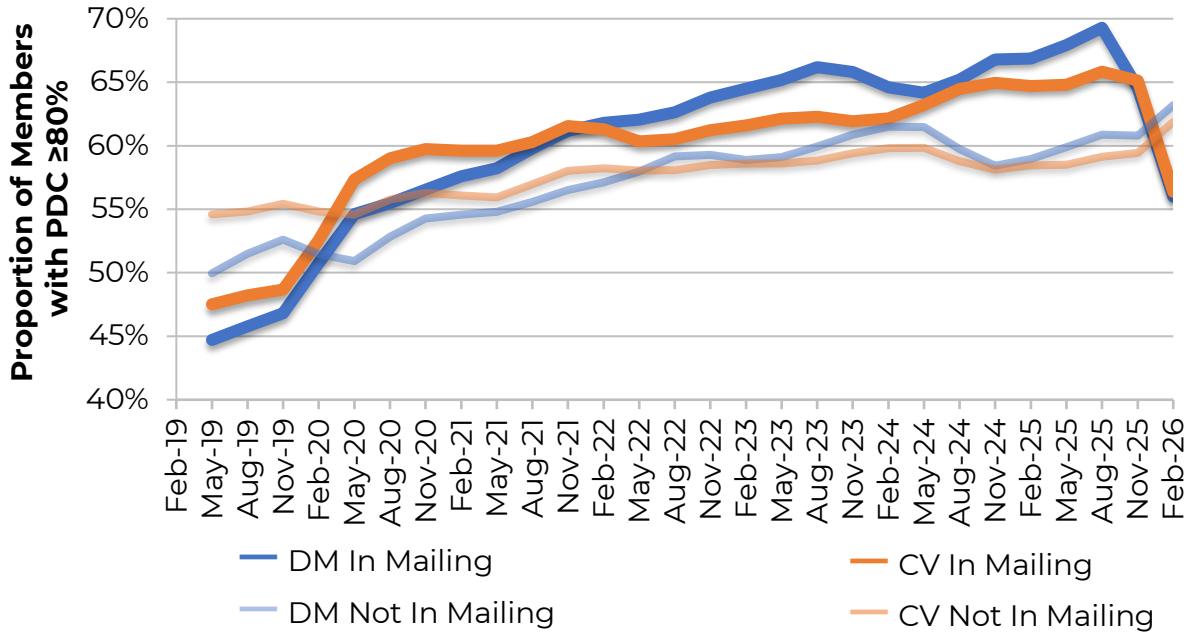
The following line graph shows trends in the proportion of members with a PDC ≥80% for those members with prescribers included in the mailing compared to those with prescribers not included in the mailing since February 2024. Please note, the vertical axis starts at 48% in order to reflect small changes.



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% (2019-2026)



Since February 2019, members included in the CV mailings improved their rates of CV medication adherence by 102% 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 71% 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 01/21/2026. Last accessed 06/16/2026.

Appendix D

Vote to Prior Authorize Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection) and Update the Approval Criteria for the Anti-Emetic Medications

Oklahoma Health Care Authority
July 2026

Market News and Updates[1,2,3]

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

- **April 2025:** The FDA approved Posfrea™ (palonosetron injection) through the 505(b)(2) approval pathway based primarily on the existing safety and efficacy data from another intravenous (IV) formulation of palonosetron in chemotherapy induced nausea and vomiting (CINV) and postoperative nausea and vomiting (PONV). Additionally, the supplemental new drug application (sNDA) provided data for the addition of the indication for pediatric patients 1 month of age to younger than 17 years of age for CINV.
- **December 2025:** The FDA approved Nereus™ (tradipitant) for the prevention of vomiting induced by motion in adults.

Nereus™ (Tradipitant) Product Summary[4,5,6,7]

Therapeutic Class: Substance P/neurokinin-1 (NK-1) receptor antagonist

Indication(s): For the prevention of vomiting induced by motion in adults

How Supplied: 85mg capsule

Dosing and Administration:

- The recommended dosage of Nereus™ is 85mg or 170mg as a single oral dose approximately 60 minutes before an event expected to cause vomiting induced by motion.
- The maximum dosage in a 24-hour period is a single dose of 85mg or 170mg.
- Nereus™ should be administered on an empty stomach, at least 1 hour prior to or 2 hours after a full meal.

Efficacy: The efficacy of Nereus™ for the prevention of vomiting induced by motion was evaluated in 2 randomized, double-blind, placebo-controlled trials called Motion Syros (Study 1) and Motion Serifos (Study 2).

- Key Inclusion Criteria:
  - 18 years of age or older
  - History of motion sickness

- Key Exclusion Criteria:
  - Nausea-inducing disorders other than motion sickness
- Intervention: Participants were randomized 1:1:1 to receive a single dose of Nereus™ 85mg, 170mg, or placebo approximately 60 minutes prior to a boat trip scheduled to last approximately 2 to 5 hours.
- Primary Outcome: The primary endpoint in both studies was the percentage of subjects with vomiting during the boat trip.
- Results:
  - Study 1: The percentage of subjects with vomiting during a boat trip was 20% in the Nereus™ 85mg group, 18% in the Nereus™ 170mg group, and 44% in the placebo group with a treatment difference of -25% in the Nereus™ 85mg group compared to placebo [95% confidence interval (CI): -36%, -14%] and -26% in the Nereus™ 170mg group compared to placebo (95% CI: -37%, -15%).
  - Study 2: The percentage of subjects with vomiting during a boat trip was 18% in the Nereus™ 85mg group, 10% in the Nereus™ 170mg group, and 38% in the placebo group with a treatment difference of -19% in the Nereus™ 85mg group compared to placebo (95% CI: -31%, -8%) and -27% in the Nereus™ 170mg group compared to placebo (95% CI: -38%, -16%).

Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment
Nereus® (tradipitant) 85mg capsule	**$255.00**	**$510.00¥**
scopolamine 1mg/3-day patch (generic)	$4.38	$4.38*
Dramamine® (dimenhydrinate) 50mg tablet	$0.38	$3.04
meclizine 25mg tablet (generic)	$0.08	$0.16β

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Please note: Dramamine® is an over-the-counter product; therefore, it is not covered by SoonerCare.
Unit = each capsule, patch, or tablet
¥Cost is based on the FDA approved maximum dose of 170mg per day.
*Cost is based on the FDA approved maximum dosing of 1 patch every 3 days.
αCost is based on the FDA approved maximum dose of 8 tablets per day.
βCost is based on the FDA approved maximum dosing of 50mg per day.

Cost Comparison: Palonosetron Products

Product	Cost Per mL	Cost Per Vial
Posfrea™ (palonosetron 0.25mg/5mL injection)	**$123.66**	**$618.30**
palonosetron 0.25mg/5mL injection (generic)	$8.03	$40.15

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

Recommendations

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

Nereus™ (Tradipitant) Approval Criteria:

1. An FDA approved indication for the prevention of vomiting induced by motion; and
2. Member must be 18 years of age or older; and
3. Member must have a history of vomiting induced by motion; and
4. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention of vomiting induced by motion (i.e., Dramamine®, meclizine, scopolamine) must be provided; and
5. Approval length will be based on the duration of need which must be documented on the request; and
6. Approval of the 170mg dose will require documentation of failure at the lower dose; and
7. A quantity limit of 16 capsules per 30 days will apply.

The College of Pharmacy recommends the prior authorization of Posfrea™ (palonosetron injection) with criteria similar to the criteria for palonosetron 0.25mg/5mL single-dose prefilled syringes (changes shown in red):

Palonosetron 0.25mg/5mL Single-Dose Prefilled Syringe and Posfrea™ (Palonosetron 0.25mg/5mL Injection) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic Aloxi® (palonosetron 0.25mg/5mL), which is available without a prior authorization, must be provided.

[1] U.S. Food and Drug Administration (FDA). Posfrea™ (Palonosetron Injection) Supplemental Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/203050Orig1s003ltr.pdf. Issued 04/16/2025. Last accessed 06/15/2026.
[2] Posfrea™ (Palonosetron Injection) Prescribing Information. Avyxa Pharma LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/203050s003lbl.pdf. Last revised 04/2025. Last accessed 06/15/2026.
[3] Vanda Pharmaceuticals, Inc. Vanda Pharmaceuticals Announces FDA Approval of Nereus™ (Tradipitant) for the Prevention of Vomiting Induced by Motion: A Historic Scientific Milestone in the Prevention of Motion Sickness. Available online at: https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-announces-fda-approval-of-nereus-tradipitant-for-the-prevention-of-vomiting-induced-by-motion-a-historic-scientific-milestone-in-the-prevention-of-motion-sickness-302650965.html. Issued 12/30/2025. Last accessed 06/15/2026.
[4] Nereus™ (Tradipitant) Prescribing Information. Vanda Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/220152Orig1s000lbl.pdf. Last revised 12/2025. Last accessed 06/15/2026.
[5] Motion Syros: A Study to Investigate the Efficacy of Tradipitant in Subjects Affected by Motion Sickness. *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT04327661. Last revised 12/11/2024. Last accessed 06/15/2026.
[6] Motion Serifos: A Study to Investigate the Efficacy of Tradipitant in Participants Affected by Motion Sickness. *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT05903924. Last revised 04/04/2025. Last accessed 06/15/2026.
[7] Dramamine® Original Dual-Action Motion Sickness Relief Tablets, 36 Count. CVS Pharmacy. Available online at: https://www.cvs.com/shop/dramamine-original-dual-action-motion-sickness-relief-tablets-36-ct-prodid-464430. Last accessed 06/15/2026.

Appendix E

Vote to Prior Authorize Bysanti™ (Milsaperidone) and Update the Approval Criteria for the Atypical Antipsychotic Medications

Oklahoma Health Care Authority
July 2026

Market News and Updates[1,2]

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

- **November 2025:** The FDA approved Caplyta® (lumateperone) for a new indication as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults. Caplyta® was previously approved for the treatment of schizophrenia or as monotherapy or adjunctive therapy for bipolar I and II depression in adults.
- **February 2026:** The FDA approved Bysanti™ (milsaperidone) for the treatment of schizophrenia and for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

Bysanti™ (Milsaperidone) Product Summary[3,4]

Therapeutic Class: Atypical antipsychotic

Indication(s):

- Treatment of schizophrenia in adults; and
- Acute treatment of manic or mixed episodes associated with bipolar I disorder

How Supplied: 1mg, 2mg, 4mg, 6mg, 8mg, 10mg, and 12mg oral tablets

Dosing and Administration:

- Bysanti™ should be titrated to reduce the risk of orthostatic hypotension.
- After titration the recommended maintenance dose of Bysanti™ is:
  - Schizophrenia: 6mg to 12mg twice daily
  - Bipolar mania: 12mg twice daily
- See the full *Prescribing Information* for titration schedules and recommended dosing based on CYP2D6 poor metabolizers and hepatic impairment.

Efficacy: The safety and efficacy of Bysanti™ were based primarily on the existing data from studies utilizing iloperidone tablets. Milsaperidone is an active metabolite that rapidly and non-enzymatically interconverts in vivo to

iloperidone and was determined to have comparable bioavailability to iloperidone tablets.

Cost Comparison:

Product	Cost Per Tablet	Cost Per Month*	Cost Per Year
Bysanti™ (milsaperidone) 12mg tablet	**$62.93**	**$3,775.80**	**$45,309.60**
Fanapt® (iloperidone) 12mg tablet	$60.02	$3,601.20	$43,214.40

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 month based on the maximum FDA recommend dosing of 12mg twice daily.

Cost Comparison: Atypical Antipsychotics for Adjunct Treatment of MDD

Product	Cost Per Unit	Cost Per Month*	Cost Per Year
Caplyta® (lumateperone) 42mg capsule	**$57.27**	**$1,718.10**	**$20,617.20**
Vraylar® (cariprazine) 3mg capsule	$50.88	$1,526.40	$18,316.80
Rexulti® (brexpiprazole) 3mg tablet	$49.58	$1,487.40	$17,848.80

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 tablet
*Cost per month based on the maximum FDA approved dosing for each product: 42mg once daily for Caplyta®, 3mg once daily for Vraylar®, and 3mg once daily for Rexulti®.

Recommendations

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

1. Creation of a new Special Prior Authorization (PA) Tier and criteria based on net costs; and
2. Updating the trial requirements for Tier-2, Tier-3, and the Special PA Tier based on DUR Board feedback and discussion; and
3. Prior authorization of Bysanti™ (milsaperidone) and placement into the Special PA Tier with additional approval criteria; and
4. Moving Latuda® (lurasidone) from Tier-2 to Tier-1 based on net costs; and
5. Moving Lybalvi® (olanzapine/samidorphan) from Tier-3 to the Special PA Tier based on net costs and updating the Lybalvi® approval criteria based on the recommended Tier changes and clinical practice; and
6. Moving Caplyta® (lumateperone), Cobenfy™ (xanomeline/trospium), Fazaclo® (clozapine orally disintegrating tablet), Opipza™ (aripiprazole oral film), quetiapine 150mg tablet, Secuado® (asenapine transdermal system), Symbyax® (olanzapine/fluoxetine), and Versacloz® (clozapine

oral suspension) from Tier-3 to the Special PA Tier based on net costs; and

7. Moving Risperdal Consta® (risperidone IM injection) and Rykindo® (risperidone IM injection) to the Special PA Tier, designating Risperdal Consta® as brand preferred, and updating the Long-Acting Injectable (LAI) Products Approval Criteria based on net costs; and
8. Updating the Atypical Antipsychotic Medications as Adjunctive Treatment of MDD Approval Criteria based on the FDA approval of Caplyta® for this indication and net costs.

Atypical Antipsychotic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
aripiprazole ODT, sol, & tab (Abilify®)¥	asenapine sublingual tab (Saphris®)	~~**aripiprazole oral film (Opipza™)⁺**~~	**aripiprazole oral film (Opipza™)⁺**
clozapine tab (Clozaril®)◊	iloperidone tab (Fanapt®)	~~**asenapine transdermal system (Secuado®)⁺**~~	**asenapine transdermal system (Secuado®)⁺**
lurasidone tab (Latuda®)	~~**lurasidone tab (Latuda®)**~~	brexpiprazole tab (Rexulti®)**~**	**clozapine ODT (Fazaclo®)⁺**
olanzapine IM inj, ODT, & tab (Zyprexa®)	paliperidone ER tab (Invega®)	cariprazine cap (Vraylar®)**~**	**clozapine oral susp (Versacloz®)⁺**
quetiapine tab (Seroquel®)		~~**clozapine ODT (Fazaclo®)⁺**~~	**lumateperone cap (Caplyta®)~**
quetiapine ER tab (Seroquel XR®)		~~**clozapine oral susp (Versacloz®)⁺**~~	**milsaperidone tab (Bysanti™)⁺**
risperidone ODT, sol, & tab (Risperdal®)		~~**lumateperone cap (Caplyta®)**~~	**olanzapine/fluoxetine cap (Symbyax®)⁺**
ziprasidone cap & IM inj (Geodon®)		~~**olanzapine/fluoxetine cap (Symbyax®)⁺~**~~	**olanzapine/samidorphan tab (Lybalvi®)ᵝ**
		~~**olanzapine/samidorphan tab (Lybalvi®)ᵝ**~~	**quetiapine 150mg tab⁺**
		~~**quetiapine 150mg tablets⁺**~~	
Unique Mechanisms of Action			
		~~**xanomeline/trospium (Cobenfy™)**~~	**xanomeline/trospium (Cobenfy™)**
Long-Acting Injectables (LAIs)^			
aripiprazole IM inj (Abilify Asimtufii®)^		~~**risperidone IM inj (Risperdal Consta®)^∞**~~	**risperidone IM inj (Risperdal Consta®)^∞**
aripiprazole IM inj (Abilify Maintena®)^		~~**risperidone IM inj (Rykindo®)^∞**~~	**risperidone IM inj (Rykindo®)^∞**
aripiprazole lauroxil IM inj (Aristada®)^			
aripiprazole lauroxil IM inj (Aristada Initio®)^			

Atypical Antipsychotic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
olanzapine pamoate IM inj (Zyprexa® Relprevv™)			
paliperidone palmitate IM inj (Erzofri®)^			
paliperidone palmitate IM inj (Invega Hafyera®)^			
paliperidone palmitate IM inj (Invega Sustenna®)^			
paliperidone palmitate IM inj (Invega Trinza®)^			
risperidone ER sub-Q inj (Perseris®)^			
risperidone sub-Q inj (Uzedy®)^			

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.

cap = capsule; ER = extended-release; IM = intramuscular; inj = injection; ODT = orally disintegrating tablet; sol = solution; sub-Q = subcutaneous; susp = suspension; tab = tablet

¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.

^Use of a long-acting injectable product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.

⁺Unique criteria applies ~~in addition to tier trial requirements.~~

ᵝUnique criteria applies to Lybalvi® (olanzapine/samidorphan).

ᵒᵒUnique criteria applies to ~~Tier-3~~ Special PA long-acting injectable (LAI) products.

~Unique criteria applies for a diagnosis of adjunctive treatment of major depressive disorder (MDD).

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. Trials of 2 Tier-1 medications ~~A Tier-1 trial at least 14 days in duration each, titrated to recommended dose,~~ that did not yield an adequate response or resulted in intolerable adverse effects; ~~and~~ or
2. Members currently stable on a Tier-2 medication may be approved for continuation of therapy.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

~~1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and~~

~~2. Trials of 2 oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or~~

3. ~~A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and~~
4. Trials of 3 Tier-1 and Tier-2 medications (at least 2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; or
5. Members currently stable on a Tier-3 medication may be approved for continuation of therapy.~~; and~~
6. ~~Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and~~
7. ~~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~~
8. ~~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~~
9. ~~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~~
10. ~~Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.~~

Atypical Antipsychotic Medications Special PA Approval Criteria:

1. ~~Trials of 1 Tier-1 medications, 1 Tier-2 medication, and 2 Tier-3 medication at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; or~~
2. ~~Member has had at least 5 trials of Tier-1, Tier-2, and Tier-3 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and~~
3. Trials of 4 Tier-1, Tier-2, and Tier-3 medications (at least 2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; or
4. Members currently stable on a Special PA medication may be approved for continuation of therapy.
5. Use of Bysanti™ (milsaperidone) will require a patient-specific, clinically significant reason why the member cannot use Fanapt® (iloperidone). Tier structure rules continue to apply.

6. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation.
7. 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.
8. 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.
9. 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.
10. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Approval Criteria for Atypical Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD):

1. Authorization of Caplyta® (lumateperone), ~~Symbyax® (olanzapine/fluoxetine),~~ Rexulti® (brexpiprazole), or Vraylar® (cariprazine) for a diagnosis of MDD requires current use of an antidepressant and previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting medication) and aripiprazole tablets that did not yield adequate response; and
2. For Caplyta®, a patient-specific, clinically significant reason why the member cannot use Rexulti® and Vraylar® must be provided; and
3. Members currently stable on the requested medication may be approved for continuation of therapy; and
4. Tier structure rules still apply.

Long-Acting Injectable (LAI) Products ~~Tier 3~~ Special PA Approval Criteria:

1. Use of LAI products will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the lower-tiered LAI products available for the medication being requested, which are available without a prior authorization; and
2. Risperdal Consta® [risperidone intramuscular (IM) injection] is brand preferred. Requests for generic risperidone IM injection will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
3. Requests for Rykindo® (risperidone IM injection) will require a patient-specific, clinically significant reason why the member cannot use brand name Risperdal Consta®; and

4. Members currently stable on the requested medication may be approved for continuation of therapy.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must meet 1 of the following:
    a. Member has a positive clinical response to olanzapine and experienced weight gain ≥7% from baseline body weight or other metabolic complications [e.g., increased waist circumference, increased metabolic parameters, worsening diabetes (i.e., increased A1c or glucose despite optimal adherent therapy for diabetes)] after starting olanzapine (baseline and current weight must be provided or documentation of metabolic complications); or
    b. Member has a trial of ~~one Tier 1 and one Tier 2~~ 2 lower-tiered medications with a lower weight gain or metabolic profile (e.g., aripiprazole, ziprasidone, lurasidone, brexpiprazole), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and
4. Member must not be taking opioids or undergoing acute opioid withdrawal; and
5. Initial approvals will be for 6 ~~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. Subsequent approvals will be for the duration of 1 year.

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[1] Vraylar® (Cariprazine) – Expanded Indication, New Strengths. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/clinical-updates/clinicalupdate_vraylar_2025-1222.pdf. Issued 12/18/2025. Last accessed 06/24/2026.

[2] Vanda Pharmaceuticals. Vanda Pharmaceuticals Announces FDA Approval of Bysanti™ (Milsaperidone) for the Treatment of Bipolar I Disorder and Schizophrenia - A New Chemical Entity Opening New Horizons in Psychiatric Innovation. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/vanda-pharmaceuticals-announces-fda-approval-of-bysanti-milsaperidone-for-the-treatment-of-bipolar-i-disorder-and-schizophrenia---a-new-chemical-entity-opening-new-horizons-in-psychiatric-innovation-302693941.html. Issued 02/20/2026. Last accessed 06/24/2026.

[3] Bysanti™ (Milsaperidone) Prescribing Information. Vanda Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220358Orig1s000lbl.pdf. Last revised 02/2026. Last accessed 06/24/2026.

[4] U.S. Food and Drug Administration (FDA). Bysanti™ (Milsaperidone) Multi-Disciplinary Review. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2026/220358Orig1s000MultidisciplineR.pdf. Issued 02/20/2026. Last accessed 06/24/2026.

Appendix F

Vote to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder), and Xofluza® (Baloxavir) and Update the Approval Criteria for the Antiviral Medications

Oklahoma Health Care Authority
July 2026

Market News and Updates[1]

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

- **May 2026:** The FDA approved Hepcludex® (bulevirtide-gmod) for the treatment of chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.

Hepcludex® (Bulevirtide-gmod) Product Summary[2,3]

Therapeutic Class: HDV attachment inhibitor

Indication(s): Treatment of chronic HDV infection in adults without cirrhosis or with compensated cirrhosis

- This indication is approved under accelerated approval based on a decrease in HDV ribonucleic acid (RNA) and alanine aminotransferase (ALT) normalization. An improvement in disease-related clinical outcomes has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied: 8.5mg as a lyophilized powder or cake in a single dose vial (SDV)

Dosing and Administration:

- The recommended dose is 8.5mg once daily administered by subcutaneous (sub-Q) injection into the upper thigh, lower abdomen, or back of the upper arm (if administered by a caregiver).
- Each Hepcludex® SDV should be reconstituted with 1mL of sterile water for injection and used immediately.
- The underlying hepatitis B virus (HBV) infection should be managed as clinically appropriate.
- Hepcludex® should be continued as long as it is associated with a response to treatment.
    - The optimal treatment duration is unknown.

- Hepcludex® has a *Boxed Warning* for the potential of severe acute exacerbations of hepatitis D and B after treatment discontinuation.

Efficacy: The safety and efficacy of Hepcludex® were evaluated in a Phase 3 multicenter, randomized, open-label, parallel arm trial.

- Key Inclusion Criteria:
  - Positive serum anti-HDV antibody or HDV RNA for at least 6 months before screening
  - Positive HDV RNA at screening
  - ALT level >1 times the upper limit of normal (ULN) but <10 times the ULN
  - Serum albumin >2.8g/dL
- Key Exclusion Criteria:
  - Child-Pugh hepatic insufficiency score >7
  - Current or previous (within the last 2 years) decompensated liver disease, including coagulopathy, hepatic encephalopathy, and esophageal varices hemorrhage
- Intervention(s): Participants were randomized and stratified by presence of compensated cirrhosis to immediate treatment with Hepcludex® 8.5mg sub-Q once daily for 144 weeks or to delayed treatment with an observational period of 48 weeks followed by Hepcludex® 8.5mg sub-Q once daily for 96 weeks. Both groups were followed for 96 weeks after treatment discontinuation.
  - Of note, the original trial protocol specified the Hepcludex® dose as 10mg; however, a dose recovery study indicated the delivered dose was 8.5mg.
- Primary Endpoint(s): Combined response, defined as undetectable HDV RNA or ≥2 $\log_{10}$ IU/mL decline from baseline and ALT normalization, at week 48
- Results:
  - At week 48, the combined response rate was 48% in the immediate treatment group (N=50) and 2% in the delayed treatment group (N=51), which was a treatment difference of 46% [96% confidence interval (CI): 31%, 61%; P<0.0001].
    - Additionally, the rate of undetectable HDV RNA was 20% in the immediate treatment group compared with 0% in the delayed treatment group.
  - At week 96, the combined response rate in the immediate treatment group was 56%.
  - At week 144, the combined response rate for the immediate treatment group was 54% compared to 56% of the delayed treatment group (96 weeks after beginning treatment in week 48).
  - At week 96 post-treatment, 24% of participants in both groups had combined response, and 22% of participants in the immediate

treatment group compared to 20% in the delayed treatment group had undetectable HDV RNA.

Cost: The Wholesale Acquisition Cost (WAC) of Hepcludex® is $776.20 per SDV, resulting in an estimated cost of $23,286 per 30 days and$279,432 per year based on the FDA-approved dosing of 8.5mg (1 reconstituted SDV) sub-Q once daily.

Cost Comparison: Oral Influenza Antiviral Medications

Product	Cost Per Unit	Cost Per Treatment
Xofluza® (baloxavir) 40mg tablet	**$161.95**	**$161.95***
Xofluza® (baloxavir) 80mg tablet	**$161.97**	**$161.97***
Relenza® (zanamivir inh pow) 5mg diskhaler	**$2.95**	**$59.00†**
oseltamivir (generic Tamiflu®) 75mg capsule	$0.83	$8.30α

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = capsule, diskhaler, tablet
inh = inhalation; pow = powder
*Cost per treatment is based on the FDA recommended dosing of 40mg as a single dose for a patient weighing <80kg or 80mg as a single dose for a patient weighing ≥80kg.
†Cost per treatment is based on the FDA recommended dosing of 10mg (2 inhalations) twice daily for 5 days.
αCost per treatment is based on the FDA recommended dosing of 75mg twice daily for 5 days.

Recommendations

The College of Pharmacy recommends the prior authorization of Hepcludex® (bulevirtide-gmod) with the following criteria (shown in red):

Hepcludex® (Bulevirtide-gmod) Approval Criteria:

1. An FDA approved diagnosis of chronic hepatitis D virus (HDV) infection; and
2. Diagnosis must be confirmed by all of the following test results conducted within the last 6 months (results must be submitted with the request):
   a. Detectable serum HDV RNA level; and
   b. Elevated alanine aminotransferase (ALT) levels between 1 and 10 times the upper limit of normal; and
3. Member must not have decompensated cirrhosis or hepatocellular carcinoma (HCC); and
4. Member must be 18 years of age or older; and
5. Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist; and
6. Prescriber must verify that underlying hepatitis B virus (HBV) infection will be managed as clinically appropriate; and

7. Prescriber must verify that the member or caregiver will be trained on the proper storage, reconstitution, and administration of Hepcludex®; and
8. A quantity limit of 30 vials per 30 days will apply; and
9. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by all of the following (results of testing must be submitted with the request):
    a. Undetectable HDV RNA or a ≥2 $\log_{10}$ IU/mL reduction in HDV RNA from baseline; and
    b. A reduction or normalization of ALT; and
    c. Member has not developed decompensated cirrhosis or HCC; and
    d. Member has not undergone a liver transplant.

The College of Pharmacy also recommends the prior authorization of Relenza® (zanamivir inhalation powder) and Xofluza® (baloxavir) based on net costs with the following criteria (shown in red):

Relenza® (Zanamivir Inhalation Powder) and Xofluza® (Baloxavir) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of acute uncomplicated influenza in members who have been symptomatic for no more than 48 hours; or
    b. Post-exposure prophylaxis of influenza following contact with an individual who has influenza; and
2. Member must be 5 years of age or older; and
3. A patient specific, clinically significant reason (beyond convenience) why the member cannot use oseltamivir (generic Tamiflu®), which is available without prior authorization, must be provided.

The College of Pharmacy also recommends updating the Epclusa® (sofosbuvir/velpatasvir), Sovaldi® (sofosbuvir tablets and oral pellets), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), and Zepatier® (elbasvir/grazoprevir) prior authorization criteria based on clinical practice, for consistency with criteria for other Hepatitis C medications, and for clarity (changes shown in red):

Epclusa® (Sofosbuvir/Velpatasvir) Tablets and Pellets Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) ~~genotype 1, genotype 2, genotype 3, genotype 4, genotype 5, or genotype 6;~~ and
3. All of the following test results must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 12 months; and
    b. Liver fibrosis assessment (METAVIR equivalent); and

c. HCV genotype (only for members with cirrhosis or being evaluated for retreatment); and
    i. Baseline resistance-associated substitution (RAS) testing for members with genotype 3 and compensated cirrhosis; and
4. For members with decompensated cirrhosis or being evaluated for retreatment, Epclusa® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
~~5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and~~
~~6. Member has chronic HCV infection defined by:~~
    ~~a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or~~
    ~~b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~
        ~~i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or~~
        ~~ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and~~
~~7. The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:~~
    ~~a. Genotype 1, 2, 3, 4, 5, 6:~~
        ~~i. Treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A):~~
            ~~1. Epclusa® for 12 weeks~~
        ~~ii. Treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Pugh B and C):~~
            ~~1. Epclusa® + weight-based ribavirin for 12 weeks~~
    ~~b. New regimens will apply as approved by the FDA~~
8. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
9. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
10. Member must sign and submit the Hepatitis C Intent to Treat contract; and
11. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and

~~12. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR 12); and~~
13. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
14. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
15. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin users); and
~~16. Member must not be taking the following medications: H2-receptor antagonists at doses >40mg famotidine equivalent, amiodarone, omeprazole or other proton pump inhibitors, topotecan, rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, efavirenz, tenofovir disoproxil fumarate, tipranavir/ritonavir, St. John's wort, and rosuvastatin doses >10mg; and~~
~~17. If member is using antacids, they must agree to separate antacid and Epclusa® administration by 4 hours; and~~
18. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Epclusa® and agree to address interactions with concomitant medications according to package labeling; and
~~19. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and~~
20. Member must not have a limited life expectancy (<12 months) that cannot be remediated by treating ~~hepatitis C virus (~~HCV~~)~~, liver transplantation, or another direct therapy; and
21. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
        ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and

iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and

22. ~~Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.~~
23. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Sovaldi® (Sofosbuvir Tablets and Oral Pellets) Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) ~~genotype 1, genotype 2, genotype 3, or genotype 4~~; and
3. Sovaldi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
4. Sovaldi must be used as a component of a combination regimen; and
5. ~~Member must be eligible for ribavirin (RBV) or daclatasvir therapy. Approvals will not be granted for regimens without RBV or daclatasvir; and~~
6. Member must not have decompensated cirrhosis; and
7. All of the following must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 6 months; and
    b. Liver fibrosis assessment (METAVIR equivalent); and
    c. HCV genotype testing; and
    d. For treatment experienced members, prior HCV treatment regimens; and
8. ~~Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and~~
9. ~~Member has chronic HCV infection defined by:~~
    a. ~~If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or~~
    b. ~~If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~

i. Positive (i.e., reactive) HCV antibody test and has a recent (within the last 3 months) detectable and quantifiable HCV RNA (>15 IU/mL); or
ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

10. The following regimens and requirements based on genotype, prior treatment experience, and cirrhosis status will apply:
a. Genotype 1:
i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:
1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
a. Genotype 2:
i. Treatment-naïve, non-cirrhotic:
1. Sovaldi® with weight-based ribavirin for 12 weeks
ii. Treatment-naïve, cirrhotic:
1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks
iii. Treatment-experienced, non-cirrhotic or cirrhotic:
1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks
2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
b. Genotype 3:
i. Treatment-naïve, non-cirrhotic
1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)
ii. Treatment-naïve, cirrhotic
1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)
iii. Treatment-experienced, non-cirrhotic
1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)
iv. Treatment-experienced, cirrhotic
1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks
2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)
c. Genotype 4:
i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:

~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~

~~d. New regimens will apply as approved by the FDA.~~

11. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
12. Members who are older than 6 years of age and request the oral pellet formulation of Sovaldi® must provide a patient-specific, clinically significant reason for use of the oral pellet formulation in place of the tablet formulation; and
13. Member must sign and submit the Hepatitis C Intent to Treat contract; and
14. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
15. ~~The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR 12); and~~
16. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
17. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
18. Female members must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin members); and
19. ~~Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, phenytoin, oxcarbazepine, tipranavir/ritonavir, didanosine or St. John's wort; and~~
20. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Sovaldi® and agree to address interactions with concomitant medications according to package labeling; and
21. ~~All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and~~
22. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
23. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and

a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
    i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
    ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
    iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and

~~24. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.~~

25. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) genotype 1, genotype 2, genotype 3, genotype 4, genotype 5, or genotype 6; and
3. Vosevi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and

~~4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on the prior authorization request; and~~

5. Member must not have decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C); and
6. All of the following must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 6 months; and
    b. Liver fibrosis assessment (METAVIR equivalent); and
    c. HCV genotype testing; and
    d. For treatment experienced members, prior HCV treatment regimens; and

~~7. Member has chronic HCV infection defined by:~~

a. ~~If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or~~
b. ~~If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~
i. ~~Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or~~
ii. ~~Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and~~

~~8. The following regimens and requirements based on treatment history will apply:~~
~~a. Adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A):~~
~~i. Genotype 1, 2, 3, 4, 5, or 6 patients who were previously treated with an HCV regimen containing an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir): Vosevi® for 12 weeks; or~~
~~ii. Genotype 1a or 3 patients who were previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor: Vosevi® for 12 weeks; or~~
~~b. New regimens will apply as approved by the FDA; and~~

7. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
8. Member must sign and submit the Hepatitis C Intent to Treat contract; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and

~~10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and~~

11. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
14. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on

therapy (and for 6 months after therapy completion for ribavirin users); and

~~15. Member must not be taking the following medications: H2-receptor antagonists at doses greater than 40mg famotidine twice daily equivalent, omeprazole doses greater than 20mg daily or other proton pump inhibitors, amiodarone, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, St. John's wort, pravastatin doses greater than 40mg daily, rosuvastatin, pitavastatin, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan; and~~

~~16. If member is using antacids they must agree to separate antacid and Vosevi® administration by four hours; and~~

17. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Vosevi® and agree to address interactions with concomitant medications according to package labeling; and

~~18. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and~~

19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
        ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
        iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and

~~20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and~~

21. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Zepatier® (Elbasvir/Grazoprevir) Approval Criteria:

1. Member must be 12 years of age or older or weigh at least 30kg; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) genotype-1 or genotype-4; and
3. Member must not have decompensated cirrhosis or moderate-to-severe hepatic impairment (Child-Pugh B and C); and
4. Zepatier® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last 3 months; and

~~5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and~~

6. All of the following must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 6 months; and
    b. Liver fibrosis assessment (METAVIR equivalent); and
    c. HCV genotype testing; and
        i. Baseline resistance-associated substitution (RAS) testing for members with genotype 1a; and
    d. Prior DAA regimens; and

~~7. If the member has genotype 1a, testing results for the presence of virus with NS5A resistance-associated polymorphisms must be indicated on the prior authorization request; and~~

~~8. Member has chronic HCV infection defined by:~~
    ~~a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or~~
    ~~b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~
        ~~i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or~~
        ~~ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and~~

~~9. The following regimens and requirements based on genotype, polymorphisms, and prior treatment status will apply (all regimens apply to patients with and without cirrhosis, HIV/HCV co-infected patients, and patients with or without renal impairment):~~
    ~~a. Genotype 1a, treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms:~~
        ~~i. Zepatier® for 12 weeks~~

~~b. Genotype 1a, treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms:~~
~~i. Zepatier® with weight-based ribavirin for 16 weeks~~
~~c. Genotype 1b, treatment-naïve or peginterferon alfa + ribavirin experienced:~~
~~i. Zepatier® for 12 weeks~~
~~d. Genotype 1a or 1b, peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, teleprevir) experienced:~~
~~i. Zepatier® with weight-based ribavirin for 12 weeks~~
~~e. Genotype 4, treatment-naïve:~~
~~i. Zepatier® for 12 weeks~~
~~f. Genotype 4, treatment-experienced:~~
~~i. Zepatier® with weight-based ribavirin for 16 weeks~~
~~g. New regimens will apply as approved by the FDA~~

10. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
11. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
12. Member must sign and submit the Hepatitis C Intent to Treat contract; and
13. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
14. ~~The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR 12); and~~
15. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
16. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
17. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin users); and
18. ~~The prescriber must verify that the member's ALT levels will be monitored prior to treatment initiation, at treatment week eight, and as clinically indicated thereafter (patients receiving 16 weeks of therapy should receive additional ALT levels at treatment week 12); and~~
19. ~~Member must not be taking the following medications: phenytoin, carbamazepine, rifampin, St. John's wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin,~~

~~ketoconazole, bosentan, etravirine, elvitegravir/cobicstat/emtricitabine/tenofovir, or modafinil; and~~

20. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Zepatier® and agree to address interactions with concomitant medications according to package labeling; and
21. ~~All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and~~
22. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
23. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
        ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
        iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and
24. ~~Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.~~
25. Approvals for treatment regimen initiation for 12 or 16 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Lastly, the College of Pharmacy recommends updating the Harvoni® (ledipasvir/sofosbuvir tablets and oral pellets) prior authorization criteria based on net costs and clinical practice and for clarity (changes shown in red):

Harvoni® (Ledipasvir/Sofosbuvir Tablets and Oral Pellets) Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) genotype-1, genotype-4, genotype-5, or genotype-6; and
3. ~~Request for the generic formulation will require a patient-specific, clinically significant reason the member cannot use the brand formulation; and~~
4. Harvoni must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
5. ~~Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and~~
6. All of the following test results must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 6 months; and
    b. Liver fibrosis assessment (METAVIR equivalent); and
    c. HCV genotype testing; and
7. ~~Member has chronic HCV infection defined by:~~
    a. ~~If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required (must be within last 3 months if requesting 8-week regimen); or~~
    b. ~~If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~
        i. ~~Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or~~
        ii. ~~Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and~~
8. ~~The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:~~
    a. ~~Genotype 1:~~
        i. ~~Treatment-naïve without cirrhosis who have a pre-treatment HCV-RNA less than 6 million IU/mL:~~
            1. ~~Harvoni for 8 weeks~~
        ii. ~~Treatment-naïve with or without compensated cirrhosis:~~
            1. ~~Treatment-naïve patients who are cirrhotic or have a pre-treatment HCV-RNA greater than 6 million IU/mL~~
            2. ~~Harvoni for 12 weeks~~
        iii. ~~Treatment-experienced without cirrhosis:~~

~~1. Harvoni for 12 weeks~~

~~iv. Treatment-experienced with compensated cirrhosis:~~

~~1. Harvoni with weight-based ribavirin for 12 weeks~~

~~2. Harvoni for 24 weeks~~

~~v. Treatment-naïve or treatment-experienced with decompensated cirrhosis:~~

~~1. Harvoni with weight-based ribavirin for 12 weeks~~

~~b. Genotype-1 or Genotype-4:~~

~~i. Treatment-naïve or treatment-experienced liver transplant recipients with or without compensated cirrhosis:~~

~~1. Harvoni with weight-based ribavirin for 12 weeks~~

~~c. Genotype-4, Genotype-5, or Genotype-6:~~

~~ii. Treatment-naïve or treatment-experienced with or without compensated cirrhosis:~~

~~1. Harvoni for 12 weeks~~

~~d. New regimens will apply as approved by the FDA~~

9. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
10. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
11. Members who are older than 6 years of age and request the oral pellet formulation of Harvoni must provide a patient-specific, clinically significant reason for use of the oral pellet formulation in place of the tablet formulation; and
11. Member must sign and submit the Hepatitis C Intent to Treat contract; and
12. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and

~~13. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and~~

14. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
15. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
16. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for those on ribavirin); and

~~17. Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin,~~

~~phenobarbital, oxcarbazepine, tipranavir/ritonavir, simeprevir, rosuvastatin, St. John's wort, or elvitegravir/cobicistat/emtricitabine in combination with tenofovir disoproxil fumarate; and~~

18. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Harvoni® and agree to address interactions with concomitant medications according to package labeling; and
19. ~~All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and~~
20. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating ~~hepatitis C virus (~~HCV~~)~~, liver transplantation, or another directed therapy; and
21. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
        ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
        iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and
22. ~~Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.~~
23. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Chronic Hepatitis Delta Virus (HDV) Infection. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-chronic-hepatitis-delta-virus-hdv-infection. Issued 05/22/2026. Last accessed 06/24/2026.

[2] Hepcludex® Prescribing Information. Gilead Sciences. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761468Orig1s000lbl.pdf. Last revised 05/22/2026. Last accessed 06/24/2026.

[3] Study to Assess Efficacy and Safety of Bulevirtide in Participants with Chronic Hepatitis Delta (CHD). *ClinicalTrials.gov.* Available online at: https://clinicaltrials.gov/study/NCT03852719?tab=study. Last revised 08/22/2025. Last accessed 06/24/2026.

Appendix G

Vote to Prior Authorize Loargys® (Pegzilarginase-nbln) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications

Oklahoma Health Care Authority
July 2026

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

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

- **February 2026:** The FDA approved Loargys® (pegzilarginase-nbln) for the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with arginase 1 deficiency (ARG1-D), in conjunction with dietary protein restriction.

News:

- An internal literature review was conducted on the established evidence for the long term use of Carbaglu® (carglumic acid), which indicated its safety and efficacy for long term management in propionic acidemia (PA) or methylmalonic acidemia (MMA) beyond 7 days.

Loargys® (Pegzilarginase-nbln) Product Summary[8,9,10,11,12]

Therapeutic Class: Human arginase 1 enzyme

Indication(s): Treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with ARG1-D, in conjunction with dietary protein restriction

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

How Supplied: 2mg/0.4mL single-dose vial (SDV)

Dosing and Administration:

- Prior to initiating Loargys®, baseline plasma arginine (pArg) concentrations should be obtained.
- Pre-medication with antihistamines should be considered.
- The recommended starting dose is 0.1mg/kg administered once weekly via IV infusion.

- After 4 weeks of treatment, pre-dose pArg should be assessed for potential dosage adjustments. The maximum recommended dosage is 0.2mg/kg once weekly.
    - For pArg <50 micromolar, the weekly dosage should be reduced by 0.05mg/kg.
    - For pArg >150 micromolar, the weekly dosage should be increased by 0.05mg/kg.
- After 8 weeks of IV administration, a subcutaneous (sub-Q) route may be considered at the same dosage.
- Initial doses of Loargys® should be given in a health care setting equipped to manage hypersensitivity reactions. If maintenance doses are well tolerated, home administration under healthcare supervision can be considered.

Efficacy: The efficacy and safety of Loargys® were evaluated in the Phase 3, randomized, multicenter, double-blind, 24-week placebo-controlled PEACE trial.

- Key Inclusion Criteria:
    - Diagnosis of ARG1-D defined as elevated pArg, pathogenic variants in the *ARG1* gene, and/or diminished erythrocyte ARG1 activity
    - 2 years of age or older
    - Average pArg >250 micromolar
    - Impairment on any secondary functional mobility assessment
    - Currently receiving stabilized dosing or standards of care treatment with protein restriction
- Interventions:
    - Patients were randomized 2:1 to Loargys® or placebo at a starting dose of 0.1mg/kg weekly.
    - Weekly dosage was adjusted to achieve pArg within 50-150 micromolar/L measured at the end of the dosing interval (168 hours post-dose).
    - The PEACE trial utilized validated cerebral palsy assessments for clinical mobility response [Gross Motor Function Measure involving walking, running, and jumping (GMFM-E) and 2-minute walk test (2MWT)].
- Endpoints:
    - The primary endpoint was a change from baseline pArg at week 24.
    - The secondary endpoint was clinical improvement assessed through functional mobility scores (GMFM-E and 2MWT).
- Results:
    - The primary endpoint in the PEACE trial was met with a statistically significant decrease in pArg levels in the Loargys® group (baseline pArg of 365 micromolar to 92 micromolar at week 24) compared to

placebo [baseline pArg of 472 micromolar to 449 micromolar at week 24; 95% confidence interval (CI): -72% (-89%, -55%); P<0.0001].
- Additionally, 90% of patients on Loargys® had pArg levels <200 micromolar at the end of the 24-week study while none of the placebo-treated patients met this target.

Cost: The Wholesale Acquisition Cost (WAC) of Loargys® is $11,469.31 for (1) 2mg/0.4mL SDV. For a member weighing 80kg, this would result in a cost of $367,017.92 every 4 weeks of treatment and an estimated cost of $4,771,232.96 per year based on the FDA maximum dose of 0.2mg/kg every week.

Recommendations

The College of Pharmacy recommends the prior authorization of Loargys® (pegzilarginase-nbln) with the following criteria (shown in red):

Loargys® (Pegzilarginase-nbln) Approval Criteria:

1. An FDA approved diagnosis of arginase 1 deficiency (ARG1-D); and
    a. Diagnosis of ARG1-D must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
        i. Persistently elevated plasma arginine levels; or
        ii. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *ARG1* gene; or
        iii. Diminished erythrocyte ARG1 activity; and
2. Member must be 2 years of age or older; and
3. Loargys® must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of ARG1-D; and
4. Loargys® must be administered under the direct supervision of a health care provider; and
5. Active management with a protein restricted diet; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
7. The maximum approvable dose of Loargys® is 0.2mg/kg once weekly; and
8. Initial approvals will be for 6 months. Subsequent approvals for the duration of 1 year will be approved if the prescriber documents the member is responding to treatment (i.e., reduction or normalization in plasma arginine levels); and
9. A quantity limit of 12mL per 28 days will apply. For members who require doses exceeding this quantity limit, a quantity limit override may be approved with the submission of supporting clinical documentation.

Additionally, the College of Pharmacy recommends updating the approval criteria for Carbaglu® (carglumic acid) based on clinical practice (changes shown in red):

Carbaglu® (Carglumic Acid) Approval Criteria:

1. An indication of the treatment of acute or chronic hyperammonemia due to 1 of the following:
    a. N-acetylglutamate synthase (NAGS) deficiency; or
    b. Propionic acidemia (PA) or methylmalonic acidemia (MMA); and
2. ~~An FDA approved indication of 1 of the following:~~
    ~~a. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; or~~
    ~~b. Maintenance therapy for the treatment of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; or~~
    ~~c. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA); and~~
3. Carbaglu® must be prescribed by a geneticist or in consultation with a geneticist; and
4. Carbaglu® is brand preferred; use of generic carglumic acid will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. For a diagnosis of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency:
    a. Documentation of active management with a low protein diet; and
    b. Initial approvals will be for the duration of 1 year. After that time, reauthorization will require the prescriber to verify the member is responding to therapy; or
6. ~~For a diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA):~~
    ~~a. Documentation the member's plasma ammonia level is ≥50micromol/L; and~~
    ~~b. Prescriber must confirm Carbaglu® is being used concurrently with other ammonia-lowering therapies [e.g., intravenous (IV) glucose, insulin, L-carnitine, protein restriction, dialysis]; and~~
    ~~c. Number of days Carbaglu® was received while hospitalized must be provided; and~~
    ~~d. Approvals will be for no longer than 7 days total (including treatment days while hospitalized) as there is currently no evidence to support the use of Carbaglu® for acute hyperammonemia due to~~

~~propionic acidemia (PA) or methylmalonic acidemia (MMA) beyond 7 days.~~

7. For a diagnosis of hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA):
    a. Prescriber must confirm Carbaglu® is being used concurrently with standard of care treatment (e.g., L-carnitine, metronidazole, protein-restricted diet); and
    b. Initial approvals will be for the duration of 6 months. Subsequent approvals, for the durations of 1 year, may be granted if the prescriber attests that the member is tolerating and responding well to therapy.

Lastly, the College of Pharmacy recommends updating the approval criteria for Olpruva® (sodium phenylbutyrate pellets for oral suspension) and Pheburane® (sodium phenylbutyrate oral pellets) based on clinical practice and recommends updating the approval criteria for Ravicti® (glycerol phenylbutyrate) based on clinical practice and net cost (changes shown in red):

Olpruva® (Sodium Phenylbutyrate Pellets for Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. Olpruva® must be prescribed by, or in consultation with, a geneticist; and
4. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
6. A maximum daily dose of 20g of sodium phenylbutyrate will apply.

Pheburane® (Sodium Phenylbutyrate Oral Pellets) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. Pheburane® must be prescribed by, or in consultation with, a geneticist; and
4. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
5. A maximum daily dose of 20g sodium phenylbutyrate will apply; and

6. A quantity limit of 1,218g of pellets (equivalent to 588g of sodium phenylbutyrate) per 29 days will apply.

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Active management with a protein restricted diet; and
3. ~~A patient-specific, clinically significant reason why member cannot use Buphenyl (sodium phenylbutyrate) must be provided; and~~
4. ~~A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and~~
5. Ravicti® must be prescribed by, or in consultation with, a geneticist; and
6. Ravicti® is brand preferred; use of generic glycerol phenylbutyrate will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
7. A maximum daily dose of 17.5mL (19g) of glycerol phenylbutyrate will apply; and
8. A quantity limit of 525mL per 30 days will apply.

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Appendix H

Vote to Prior Authorize Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Cafergot® (Ergotamine/ Caffeine Tablet), Desmoda™ (Desmopressin Oral Solution), Dicyclomine 40mg Tablet, Griseofulvin Ultramicrosize 165mg Tablet, Hydroxyzine Oral Solution Unit Dose Cups (UDCs), Khindivi™ (Hydrocortisone Oral Solution), Migergot® (Ergotamine/Caffeine Suppository), Ontralfy™ (Tizanidine Oral Solution), PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet, Quiofic™ (Folic Acid Oral Solution), Relgaabi™ (Gabapentin 200mg Capsule), and Vykoura™ (Leucovorin Injection) and Update the Approval Criteria for the Various Special Formulations

Oklahoma Health Care Authority
July 2026

Introduction

Multiple formulations of medications are made for ease of administration, to increase bioavailability, or as new technologies are created, to provide a more efficient treatment response. Some of the new formulations incur greater costs for production, resulting in greater costs for the payer and consumer. A clinical review of each product and its comparative cost to other formulations is provided in the following report for reference.

Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate) Product Summary and Recommendations[1,2]

Therapeutic Class: Contraceptives

Indication(s): For use by females of reproductive potential to prevent pregnancy

How Supplied:

- 21 orange tablets each containing 0.15mg desogestrel and 0.03mg ethinyl estradiol

- 7 blue tablets each containing ferrous bisglycinate 36.5mg

Dosing and Administration:
- Take 1 tablet by mouth at the same time daily

Other Formulation(s) Available:
- Branded generics Apri®, Cyred EQ®, Enskyce™, Isibloom®, Juleber™, Kalliga™, Reclipsen™ (Desogestrel/Ethinyl Estradiol 0.15mg/0.03mg Tablets):
  - These branded generics are supplied as 21 active tablets each containing 0.15mg desogestrel and 0.03mg ethinyl estradiol and 7 tablets containing inert ingredients.

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per Year*
Averi™ (desogestrel/ethinyl estradiol/ferrous bisglycinate 0.15mg/0.03mg/36.5mg tablets)	**$7.11**	**$2,588.04**
Apri® (desogestrel/ethinyl estradiol 0.15mg/0.03mg tablets)	$0.13	$47.32

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per year based on the U.S. Food and Drug Administration (FDA) approved dose of 1 tablet daily.

The College of Pharmacy recommends the prior authorization of Averi™ (desogestrel/ethinyl estradiol/ferrous sulfate) with criteria similar to Femlyv™ [norethindrone acetate/ethinyl estradiol orally disintegrating tablet (ODT)], Nextstellis® (drospirenone/estetrol tablet) and Slynd® (drospirenone tablet) with the following criteria (shown in red):

Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Femlyv™ [Norethindrone Acetate and Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Nextstellis® (Drospirenone/Estetrol Tablet), and Slynd® (Drospirenone Tablet) Approval Criteria:
1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without prior authorization must be provided.

Cafergot® (Ergotamine/Caffeine Tablet) and Migergot® (Ergotamine/ Caffeine Suppository) Product Summary and Recommendations[3,4,5]

Therapeutic Class: Ergot alkaloids/stimulant

Indication(s): Therapy to abort or prevent vascular headache in adults (e.g., migraine, migraine variants or so-called “histaminic cephalalgia”)

How Supplied:
- Cafergot®: Tablet containing 1mg of ergotamine and 100mg of caffeine

- Migergot®: Suppository containing 2mg of ergotamine and 100mg of caffeine

Dosing and Administration:

- For the best results, dosage should start at the first sign of an attack.
- Cafergot®: Take 2 tablets at the start of attack, and 1 additional tablet may be taken every half hour if needed for full relief with a maximum of 6 tablets per attack and 10 tablets per week.
- Migergot®: Insert 1 suppository rectally at the start of the attack, and if needed, 1 additional suppository may be used after 1 hour with a maximum of 5 suppositories per week (10mg of ergotamine).

Other Formulation(s) Available:

- Ergomar® (Ergotamine) 2mg Sublingual (SL) Tablet:
  - Ergomar® has the same indication as Cafergot® and Migergot®; however, it is available without caffeine and should be administered SL.
  - The FDA maximum dose per week is 10mg of ergotamine, which is the same as Cafergot® and Migergot®.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days*
Migergot® (ergotamine/caffeine 2mg/100mg suppository)	**$225.74**	**$4,514.80**
Cafergot® (ergotamine/caffeine 1mg/100mg tablet)	**$36.03**	**$1,441.20**
Ergomar® (ergotamine 2mg SL tablet)	$42.09	$841.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 28 days is based on the FDA maximum dose of ergotamine which is 10mg per week.
Unit = tablet or suppository
SL = sublingual

The College of Pharmacy recommends the prior authorization of Cafergot® (ergotamine/caffeine tablets) and Migergot® (ergotamine/caffeine suppository) with placement into the Special Prior Authorization (PA) Tier of the Anti-Migraine Product Based Prior Authorization (PBPA) category with the following additional criteria (changes shown in red):

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Cafergot® (ergotamine/caffeine tablets), Ergomar® (ergotamine sublingual tablets), and Migergot® (ergotamine/caffeine suppository) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
   a. Member must not have any of the contraindications for use of Cafergot®, Ergomar®, and Migergot® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become

pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and

b. The following ~~A~~ quantity limits ~~of 20 tablets per 28 days~~ will apply~~.~~:
    i. Cafergot®: 40 tablets per 28 days; or
    ii. Ergomar®: 20 tablets per 28 days; or
    iii. Migergot®: 20 suppositories per 28 days.

2. Use of Brekiya® [dihydroergotamine (DHE) autoinjector] or D.H.E. 45® (DHE injection) will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray) and lower-tiered triptan medications.
3. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]⁺:
    a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
    b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
    c. A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.

    *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.
    ⁺Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.
4. Use of Reyvow® (lasmiditan) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor
5. Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use Treximet® (sumatriptan/naproxen) and a different combination of a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID) (i.e., rizatriptan with ibuprofen).
6. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.

7. Use of Imitrex® STATdose System (sumatriptan injection), Tosymra® (sumatriptan nasal spray), or Zembrace® SymTouch® (sumatriptan injection) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
8. Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.

Desmoda™ (Desmopressin Oral Solution) Product Summary and Recommendations[6,7,8,9,10]

Therapeutic Class: Vasopressin analog

Indication(s):
- Management of arginine vasopressin deficiency (AVP-D), also known as central diabetes insipidus, as antidiuretic replacement therapy for adults and pediatric patients
  - Limitations of Use: Desmoda™ is not indicated for the treatment of AVP-resistance (AVP-R), also known as nephrogenic diabetes insipidus.

How Supplied: 0.05mg/1mL oral solution in a 145mL bottle

Dosing and Administration:
- The recommended starting dose for adults and pediatric patients is 0.05mg (50mcg) twice daily.
- The daily dose of Desmoda™ should be titrated as needed to obtain an adequate antidiuretic response.
- Desmoda™ should be taken on an empty stomach, at least 1 hour before or 2 hours after food.

Other Formulation(s) Available:
- Desmopressin 10mcg/0.1mL Nasal Spray:
  - Desmopressin nasal spray has the same indication as Desmoda™; however, the dosing is different. The intranasal desmopressin formulation is approximately 10 to 40-fold more potent than the oral formulation.
  - The recommended starting dose in adults is 10mcg once daily into 1 nostril up to 40mcg once daily (or 40mcg divided into 2 or 3 daily doses).
- Desmopressin 0.1mg and 0.2mg Tablets:
  - Desmopressin tablets are indicated for AVP-D and primary nocturnal enuresis.

- Dosing for the tablets is similar to Desmoda™ with a starting daily dose of 0.05mg (half of the 0.1mg tablet) twice daily. The optimal dose ranges from 0.1mg to 0.8mg daily and is administered in divided doses.
- Tablets should be swallowed whole, but they can be crushed for those who cannot swallow tablets.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Desmoda™ (desmopressin 0.05mg/mL oral sol)	**$122.50**	**$58,800.00***	**$705,600.00**
desmopressin 10mcg/0.1mL nasal spray (generic)	$8.72	$104.64⁺	$1,255.68
desmopressin 0.2mg tablet (generic)	$0.35	$42.00*	$504.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
sol = solution; unit= tablet or mL
*Cost per 30 days is based on the FDA approved maximum dose of 0.8mg daily.
⁺Cost per 30 days is based on the FDA approved maximum dose of 40mcg/day.

The College of Pharmacy recommends the prior authorization of Desmoda™ (desmopressin oral solution) with the following criteria (shown in red):

Desmoda™ (Desmopressin Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of arginine vasopressin deficiency (AVP-D), also known as central diabetes insipidus; and
2. A patient specific, clinically significant reason why the member cannot use desmopressin nasal spray and desmopressin oral tablets, even when tablets are crushed, which are both available without a prior authorization, must be provided.

Dicyclomine 40mg Tablet Product Summary and Recommendations[11,12]

Therapeutic Class: Anticholinergic

Indication(s): Treatment of patients with functional bowel/irritable bowel syndrome

How Supplied: 40mg tablet

Dosing and Administration:

- The recommended initial dose is 20mg 4 times per day.
- After 1 week of treatment with the initial dose, the dose may be increased to 40mg 4 times per day unless side effects limit dosage escalation.
- If efficacy is not achieved within 2 weeks or side effects require doses below 80mg per day, the drug should be discontinued.

- Documented safety data are not available for doses above 80mg daily for periods longer than 2 weeks.

Other Formulation(s) Available:
- Dicyclomine 20mg tablet
- Dicyclomine 10mg capsule

Formulation Cost Comparison:

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
dicyclomine 40mg tablet (generic)	**$16.40**	**$1,968.00**	**$23,616.00**
dicyclomine 20mg tablet (generic)	$0.06	$14.40	$172.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the FDA approved maximum dose of 40mg 4 times daily.

The College of Pharmacy recommends the prior authorization of dicyclomine 40mg tablet with the following criteria (shown in red):

Dicyclomine 40mg Tablet Approval Criteria:
1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason why the member cannot use the 20mg tablet, which is available without a prior authorization, to achieve the dose must be provided.

Griseofulvin Ultramicrosize 165mg Tablet Product Summary and Recommendations[13,14,15,16]

Therapeutic Class: Antifungal

Indication(s): Treatment of ringworm infections of the skin, hair, and nails, namely: tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis, tinea unguium (onychomycosis) when caused by 1 or more genera of fungi

How Supplied: 165mg ultramicrosize tablet

Dosing and Administration:
- Accurate diagnosis of the infecting organism is essential and should be identified.
- Medication should be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination.
- Treatment period lengths depend on the type of the infection but can range from 4 weeks up to 6 months.
- Adults: 330mg (as a single dose or in divided amounts) for tinea corporis, tinea cruris, and tinea capitis. For infections that are more

difficult to eradicate, such as tinea pedis and tinea unguium, a divided daily dose of 660mg is recommended.

- Children (>2 years): Approximately 3.3mg per pound of body weight per day is an effective dose for most children. On this basis, the following dosing schedule is suggested:
  - 30-50lbs: 82.5mg (one-half tablet) to 165mg daily
  - >50lbs: 165mg to 330mg daily

Other Formulation(s) Available:

- Griseofulvin Ultramicrosize 125mg and 250mg Tablets:
  - The ultramicrosize 125mg tablet and 250mg tablet have the same indications and similar dosing to the ultramicrosize 165mg tablet.
  - Adults: 375mg (as a single dose or in divided doses) for tinea corporis, tinea cruris, and tinea capitis. For infections that are more difficult to eradicate, such as tinea pedis and tinea unguium, a divided daily dose of 750mg is recommended.
  - Children (>2 years): Approximately 7.3mg per kg of body weight per day. On this basis, the following dosing schedule is suggested:
    - 16-27kg: 125mg to 187.5mg daily
    - >27kg: 187.5mg to 375mg daily
- Griseofulvin 500mg Microsize Tablet and Griseofulvin 125mg/5mL Suspension:
  - The microsize tablet and suspension have the same indications as the ultramicrosize tablets; however, the recommended dosing is different.
  - Adults: 500mg daily (125mg 4 times daily, 250mg 2 times daily, or 500mg/day). Patients with less severe or extensive infections may require less, whereas those with widespread lesions may require a starting dose of 0.75-1g/day. This may be reduced gradually to 500mg or less after a response has been noted. In all cases, the dose should be individualized.
  - Children (>2 years): A dose of 10mg/kg daily is usually adequate. Dose should be individualized, as with adults. Clinical relapses will occur if the medication is not continued until the infecting organism is eradicated.
    - 30-50lbs: 125mg to 250mg daily
    - >50lbs: 250mg to 500mg daily, in divided doses

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Day	Cost Per Treatment*
griseofulvin ultramicrosize 165mg tab (generic)	**$30.79**	**$123.16**	**$22,168.80**
griseofulvin microsize 500mg tab (generic)	$5.78	$11.56	$2,080.80
griseofulvin ultramicrosize 250mg tab (generic)	$3.41	$10.23	$1,841.40

griseofulvin 125mg/5mL sus (generic)	$0.25	$10.00	$1,800.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet; tab = tablet; sus = suspension
*Cost per treatment is based on a 6-month treatment course for tinea pedis with the FDA approved maximum dosing of 660mg daily for the ultramicrosize 165mg tablet, 1,000mg daily for the microsize tablet and suspension, and 750mg daily for the ultramicrosize 250mg tablet.

The College of Pharmacy recommends the prior authorization of griseofulvin ultramicrosize 165mg tablet with the following criteria (shown in red):

Griseofulvin Ultramicrosize 165mg Tablet Approval Criteria:

1. An FDA approved indication for the treatment of ringworm infections of the skin, hair, and nails; and
2. The infection must be caused by 1 or more of the genera of fungi listed in the package labeling; and
3. A patient specific, clinically significant reason why the member cannot use other formulations of griseofulvin available without a prior authorization (i.e., griseofulvin microsize 500mg tablet, griseofulvin 125mg/5mL suspension, and griseofulvin ultramicrosize 125mg and 250mg tablets) must be provided.

Hydroxyzine Oral Solution Unit Dose Cups (UDCs) Product Summary and Recommendations[17,18]

Therapeutic Class: Antihistamine

Indication(s):

- Symptomatic relief of anxiety and tension
- Management of pruritus due to allergic conditions
- Sedative when used as premedication following general anesthesia

How Supplied:

- UDC containing 5mL of hydroxyzine 10mg/5mL
- UDC containing 25mL of hydroxyzine 50mg/25mL

Dosing and Administration:

- Anxiety: 50mg to 100mg orally 4 times daily
- Pruritus: 25mg orally 3 to 4 times daily
- Sedation: 50mg to 100mg orally 1 time used with premedication following general anesthesia

Other Formulation(s) Available:

- Hydroxyzine 10mg/5mL oral solution stock bottle

Formulation Cost Comparison:

Product	Cost Per mL	Cost Per 30 Days*	Cost Per Year
hydroxyzine 50mg/25mL UDC (generic)	**$4.06**	**$12,180.00**	**$146,160.00**
hydroxyzine 10mg/5mL UDC (generic)	**$0.58**	**$1,740.00**	**$20,880.00**
hydroxyzine 10mg/5mL oral solution (generic)	$0.11	$330.00	$3,960.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
UDC = unit dose cup
*Cost per 30 days is based on the FDA approved dose for anxiety of 50mg orally 4 times daily.

The College of Pharmacy also recommends the prior authorization of hydroxyzine oral solution UDCs with the following criteria (shown in red):

Hydroxyzine 10mg/5mL and 50mg/25mL Oral Solution Unit-Dose Cups (UDCs) Approval Criteria:

1. A patient-specific, clinically significant reason why the member requires the UDCs in place of the bulk solution, which is available without a prior authorization, must be provided.

Khindivi™ (Hydrocortisone Oral Solution) Product Summary and Recommendations[19,20,21,22]

Therapeutic Class: Corticosteroid

Indication(s): Replacement therapy in pediatric patients 5 years of age and older with adrenocortical insufficiency

How Supplied: 1mg/mL berry flavored oral solution

Dosing and Administration:

- The dose of Khindivi™ should be individualized using the lowest possible dosage.
- When stress dosing is needed, a different hydrocortisone-containing drug product should be used.
- The recommended starting dose is 8 to 10mg/m^2 daily. Higher doses may be needed based on the patient's age and symptoms of the disease. Use of lower starting doses may be sufficient in patients with residual but decreased endogenous cortisol production.
- The dose should be rounded to the nearest 0.5mg or 1mg.
- The total daily dose should be divided into 3 doses and administered 3 times daily. Older patients may have their daily dose divided by 2 and administered twice daily.
- Khindivi™ should be administered using the oral syringe provided by the pharmacy. Khindivi™ may be administered through a gastric tube.

Flush gastric tube with 20mL of water to ensure the entire dose is delivered.

- When switching from other oral hydrocortisone formulations, the same total daily hydrocortisone dosage should be used. If symptoms of adrenal insufficiency occur, increase total daily dosage.

Other Formulation(s) Available:

- Alkindi Sprinkle® (Hydrocortisone Oral Granules):
  - Alkindi Sprinkle® and Khindivi™ have the same indication and recommended dosing.
  - Alkindi Sprinkle® is supplied as oral granules contained within capsules available as 0.5mg, 1mg, 2mg, and 5mg strengths.
  - The capsules should not be swallowed, nor the granules chewed or crushed. The capsule should be opened and its contents placed directly into the patient's mouth or sprinkled onto soft food (such as yogurt or fruit puree) and given immediately. The granules should not be added to liquid as this can cause a dose reduction and result in a bitter taste.
  - Alkindi Sprinkle® should not be used in nasogastric or gastric tubes as they may cause tube blockage.
- Hydrocortisone Tablet:
  - Hydrocortisone tablets have various indications including endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic disorders, neoplastic diseases, and others.
  - The initial dosage of hydrocortisone tablets varies from 20mg to 240mg per day depending on the specific disease entity being treated. In situations of less severity, lower doses will generally suffice while in selected patients, higher initial doses may be required.
  - Hydrocortisone tablets are scored and available in 3 strengths: 5mg, 10mg, and 20mg.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Khindivi™ (hydrocortisone 1mg/mL solution)	**$26.54**	**$4,777.20**	**$57,326.40**
Alkindi Sprinkle® (hydrocortisone 2mg granule)	$42.47	$3,822.30	$45,867.60
hydrocortisone 5mg tablet (generic)	$0.14	$6.30	$75.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = granule-filled capsule, mL, or tablet
*Cost per 30 days is based on the FDA recommended starting dose of 8mg/m^2 (divided into 3 doses/day and rounded to the nearest 0.5mg or 1mg dose) for hydrocortisone for a pediatric patient with a body surface area of 0.8m^2. This would result in a dose of 2mg 3 times daily (using one-half tablet to achieve a 2.5mg dose for the hydrocortisone tablets).

The College of Pharmacy recommends the prior authorization of Khindivi™ (hydrocortisone oral solution) with criteria similar to Alkindi Sprinkle® (hydrocortisone oral granule) (changes shown in red):

Alkindi Sprinkle® (Hydrocortisone Oral Granule) and Khindivi™ (Hydrocortisone Oral Solution) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed or split, which are available without prior authorization, must be provided (e.g., clinically indicated dose cannot be achieved with available tablet formulation); and
3. For Khindivi™, a patient-specific, clinically significant reason why the member cannot use Alkindi Sprinkle® must be provided.

Ontralfy™ (Tizanidine Oral Solution) Product Summary and Recommendations[23,24,25]

Therapeutic Class: Muscle relaxant

Indication(s): Treatment of spasticity in adults

How Supplied: 2mg/5mL strawberry flavored oral solution in a 473mL bottle

Dosing and Administration:

- The recommended starting dose is 2mg (5mL) orally every 6-8 hours, as needed, to a maximum of 3 doses in 24 hours.
- The dose should gradually be increased every 1-4 days by 2-4mg (5-10mL) at each dose based on clinical response and tolerability.
- The maximum total daily dose is 36mg (90mL). Single doses greater than 16mg (40mL) have not been studied.

Other Formulation(s) Available:

- Tizanidine 2mg, 4mg tablets
- Tizanidine 2mg, 4mg, 6mg, 8mg capsules

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Ontralfy™ (tizanidine 2mg/5mL solution)	**$1.59**	**$4,293.00**	**$51,516.00**
tizanidine 6mg capsule (generic)	$0.13	$23.40	$280.80
tizanidine 4mg tablet (generic)	$0.03	$8.10	$97.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on usage up to the maximum daily dose of 36mg per day for each product.
Unit = capsule, mL, or tablet

The College of Pharmacy also recommends the prior authorization of Ontralfy™ (tizanidine oral solution) with placement into the Special PA Tier of the Muscle Relaxant PBPA category with the following additional criteria (changes shown in red).

Ontralfy™ (Tizanidine Oral Solution) Approval Criteria:

1. An FDA approved indication for the treatment of spasticity; and
2. A patient-specific, clinically significant reason why the member cannot use Tier-1 tizanidine tablets, even when tablets are crushed or split, which are available without prior authorization, must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use generic tizanidine 2mg, 4mg, or 6mg capsules to achieve the requested dose, even when the capsules are opened and sprinkled on applesauce, must be provided.

PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet Summary and Recommendations[26,27,28,29,30,31,32,33,34]

Therapeutic Class: Electrolyte

Indication(s): Treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient

How Supplied:

- PoKonza™ 10mEq/15mL solution is available in an orange flavored solution in a 237mL bottle.
- PoKonza™ 15mEq packet is available in an orange flavored powder in single-dose pouches.
- Potassium chloride 40mEq packet is available in an orange flavored powder in single-dose pouches.

Dosing and Administration:

- Treatment of Hypokalemia:
  - Adults: Initial doses range from 40-100mEq/day in 2-5 divided doses; doses should be limited to 40mEq per dose and total daily doses should not exceed 200mEq.
  - Pediatric Patients (Birth to 16 Years of Age): 2-4mEq/kg/day in divided doses; doses should not exceed 1mEq/kg as a single dose or 40mEq whichever is lower and total daily doses should not exceed 100mEq.
- Maintenance or Prophylaxis of Hypokalemia:
  - Adults: 20mEq per day
  - Pediatric Patients (Birth to 16 Years of Age): 1mEq/kg/day; doses should not exceed 3mEq/kg/day.

- The contents of 1 packet of PoKonza™, 1 packet of potassium 40mEq, or 1 dose of PoKonza™ oral solution should be diluted in at least 4oz of cold water and taken with meals or immediately after eating.

Other Formulation(s) Available:

- Potassium Chloride ER Tablet, Potassium Chloride ER Dispersible Tablet, Potassium Chloride ER Sprinkle Capsule, Potassium Chloride Oral Solution, and Potassium Chloride Packet for Oral Solution:
  - All formulations have the same indications and recommended dose; however, the administration is different.
  - Potassium chloride ER tablet is a film coated tablet and must be swallowed whole. It is available in 8mEq, 10mEq, and 20mEq strengths.
  - For those who have difficulties swallowing, potassium chloride ER dispersible tablet, potassium chloride ER sprinkle capsules, potassium chloride oral solution, and potassium chloride packet for oral solution are available.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days
PoKonza™ (potassium chloride 10mEq/15mL solution)	**$10.08**	**$4,536.00⁺**
potassium chloride 40mEq packet (generic)	**$86.07**	**$2,582.10***
PoKonza™ (potassium chloride 15mEq packet)	**$43.04**	**$1,291.20***
PoKonza™ (potassium chloride 10mEq packet)	$28.42	$852.60*
potassium chloride 40mEq/15mL oral solution (generic)	$0.05	$22.50⁺
potassium chloride 20mEq packet (generic)	$0.63	$18.90*
potassium chloride 20mEq ER tablet (generic)	$0.16	$4.80*
potassium chloride 10mEq ER sprinkle capsule (generic)	$0.13	$3.90*
potassium chloride 20mEq dispersible tablet (generic)	$0.12	$3.60*

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit= capsule, mL, packet, or tablet; ER = extended-release
⁺Cost per 30 days is based on 15mL daily.
*Cost per 30 days is based on 1 capsule, packet, or tablet daily.

The College of Pharmacy also recommends the prior authorization of PoKonza™ 10mEq/15mL solution, PoKonza™ 15mEq packet, and potassium chloride 40mEq packet with criteria similar to the other potassium chloride products (changes shown in red):

Klor-Con® (Potassium Chloride 20mEq Packet), ~~and~~ PoKonza™ (Potassium Chloride ~~10mEq~~ Oral Solution and Packet), and Potassium Chloride 40mEq Packet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all the following must be provided:
    a. Potassium chloride tablet; and
    b. Potassium chloride extended-release (ER) dispersible tablet; and
    c. Potassium chloride ER sprinkle capsule; and
    d. Potassium chloride oral solution.

Quiofic™ (Folic Acid Oral Solution) Product Summary and Recommendations[35,36,37]

Therapeutic Class: Folate analog

Indication(s): Treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients

How Supplied: 0.2mg/mL mixed berry flavored oral solution in a 75mL bottle

Dosing and Administration:

- The recommended starting dose of Quiofic™ in pediatric and adult patients is up to 1mg orally daily.
- Quiofic™ may be taken with or without food.
- The recommended maintenance dosing, after clinical symptoms have subsided and the blood picture has become normal, use a daily maintenance dosing as follows:
    - Birth to 23 months: 0.1mg orally daily
    - 2 years to less than 4 years: up to 0.3mg orally daily
    - ≥4 years and adults: 0.4mg orally daily
    - Pregnant and lactating women: 0.8mg daily; but never less than 0.1mg orally per day
- Higher maintenance doses may be needed in the presence of alcoholism, hemolytic anemia, anticonvulsant therapy, or chronic infection.
- Patients should be frequently monitored for relapses and doses adjusted accordingly.

Other Formulation(s) Available:

- Folic Acid 1mg Tablets:
    - Folic acid tablets and solution have the same indication and recommended dosing.
    - There are other strengths of folic acid available over the counter including the 400mcg and 800mcg strengths, which are not covered by SoonerCare.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per 30 days*	Cost Per Year
Quiofic™ (folic acid 0.2mg/mL oral solution)	**$20.78**	**$3,117.00**	**$37,404.00**
folic acid 1mg tablet (generic)	$0.02	$0.60	$7.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or tablet
*Cost per 30 days is based on the FDA maximum approved dose of 1mg daily.

The College of Pharmacy recommends the prior authorization of Quiofic™ (folic acid solution) with the following criteria (shown in red):

Quiofic™ (Folic Acid Oral Solution) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the tablet formulation, even when the tablets are crushed, which is available without prior authorization, must be provided; and
2. A quantity limit of 150mL per 30 days will apply.

Relgaabi™ (Gabapentin 200mg Capsule) Product Summary and Recommendations[38,39,40]

Therapeutic Class: Anticonvulsant

Indication(s):

- Management of postherpetic neuralgia in adults
- Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years of age or older

How Supplied: 200mg, 300mg, and 400mg capsules

Dosing and Administration:

- Postherpetic Neuralgia: In adults, Relgaabi™ may be initiated on day 1 as a single 300mg dose, on day 2 as 600mg/day (300mg 2 times a day), and on day 3 as 900mg/day (300 mg 3 times a day). The dose can subsequently be titrated up as needed for pain relief to a dose of 1,800mg/day (600mg 3 times a day).
- Partial Onset Seizures:
  - Patients ≥12 years of age: The starting dose is 300mg 3 times daily, and the maintenance dose is 300mg to 600mg 3 times daily with a maximum dose up to 2,400mg/day.
  - Pediatric patients 3 to 11 years old: The starting dose range is 10mg/kg/day to 15mg/kg/day, given in 3 divided doses, and the recommended maintenance dose reached by upward titration over a period of approximately 3 days. The recommended

maintenance dose is based on age and weight, see package labeling for more information.

Other Formulation(s) Available:

- Gabapentin 100mg, 300mg, 400mg capsules
- Gabapentin 600mg and 800mg tablets

Formulation Cost Comparison:

Product	Cost Per Capsule	Cost Per 30 Days*	Cost Per Year
Relgaabi™ (gabapentin 200mg capsule)	**$15.30**	**$1,377.00**	**$16,524.00**
gabapentin 100mg capsule (generic)	$0.02	$3.60	$43.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on a dose of 200mg 3 times daily

The College of Pharmacy recommends the prior authorization Relgaabi™ (gabapentin 200mg capsule) with the following criteria (shown in red):

Relgaabi™ (Gabapentin 200mg Capsule) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use 2 of the 100mg gabapentin capsules, which are available without prior authorization, to achieve the 200mg dose must be provided; and
2. A quantity limit of 270 capsules per 30 days will apply.

Vykoura™ (Leucovorin Injection) Product Summary and Recommendations[41,42,43,44,45,46,47]

Therapeutic Class: Folate analog

Indication(s):

- Rescue after high-dose methotrexate (MTX) therapy in adult and pediatric patients
- Reducing the toxicity of MTX in adult and pediatric patients with impaired MTX elimination or folic acid antagonists or dihydrofolate reductase (DHFR) inhibitors following an overdose in adult and pediatric patients
- Treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients when oral therapy is not feasible
- Treatment of patients with metastatic colorectal cancer in combination with fluorouracil
    - Limitations of Use: Vykoura™ is not indicated for pernicious anemia and megaloblastic anemia secondary to the lack of vitamin B_{12}, because of the risk of progression of neurologic manifestations despite hematologic remission.

How Supplied: Vykoura™ is supplied in single-dose vials delivering 10mg/mL of leucovorin in the following vial sizes: 50mg/5mL, 350mg/35mL, 500mg/50mL.

Dosing and Administration:

- Vykoura™ is indicated for intravenous (IV) and intramuscular (IM) administration only. It should not be given intrathecally. It may be harmful or fatal if given intrathecally.
- The recommended dosing is based on diagnosis, as follows (additional information available in the full *Prescribing Information*):
  - Rescue After High-Dose MTX Therapy: The dose is based on serum MTX levels obtained 24 hours following the MTX infusion. The recommended dose for patients who receive a dose of 12-15g/m^2 of MTX with normal MTX elimination is 15mg IV or IM every 6 hours for 60 hours for a total of 10 doses.
  - Reduce Toxicity of Folic Acid Antagonists, DHFR inhibitors, or Impaired MTX Elimination: Administer Vykoura™ 10mg/m^2 IV or IM every 6 hours until the serum MTX level is less than 0.01 micromolar (1×10^{-8} M).
  - Advanced Colorectal Cancer in Combination with Fluorouracil: Dosage of Vykoura™ in combination with fluorouracil varies by regimen and ranges from 20mg/m^2 to 500mg/m^2. Consult institutional guidelines for recommended dosing, dosing frequency, and duration of therapy.
  - Megaloblastic Anemia Due to Folic Acid Deficiency: Up to 1mg daily administered IV until adequate hematologic response is achieved. There is no evidence that doses greater than 1mg/day have greater efficacy than those of 1mg; additionally, loss of folate in urine becomes roughly logarithmic as the amount administered exceeds 1mg.

Other Formulation(s) Available:

- Leucovorin Injection Powder for Solution:
  - Leucovorin injection powder has the same indications and recommended dosing as Vykoura™; however, it must be reconstituted before administration.
  - It is available in 50mg, 100mg, 200mg, 350mg, and 500mg vials.
- Leucovorin Injection Solution:
  - Leucovorin injection solution has the same indications and recommended dosing as Vykoura™. Both products are available in ready-to-use vials that do not need to be reconstituted. Leucovorin injection solution is only available in a 100mg/10mL vial.
- Khapzory® (Levoleucovorin Injection) and Levoleucovorin Calcium 50mg Vial and 10mg/mL Solution:

- The indications for levoleucovorin calcium and Khapzory® are the same as leucovorin except leucovorin has an additional indication for treatment of megaloblastic anemias due to folic acid deficiency when oral therapy is not feasible.
- The recommended dosing for levoleucovorin is half that of leucovorin for all overlapping indications.
- Levoleucovorin is for IV administration only.
- Levoleucovorin calcium is available in a 50mg vial that must be reconstituted and then in a 175mg/17.5mL and 250mg/25mL ready-to-use solution.
- Khapzory® is available in a 175mg vial that must be reconstituted. Khapzory® is the only sodium-based levoleucovorin formulation.

Formulation Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment*
Vykoura™ (leucovorin inj) 350mg/35mL	**$25.00**	**$4,375.00**
Khapzory® (levoleucovorin inj) 175mg vial	$775.88	$3,879.40
levoleucovorin inj solution 175mg/17.5mL (generic)	$7.04	$616.00
leucovorin inj solution 100mg/10mL (generic)	$2.20	$385.00
leucovorin inj powder 350mg vial (generic)	$70.00	$350.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = mL or vial; inj = injection
*Cost per treatment is based on the recommended dosing for advanced colorectal cancer in combination with fluorouracil at 100mg/m^2 for levoleucovorin and 200mg/m^2 for leucovorin in a patient with a body surface area of 1.75m^2 for 5 total doses.

The College of Pharmacy also recommends the prior authorization of Vykoura™ (leucovorin injection) with criteria similar to Khapzory® (levoleucovorin injection) approval criteria (changes shown in red):

Khapzory® (Levoleucovorin Injection) and Vykoura™ (Leucovorin Injection) Approval Criteria:

1. An FDA approved indication; and ~~of 1 of the following:~~
   ~~a. Rescue after high-dose methotrexate (MTX) therapy in members with osteosarcoma; or~~
   ~~b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or~~
   ~~c. Treatment of members with metastatic colorectal cancer in combination with fluorouracil; and~~
2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection, which are both available without prior authorization, must be provided.

Additional Recommendations

Finally, the College of Pharmacy recommends the prior authorization of Annovera™ (segesterone acetate/ethinyl estradiol vaginal system) based on net cost with the following criteria (shown in red):

Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) and all other available formulations of estrogen/progestin contraception available without prior authorization must be provided; and
3. A quantity limit of 1 vaginal system per year will apply.

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Appendix I

Vote to Prior Authorize Inlexzo™ (Gemcitabine Intravesical System), Kyxata™ (Carboplatin), Lifyorli™ (Relacorilant), and Zusduri™ (Mitomycin Intravesical Solution) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications

Oklahoma Health Care Authority
July 2026

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

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

- **June 2025:** The FDA approved Zusduri™ (mitomycin intravesical solution) for the treatment of adult patients with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (NMIBC).
- **August 2025:** The FDA approved Kyxata™ (carboplatin) through the 505(b)(2) pathway based on prior studies utilizing carboplatin. Kyxata™ is supplied as a solution for intravenous (IV) use in multiple-dose vials available in 20mg/2mL, 80mg/8mL, and 500mg/50mL strengths.
- **September 2025:** The FDA approved Inlexzo™ (gemcitabine intravesical system) for the treatment of adult patients with Bacillus Calmette-Guerin (BCG)-unresponsive NMIBC with carcinoma *in situ* (CIS) with or without papillary tumors.
- **November 2025:** The FDA approved Padcev® (enfortumab vedotin-ejfv) for a new indication, in combination with pembrolizumab or pembrolizumab/berahyaluronidase alfa-pmph, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, for the treatment of adult patients with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy.
- **December 2025:** The FDA approved Akeega® (niraparib/abiraterone) for a new indication for the treatment of adult patients with deleterious or suspected deleterious *BRCA2*-mutated metastatic castration-sensitive prostate cancer (CSPC).
- **March 2026:** The FDA approved Lifyorli™ (relacorilant), in combination with nab-paclitaxel, for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens, at least 1 of which included bevacizumab.
- **June 2026:** The FDA approved Welireg® (belzutifan) for a new indication, in combination with pembrolizumab or pembrolizumab/berahyaluronidase alfa-pmph, for the adjuvant treatment of adult patients with renal cell carcinoma (RCC) with a clear cell component at

intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for neuroendocrine and adrenal tumors allow for the use of everolimus in patients with unresectable, locally advanced, or metastatic neuroendocrine tumors (NET) of pancreatic (PNET), gastrointestinal, or lung origin and no functional carcinoid tumors.
- The NCCN guidelines for prostate cancer allow for the use of the following:
  - Enzalutamide in the treatment of non-metastatic and metastatic castration-resistant prostate cancer (CRPC) as a single agent or in combination with talazoparib; and
  - Enzalutamide in the treatment of metastatic CSPC as a single agent; and
  - Abiraterone in the treatment of metastatic CRPC in combination with methylprednisolone; and
  - Niraparib in the treatment of CRPC with suspected and/or deleterious *BRCA* mutation in conjunction with prednisone or methylprednisolone in patients who have not progressed on prior abiraterone therapy; and
  - Niraparib in the treatment of metastatic CSPC with high-volume metastases and suspected and/or deleterious BRCA mutation in conjunction with prednisone or methylprednisolone in patients who have not progressed on prior abiraterone therapy.

Inlexzo™ (Gemcitabine Intravesical System) Product Summary[10]

Therapeutic Class: Nucleoside metabolic inhibitor-containing intravesical system

Indication(s): Treatment of adult patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors

How Supplied: 1 single-dose 225mg gemcitabine intravesical system consisting of a flexible bi-oval shaped tube

Dosing and Administration: The recommended dosage is 1 intravesical system (225mg of gemcitabine) inserted into the bladder once every 3 weeks for up to 6 months (8 doses), followed by once every 12 weeks for up to 18 months (6 doses), or until persistent or recurrent NMIBC, disease progression, or unacceptable toxicity. Inlexzo™ should be removed after each 3-week indwelling period.

Cost: The Wholesale Acquisition Cost (WAC) is $69,000 per intravesical system. This would result in an estimated cost of $552,000 for the initial 6 months of treatment.

Lifyorli™ (Relacorilant) Product Summary[11]

Therapeutic Class: Glucocorticoid receptor antagonist

Indication(s): Treatment, in combination with nab-paclitaxel, of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens, at least 1 of which included bevacizumab

How Supplied: 25mg and 100mg oral capsules

Dosing and Administration:

- The recommended dose is 150mg orally once on the day before, the day of, and the day after each nab-paclitaxel infusion until disease progression or unacceptable toxicity.
- A dose reduction to 125mg may be required for adverse reactions.
- The recommended dosing of nab-paclitaxel for this indication is 80mg/m^2 as an intravenous infusion on days 1, 8, and 15 of each 28-day cycle until disease progression or unacceptable toxicity.

Cost: The WAC is $1,403.70 per capsule, and the recommended 150mg dose would require a total of 27 capsules for each 28-day cycle. This would result in an estimated cost of $37,899.90 per 28 days or $492,698.70 per year based on recommended dosing.

Zusduri™ (Mitomycin Intravesical Solution) Product Summary[12]

Therapeutic Class: Alkylating drug

Indication(s): Treatment of adult patients with recurrent low-grade intermediate-risk NMIBC

How Supplied: Supplied as a kit containing the following:

- (2) 40mg single-dose vials of mitomycin for intravesical solution; and
- (1) vial of 60mL sterile hydrogel for reconstitution

Dosing and Administration:

- The recommended dose is 75mg (56mL) instilled once weekly for 6 weeks into the bladder via a urinary catheter.
- Zusduri™ is for intravesical instillation only and should not be administered by pyelocalyceal instillation or by any other route.

Cost: The WAC is $21,500 per kit. This would result in an estimated cost of $129,000 for the recommended 6 weeks of treatment.

Cost Comparison: Carboplatin Products

Product	Cost Per mg	Cost Per 21 Days*	Cost Per Year
Kyxata™ (carboplatin) (J9278)	**$5.24**	**$3,406.00**	**$57,902.00**
carboplatin (generic) (J9045)	$0.06	$39.00	$663.00

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS).
*Cost per 21 days based on a dose of area under the curve (AUC) 5 on day 1 of each 21-day cycle for a member with normal renal function with creatinine clearance capped at 125mL/min (using a total of 650mg per dose).

Recommendations

The College of Pharmacy recommends the prior authorization of Inlexzo™ (gemcitabine intravesical system), Lifyorli™ (relacorilant), and Zusduri™ (mitomycin intravesical solution) with the following criteria (shown in red):

Inlexzo™ (Gemcitabine Intravesical System) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC with carcinoma in situ (CIS), with or without papillary tumors; and
2. Disease is unresponsive to Bacillus Calmette-Guérin (BCG) treatment; and
3. Member must be 18 years of age or older; and
4. Used for intravesical administration only; and
5. Initial approvals will be for 6 months for 8 doses administered every 3 weeks; and
6. Subsequent approvals will be for 6 months for 2 doses administered every 12 weeks; and
7. Approval will be limited to a maximum total of 14 doses.

Lifyorli™ (Relacorilant) Approval Criteria [Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. Disease is platinum resistant; and
3. Member has received a prior systemic treatment regimen that included bevacizumab; and
4. Used in combination with nab-paclitaxel; and
5. Member must be 18 years of age or older.

Zusduri™ (Mitomycin Intravesical Solution) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC; and
2. Disease is low-grade, intermediate-risk; and

3. Disease is recurrent; and
4. Administered by intravesical instillation only; and
5. Member must be 18 years of age or older; and
6. Approval will be limited to a total of 6 weekly instillations.

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

Kyxata™ (Carboplatin; J9278) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use generic carboplatin products (J9045), which are available without prior authorization, must be provided.

Next, the College of Pharmacy recommends updating the approval criteria for Padcev® (enfortumab vedotin-ejfv) and Welireg® (belzutifan) based on recent FDA approvals (changes and new criteria noted in red):

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

1. Diagnosis of muscle invasive bladder cancer (MIBC); and
    a. Used as neoadjuvant treatment and continued as adjuvant treatment after cystectomy; and
    b. Used in combination with pembrolizumab; and
    c. Member is ineligible for cisplatin-containing chemotherapy; or
2. Diagnosis of locally advanced or metastatic urothelial cancer; and
    a. Used in 1 of the following settings:
        i. As a single agent and member has previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting; or
        ii. As a single agent and member has received at least 1 prior therapy and is ineligible for cisplatin-containing chemotherapy; or
        iii. Used in combination with pembrolizumab.

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

1. Diagnosis of advanced RCC with a clear cell component; and
    a. 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

b. As a single agent; or
2. Diagnosis of RCC with a clear cell component; and
   a. Disease is intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions; and
   b. Used in combination with pembrolizumab; and
   c. Approval will be for a maximum of 54 weeks.

Next, the College of Pharmacy recommends updating the approval criteria for Akeega® (niraparib/abiraterone acetate) based on recent FDA approvals and NCCN recommendations (changes and new criteria noted in red):

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

1. Diagnosis of metastatic CSPC with high-volume metastasis; and
   a. High-volume defined as presence of visceral metastasis or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis; and
2. Presence of deleterious or suspected deleterious *BRCA2* mutation based upon an FDA-approved test; and
3. Used in conjunction with prednisone; and
4. Used in conjunction with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

Next, the College of Pharmacy recommends updating the Afinitor® (everolimus), Xtandi® (enzalutamide), Yonsa® (abiraterone acetate), Zejula® (niraparib), and Zytiga® (abiraterone) approval criteria based on NCCN guideline recommendations and net cost (changes shown in red):

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

1. Diagnosis of unresectable, locally advanced, or metastatic NET of pancreatic (PNET), gastrointestinal, or lung origin; and
~~2. Progressive disease from a previous treatment.~~
3. Member does not have functional carcinoid tumor.

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

1. Diagnosis of non-metastatic CRPC; and
   a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
   b. PSA doubling time (PSADT) is ≤10 months; or
2. Diagnosis of metastatic CRPC; and
   a. Concomitant treatment with a GnRH analog or prior history of bilateral orchiectomy; and

b. If disease is homologous recombination repair (HRR) gene-mutated, must be used in combination with talazoparib.

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

1. Diagnosis of metastatic CSPC; ~~or~~ and
   a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; or
2. Diagnosis of non-metastatic CSPC with biochemical recurrence at high risk for metastasis (high-risk BCR).

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

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with ~~a corticosteroid~~ methylprednisolone; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. A patient-specific, clinically significant reason why the member cannot use generic abiraterone tablets must be provided.

Zejula® (Niraparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

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

Zejula® (Niraparib) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC with high-volume metastases; and
   a. High-volume defined as presence of visceral metastasis or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis; and
2. Presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
3. Used in combination with abiraterone and prednisone or abiraterone acetate and methylprednisolone; and

4. Used in combination with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

Zytiga® (Abiraterone) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Zytiga® (Abiraterone) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic, high-risk, CSPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Lastly, the College of Pharmacy recommends removing the prior authorization requirement for Camcevi® (leuprolide) and updating the Orgovyx® (relugolix) approval criteria based on net cost (changes shown in red):

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

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

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

1. Diagnosis of advanced prostate cancer; and

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

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Appendix J

Fiscal Year 2025 Annual Review of Anti-Ulcer Medications

Oklahoma Health Care Authority
July 2026

Current Prior Authorization Criteria

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
esomeprazole (Nexium® caps)	dexlansoprazole (Dexilant® caps) – **Brand Preferred**	esomeprazole (Nexium® I.V.)	bismuth subcitrate potassium/metronidazole/ tetracycline (Pylera® caps)
esomeprazole (Nexium® packet) – **Brand Preferred**	pantoprazole (Protonix® I.V.)	omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)
lansoprazole (Prevacid® caps)		pantoprazole (Protonix® susp)	esomeprazole kit (ESOMEP-EZS™)
lansoprazole ODT (Prevacid® ODT) – **Brand Preferred**			famotidine (Pepcid® susp)
omeprazole (Prilosec® caps)			glycopyrrolate (Glycate® tabs)
pantoprazole (Protonix® tabs)			glycopyrrolate ODT (Dartisla® ODT)
rabeprazole (Aciphex® tabs)			lansoprazole/amoxicillin/ clarithromycin (PrevPac®)
sucralfate (Carafate® tabs)			nizatidine (Axid® caps & soln)
			omeprazole/amoxicillin/ rifabutin (Talicia® caps)
			omeprazole/sodium bicarbonate (Konvomep® for oral suspension)
			omeprazole/sodium bicarbonate (Zegrid® caps & pack)
			pantoprazole in 0.9% NaCl for IV injection
			sucralfate (Carafate® susp)
			vonoprazan (Voquezna® tabs)

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA+**
			vonoprazan fumarate/ amoxicillin trihydrate (Voquezna® Dual Pak®)
			vonoprazan fumarate/ amoxicillin trihydrate/ clarithromycin (Voquezna® Triple Pak®)

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reasoning for use.
+Individual criteria specific to each product applies.
caps = capsules; IV = intravenous; ODT = orally disintegrating tablet; NaCl = sodium chloride; PA = prior authorization;
soln = solution; susp = suspension; tabs = tablet

Anti-Ulcer Medications Tier-2 Approval Criteria:

1. A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

Anti-Ulcer Medications Tier-3 Approval Criteria:

1. A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications; and
4. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and intravenous (IV) solutions require special reasoning for use.

Proton Pump Inhibitors for Pediatric Members Approval Criteria:

1. A recent 14-day trial of a histamine type 2 receptor (H2) antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Recurrent or severe disease such as:
   a. Gastrointestinal (GI) bleed; or
   b. Zollinger-Ellison Syndrome or similar disease; and
3. Tier structure rules still apply.

Axid® (Nizatidine Capsule) Approval Criteria:

1. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.

Axid® (Nizatidine Solution) Approval Criteria:

1. A previous 14-day trial of famotidine suspension or a patient-specific, clinically significant reason why famotidine suspension is not appropriate for the member must be provided; and
2. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

Carafate® (Sucralfate Suspension) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the tablet formulation, which is available without prior authorization, must be provided.

Dartisla® ODT [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 18 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided; and
3. A quantity limit of 120 tablets per 30 days will apply.

Esomep-EZS™ (Esomeprazole Kit) Approval Criteria:

1. A previous 14-day trial of esomeprazole magnesium and a patient-specific, clinically significant reason why other lower tiered proton pump inhibitors (PPIs), including omeprazole and esomeprazole, along with over-the-counter (OTC) pill swallowing spray are not appropriate for the member must be provided; and
2. Current Tier structure rules will also apply.

Glycate® (Glycopyrrolate Tablet) Approval Criteria:

1. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided.

Konvomep® (Omeprazole/Sodium Bicarbonate for Oral Suspension) and Zegerid® (Omeprazole/Sodium Bicarbonate Capsule) Approval Criteria:

1. Member must be 18 years of age or older; and
2. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided; and

3. For Konvomep®, requests for the 90mL or 150mL package will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size.

Pantoprazole in 0.9% NaCl for Intravenous (IV) Injection Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Tier-2 Protonix® I.V. (pantoprazole) must be provided.

Pepcid® (Famotidine Suspension) Approval Criteria:

1. Famotidine suspension will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.

PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin) Approval Criteria:

1. An FDA approved indication for the eradication of *Helicobacter pylori* (*H. pylori*) infection and reduce the risk of duodenal ulcer recurrence; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components, which are available without prior authorization must be provided; and
3. A quantity limit of 112 tablets/capsules per 14 days will apply.

Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori infection* (e.g., omeprazole, amoxicillin, and rifabutin), which are available without prior authorization, must be provided; and
4. A quantity limit of 120 capsules per 10 days will apply.

Tagamet® (Cimetidine Tablet) Approval Criteria:

1. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of *Helicobacter pylori* (*H. pylori*) infection; and

2. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and rifabutin), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of potassium-competitive acid blocker (PCAB) dual therapy (e.g., vonoprazan fumarate and amoxicillin) must be provided; and
5. A quantity limit of 168 capsules per 14 days will apply.

Voquezna® (Vonoprazan Fumarate) Approval Criteria [Erosive and Non-Erosive Gastroesophageal Reflux Disease (GERD) Diagnosis]:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Voquezna® (Vonoprazan Fumarate), Voquezna® Dual Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate), and Voquezna® Triple Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate/Clarithromycin) Approval Criteria [*Helicobacter pylori* (*H. pylori*) Diagnosis]:

1. An FDA approved indication for the treatment of *H. pylori* infection; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and rifabutin), which are available without prior authorization, must be provided; and
5. For the Voquezna® Dual Pak® and Voquezna® Triple Pak®, a patient-specific, clinically significant reason why the member cannot use the individual components of the product requested must be provided; and
6. A quantity limit of 112 tablets/capsules per 14 days will apply.

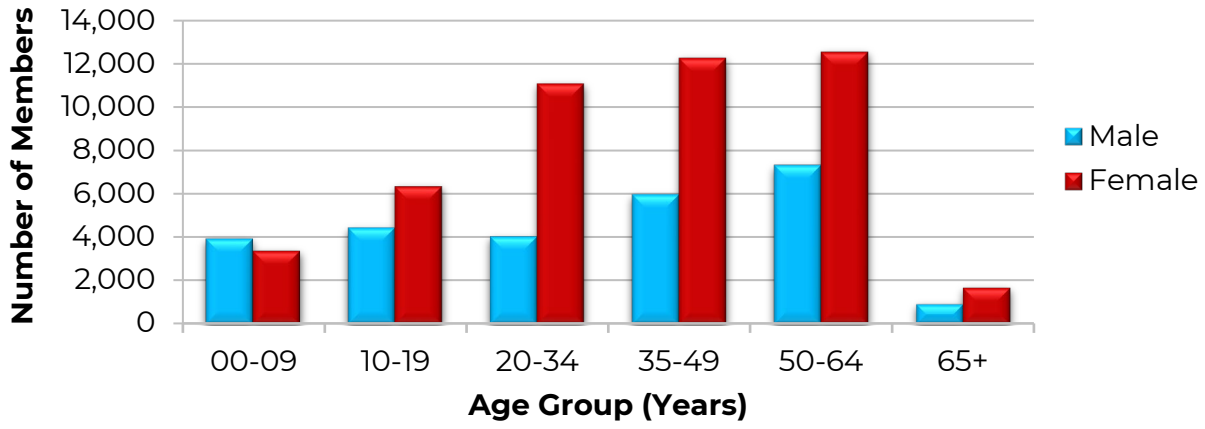
Utilization of Anti-Ulcer Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

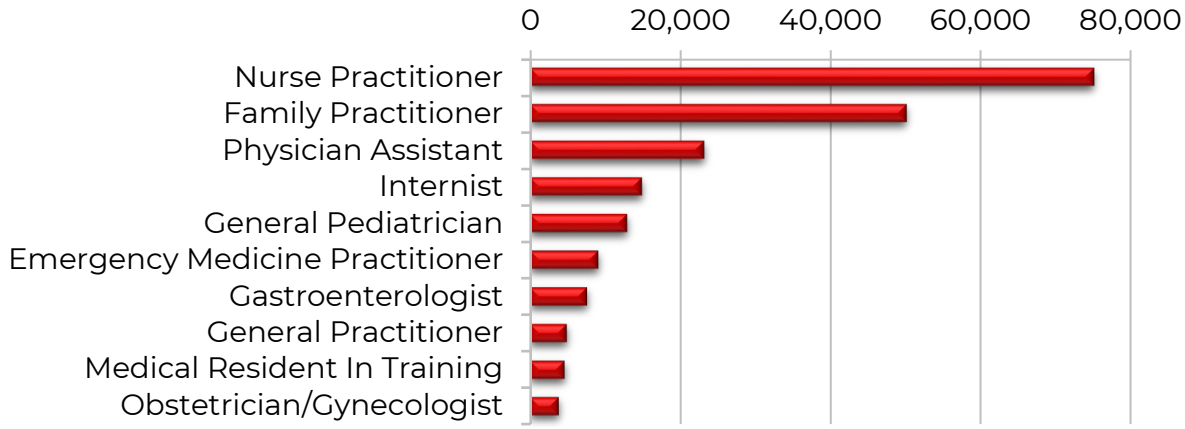
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	70,369	196,342	$4,990,875.75	$25.42	$0.53	13,304,739	9,355,519
Aetna	6,492	9,321	$221,959.11	$23.81	$0.48	616,815	458,752
Humana	7,942	11,847	$285,837.78	$24.13	$0.48	812,066	591,638
OCH	6,580	9,241	$220,526.10	$23.86	$0.50	606,389	443,611
2024 Total	**77,274**	**226,751**	**$5,719,198.74**	**$25.22**	**$0.53**	**15,340,009**	**10,849,520**
Fiscal Year 2025							
FFS	31,305	96,801	$2,401,496.32	$24.81	$0.54	6,641,027	4,444,624
Aetna	15,219	38,728	$894,237.78	$23.09	$0.46	2,580,285	1,939,155
Humana	17,659	49,423	$1,098,277.96	$22.22	$0.44	3,346,131	2,470,578
OCH	16,116	39,368	$920,731.59	$23.39	$0.44	2,796,373	2,073,774
2025 Total	**73,954**	**224,320**	**$5,314,743.65**	**$23.69**	**$0.49**	**15,363,816**	**10,928,131**
% Change	**-4.30%**	**-1.10%**	**-7.10%**	**-6.10%**	**-7.50%**	**0.20%**	**0.70%**
Change	**-3,320**	**-2,431**	**-$404,455.09**	**-$1.53**	**-$0.04**	**23,807**	**78,611**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Anti-Ulcer Medications: Pharmacy Claims (All Plans)



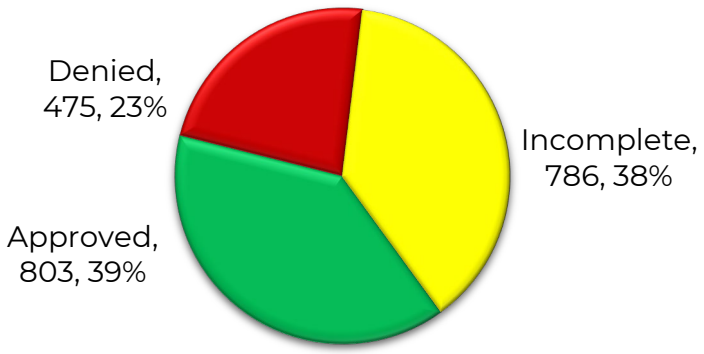
Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anti-Ulcer Medications

There were 2,064 prior authorization requests submitted for anti-ulcer medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	460	42%	508	47%	124	11%	**1,092**
Aetna	50	12%	214	52%	151	36%	**415**
Humana	18	21%	0	0%	69	79%	**87**
OCH	275	59%	64	14%	131	28%	**470**
Total	**803**	**39%**	**786**	**38%**	**475**	**23%**	**2,064**

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

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Voquezna® (vonoprazan): August 2030
- Voquezna® Dual Pak® (vonoprazan/amoxicillin): August 2030
- Voquezna® Triple Pak® (vonoprazan/amoxicillin/clarithromycin): August 2030
- Dexilant® (dexlansoprazole): March 2032
- Konvomep® (omeprazole/sodium bicarbonate for oral suspension): March 2040
- Talicia® (omeprazole/amoxicillin/rifabutin): May 2042

Recommendations

The College of Pharmacy recommends the following changes to the Anti-Ulcer Medications Product Based Prior Authorization (PBPA) Tier chart and additional criteria (changes shown in red):

1. Adding Tagamet® (cimetidine) solution and Pepcid® (famotidine) tablets and injection, which are available without prior authorization, to Tier-1 for clarity; and
2. No longer designating Prevacid® orally disintegrating tablet (ODT) (lansoprazole ODT) as brand preferred based on net cost; and
3. Updating the Anti-Ulcer Medications Tier-2 and Tier-3 Approval Criteria to allow for a patient-specific, clinically significant reason why a member cannot use lower-tiered products instead of requiring a 14-day trial based on DUR Board input; and
4. Rephrasing criteria regarding age restrictions for clarity; and
5. Updating the Talicia® (omeprazole/amoxicillin/rifabutin) criteria based on clinical practice.

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
cimetidine (Tagamet® soln)	dexlansoprazole (Dexilant® caps) – **Brand Preferred**	esomeprazole inj (Nexium® I.V.)	bismuth subcitrate potassium/metronidazole/ tetracycline (Pylera® caps)
esomeprazole (Nexium® caps)	pantoprazole (Protonix® I.V.)	omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)
esomeprazole (Nexium® packet) – **Brand Preferred**		pantoprazole (Protonix® susp)	esomeprazole kit (ESOMEP-EZS™)
famotidine (Pepcid® tabs, inj)			famotidine (Pepcid® susp)
lansoprazole (Prevacid® caps**, ODT**)			glycopyrrolate (Glycate® tabs)

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA+**
~~**lansoprazole ODT (Prevacid® ODT) – Brand Preferred**~~			glycopyrrolate ODT (Dartisla® ODT)
omeprazole (Prilosec® caps)			lansoprazole/amoxicillin/ clarithromycin (PrevPac®)
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/amoxicillin/ rifabutin (Talicia® caps)
sucralfate (Carafate® tabs)			omeprazole/sodium bicarbonate (Konvomep® for oral suspension)
			omeprazole/sodium bicarbonate (Zegrid® caps & pack)
			pantoprazole in 0.9% NaCl for IV inj
			sucralfate (Carafate® susp)
			vonoprazan (Voquezna® tabs)
			vonoprazan fumarate/ amoxicillin trihydrate (Voquezna® Dual Pak®)
			vonoprazan fumarate/ amoxicillin trihydrate/ clarithromycin (Voquezna® Triple Pak®)

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reasoning for use.
+Individual criteria specific to each product applies.
caps = capsules; **inj = injection**; IV = intravenous; ODT = orally disintegrating tablet; NaCl = sodium chloride; PA = prior authorization; soln = solution; susp = suspension; tabs = tablet

Anti-Ulcer Medications Tier-2 Approval Criteria:

1. ~~A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that resulted in inadequate relief of symptoms or intolerable adverse effects; or~~
2. ~~Contraindication(s) to all available Tier-1 medications; or~~
3. A patient-specific clinically significant reason why all Tier-1 products for the requested route of administration, titrated to the recommended dose, are not appropriate for the member must be provided; or
4. An indication not covered by lower tiered medications.

Anti-Ulcer Medications Tier-3 Approval Criteria:

~~1. A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or~~

~~2. Contraindication(s) to all available Tier-1 and Tier-2 medications; or~~

3. A patient-specific clinically significant reason why all Tier-1 and Tier-2 products for the requested route of administration, titrated to the recommended dose, are not appropriate for the member must be provided; or
4. An indication not covered by lower tiered medications; and
5. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and intravenous (IV) solutions require special reasoning for use.

~~**Proton Pump Inhibitors for Pediatric Members Approval Criteria:**~~

~~1. A recent 14-day trial of a histamine type 2 receptor (H2) antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or~~

~~2. Recurrent or severe disease such as:~~

~~a. Gastrointestinal (GI) bleed; or~~

~~b. Zollinger-Ellison Syndrome or similar disease; and~~

~~3. Tier structure rules still apply.~~

Anti-Ulcer Medications Special Prior Authorization (PA) Approval Criteria:

1. Axid® (Nizatidine Capsule) Approval Criteria:
   a. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.
2. Axid® (Nizatidine Solution) Approval Criteria:
   a. A previous 14-day trial of famotidine suspension or a patient-specific, clinically significant reason why famotidine suspension is not appropriate for the member must be provided; and
   b. Nizatidine solution (Axid®) will ~~have an age restriction of~~ be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.
3. Carafate® (Sucralfate Suspension) Approval Criteria:
   a. A patient specific, clinically significant reason why the member cannot use the tablet formulation, which is available without prior authorization, must be provided.
4. Dartisla® ODT [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Approval Criteria:

a. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 18 years of age and older; and
b. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided; and
c. A quantity limit of 120 tablets per 30 days will apply.

5. Esomep-EZS™ (Esomeprazole Kit) Approval Criteria:
   a. A previous 14-day trial of esomeprazole magnesium and a patient-specific, clinically significant reason why other lower tiered proton pump inhibitors (PPIs), including omeprazole and esomeprazole, along with over-the-counter (OTC) pill swallowing spray are not appropriate for the member must be provided; and
   b. Current Tier structure rules will also apply.
6. Glycate® (Glycopyrrolate Tablet) Approval Criteria:
   a. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 12 years of age and older; and
   b. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided.
7. Konvomep® (Omeprazole/Sodium Bicarbonate for Oral Suspension) and Zegerid® (Omeprazole/Sodium Bicarbonate Capsule) Approval Criteria:
   a. Member must be 18 years of age or older; and
   b. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided; and
   c. For Konvomep®, requests for the 90mL or 150mL package will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size.
8. Pantoprazole in 0.9% NaCl for Intravenous (IV) Injection Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use Tier-2 Protonix® I.V. (pantoprazole) must be provided.
9. Pepcid® (Famotidine Suspension) Approval Criteria**:**
   a. Famotidine suspension will ~~have an age restriction of~~ be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.
10. PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin) Approval Criteria:

a. An FDA approved indication for the eradication of *Helicobacter pylori* (*H. pylori*) infection and reduce the risk of duodenal ulcer recurrence; and
b. A patient-specific, clinically significant reason why the member cannot use the individual components, which are available without prior authorization must be provided; and
c. A quantity limit of 112 tablets/capsules per 14 days will apply.

11. Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) Approval Criteria:
    a. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
    b. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
    c. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori infection* (e.g., omeprazole, amoxicillin, and rifabutin), which are available without prior authorization, must be provided; and
    d. A quantity limit of 120 capsules per 10 days will apply.
12. Tagamet® (Cimetidine Tablet) Approval Criteria:
    a. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.
13. Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule) Approval Criteria:
    a. An FDA approved indication for the treatment of *Helicobacter pylori* (*H. pylori*) infection; and
    b. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
    ~~c. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and rifabutin), which are available without prior authorization, must be provided; and~~
    d. A patient-specific, clinically significant reason why the member cannot use the individual components of potassium-competitive acid blocker (PCAB) dual therapy (e.g., vonoprazan fumarate and amoxicillin) must be provided; and
    e. A quantity limit of 168 capsules per 14 days will apply

14. Voquezna® (Vonoprazan Fumarate) Approval Criteria [Erosive and Non-Erosive Gastroesophageal Reflux Disease (GERD) Diagnosis]:
    a. An FDA approved diagnosis; and
    b. Member must be 18 years of age or older; and
    c. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
    d. A quantity limit of 30 tablets per 30 days will apply.
15. Voquezna® (Vonoprazan Fumarate), Voquezna® Dual Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate), and Voquezna® Triple Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate/Clarithromycin) Approval Criteria [*Helicobacter pylori* (*H. pylori*) Diagnosis]:
    a. An FDA approved indication for the treatment of *H. pylori* infection; and
    b. Member must be 18 years of age or older; and
    c. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
    d. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and rifabutin), which are available without prior authorization, must be provided; and
    e. For the Voquezna® Dual Pak® and Voquezna® Triple Pak®, a patient-specific, clinically significant reason why the member cannot use the individual components of the product requested must be provided; and
    f. A quantity limit of 112 tablets/capsules per 14 days will apply.

Utilization Details of Anti-Ulcer Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
OMEPRAZOLE PRODUCTS						
OMEPRAZOLE CAP 40MG	40,621	15,824	$570,759.67	$14.05	2.57	10.74%
OMEPRAZOLE CAP 20MG	37,771	15,417	$498,002.65	$13.18	2.45	9.37%
OMEPRAZOLE CAP 10MG	1,520	684	$22,381.77	$14.72	2.22	0.42%
OMEPRAZOLE TAB 20MG	1	1	$22.99	$22.99	1	0.00%
SUBTOTAL	**79,913**	**31,926**	**$1,091,167.08**	**$13.65**	**2.5**	**20.53%**
PANTOPRAZOLE PRODUCTS						
PANTOPRAZOLE TAB 40MG	56,593	22,064	$768,266.65	$13.58	2.56	14.46%
PANTOPRAZOLE TAB 20MG	8,073	3,628	$113,049.42	$14.00	2.23	2.13%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**64,666**	**25,692**	**$881,316.07**	**$13.63**	**2.52**	**16.58%**
FAMOTIDINE PRODUCTS						
FAMOTIDINE TAB 20MG	23,616	11,242	$317,599.78	$13.45	2.1	5.98%
FAMOTIDINE TAB 40MG	8,544	3,903	$122,905.17	$14.38	2.19	2.31%
FAMOTIDINE INJ 20MG/2ML	221	10	$3,819.73	$17.28	22.1	0.07%
FAMOTIDINE INJ 200MG/20ML	188	8	$3,496.04	$18.60	23.5	0.07%
FAMOTIDINE INJ 40MG/4ML	84	2	$1,911.96	$22.76	42	0.04%
FAMOTIDINE INJ 10MG/ML	46	7	$1,234.50	$26.84	6.57	0.02%
FAMOTIDINE TAB 10MG	5	4	$76.45	$15.29	1.25	0.00%
SUBTOTAL	**32,704**	**15,176**	**$451,043.63**	**$13.79**	**2.15**	**8.49%**
SUCRALFATE PRODUCTS						
SUCRALFATE TAB 1GM	11,084	6,191	$274,693.44	$24.78	1.79	5.17%
CARAFATE TAB 1GM	1	1	$582.46	$582.46	1	0.01%
SUBTOTAL	**11,085**	**6,192**	**$275,275.90**	**$24.83**	**1.79**	**5.18%**
ESOMEPRAZOLE PRODUCTS						
ESOMEPRAZOLE CAP 40MG DR	5,544	1,937	$107,661.59	$19.42	2.86	2.03%
ESOMEPRAZOLE CAP 20MG DR	1,849	721	$37,882.57	$20.49	2.56	0.71%
NEXIUM GRA 10MG DR	657	191	$195,004.14	$296.81	3.44	3.67%
NEXIUM GRA 20MG DR	612	142	$180,788.68	$295.41	4.31	3.40%
NEXIUM GRA 5MG DR	318	115	$94,829.11	$298.20	2.77	1.78%
NEXIUM GRA 40MG DR	227	42	$69,080.00	$304.32	5.4	1.30%
NEXIUM GRA 2.5MG DR	125	56	$35,949.26	$287.59	2.23	0.68%
ESOMEPRAZOLE GRA 20MG DR	31	9	$7,847.04	$253.13	3.44	0.15%
ESOMEPRAZOLE GRA 10MG DR	24	11	$5,169.81	$215.41	2.18	0.10%
NEXIUM CAP 40MG	8	2	$2,524.76	$315.60	4	0.05%
ESOMEPRAZOLE GRA 5MG DR	4	4	$942.74	$235.69	1	0.02%
ESOMEPRAZOLE GRA 2.5MG DR	2	2	$491.09	$245.55	1	0.01%
ESOMEPRAZOLE GRA 40MG DR	1	1	$307.81	$307.81	1	0.01%
SUBTOTAL	**9,402**	**3,233**	**$738,478.60**	**$78.54**	**2.91**	**13.89%**
LANSOPRAZOLE PRODUCTS						
LANSOPRAZOLE CAP 30MG DR	2,126	675	$33,301.10	$15.66	3.15	0.63%
LANSOPRAZOLE CAP 15MG DR	383	140	$7,232.76	$18.89	2.74	0.14%
PREVACID TAB 30MG STB	338	52	$144,559.92	$427.69	6.5	2.72%
PREVACID TAB 15MG STB	192	53	$75,794.44	$394.76	3.62	1.43%
LANSOPRAZOLE TAB 15MG ODT	17	8	$1,552.47	$91.32	2.13	0.03%
LANSOPRAZOLE TAB 30MG ODT	2	2	$190.36	$95.18	1	0.00%
SUBTOTAL	**3,058**	**930**	**$262,631.05**	**$85.88**	**3.29**	**4.94%**
GLYCOPYRROLATE PRODUCTS						
GLYCOPYRROLATE TAB 1MG	1,830	409	$32,272.11	$17.64	4.47	0.61%
GLYCOPYRROLATE TAB 2MG	1,009	173	$23,355.88	$23.15	5.83	0.44%
SUBTOTAL	**2,839**	**582**	**$55,627.99**	**$19.59**	**4.88**	**1.05%**
RABEPRAZOLE PRODUCTS						
RABEPRAZOLE TAB 20MG	754	278	$18,740.05	$24.85	2.71	0.35%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**754**	**278**	**$18,740.05**	**$24.85**	**2.71**	**0.35%**
CIMETIDINE PRODUCTS						
CIMETIDINE SOL 300MG/5ML	20	19	$10,037.56	$501.88	1.05	0.19%
SUBTOTAL	**20**	**19**	**$10,037.56**	**$501.88**	**1.05**	**0.19%**
TIER-1 TOTAL	**204,441**	**84,028**	**$3,784,317.93**	**$18.51**	**2.43**	**71.20%**
TIER-2 UTILIZATION						
DEXLANSOPRAZOLE PRODUCTS						
DEXLANSOPRAZOLE CAP 60MG DR	3,547	593	$528,942.95	$149.12	5.98	9.95%
DEXLANSOPRAZOLE CAP 30MG DR	725	158	$112,264.18	$154.85	4.59	2.11%
DEXILANT CAP 60MG DR	164	31	$50,138.91	$305.73	5.29	0.94%
DEXLANSOPRAZ CAP 30MG	132	37	$20,727.66	$157.03	3.57	0.39%
DEXILANT CAP 30MG DR	30	7	$9,186.09	$306.20	4.29	0.17%
SUBTOTAL	**4,598**	**826**	**$721,259.79**	**$156.86**	**5.57**	**13.57%**
PANTOPRAZOLE PRODUCTS						
PANTOPRAZOLE INJ SOD 40MG	223	9	$4,867.69	$21.83	24.78	0.09%
PROTONIX INJ 40MG	2	1	$93.88	$46.94	2	0.00%
SUBTOTAL	**225**	**10**	**$4,961.57**	**$22.05**	**22.5**	**0.09%**
TIER-2 TOTAL	**4,823**	**836**	**$726,221.36**	**$150.57**	**5.77**	**13.66%**
TIER-3 UTILIZATION						
PANTOPRAZOLE PRODUCTS						
PANTOPRAZOLE PAK 40MG SUS	17	9	$3,651.68	$214.80	1.89	0.07%
PROTONIX PAK 40MG	11	1	$4,630.02	$420.91	11	0.09%
SUBTOTAL	**28**	**10**	**$8,281.70**	**$295.78**	**2.8**	**0.16%**
OMEPRAZOLE PRODUCTS						
PRILOSEC POW 2.5MG	12	6	$5,794.01	$482.83	2	0.11%
PRILOSEC POW 10MG	10	5	$4,444.64	$444.46	2	0.08%
SUBTOTAL	**22**	**11**	**$10,238.65**	**$465.39**	**2**	**0.19%**
TIER-3 TOTAL	**50**	**21**	**$18,520.35**	**$370.41**	**2.38**	**0.35%**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
FAMOTIDINE PRODUCTS						
FAMOTIDINE SUS 40MG/5ML	12,888	5,528	$407,862.80	$31.65	2.33	7.67%
SUBTOTAL	**12,888**	**5,528**	**$407,862.80**	**$31.65**	**2.33**	**7.67%**
SUCRALFATE PRODUCTS						
SUCRALFATE SUS 1GM/10ML	1,805	1,010	$247,061.82	$136.88	1.79	4.65%
CARAFATE SUS 1GM/10ML	2	2	$295.97	$147.99	1	0.01%
SUBTOTAL	**1,807**	**1,012**	**$247,357.79**	**$136.89**	**1.79**	**4.65%**
VONOPRAZAN PRODUCTS						
VOQUEZNA TAB 20MG	92	31	$59,352.12	$645.13	2.97	1.12%
VOQUEZNA TAB 10MG	61	18	$40,199.41	$659.01	3.39	0.76%
SUBTOTAL	**153**	**49**	**$99,551.53**	**$650.66**	**3.12**	**1.87%**
CIMETIDINE PRODUCTS						
CIMETIDINE TAB 400MG	46	22	$1,410.94	$30.67	2.09	0.03%
CIMETIDINE TAB 200MG	24	11	$474.29	$19.76	2.18	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CIMETIDINE TAB 300MG	23	10	$571.57	$24.85	2.3	0.01%
CIMETIDINE TAB 800MG	11	6	$508.33	$46.21	1.83	0.01%
SUBTOTAL	**104**	**49**	**$2,965.13**	**$28.51**	**2.12**	**0.06%**
TRIPLE THERAPY COMBINATION PRODUCTS						
BISMTH/METR/TETRA CAP 140/125/MG	16	16	$8,728.70	$545.54	1	0.16%
TALICIA CAP 250/12.5/10MG	12	10	$9,568.53	$797.38	1.2	0.18%
PYLERA CAP 140/125/125MG	4	4	$1,915.07	$478.77	1	0.04%
LANSO/AMOX/CLARI 500/5,000/30MG	2	2	$1,092.08	$546.04	1	0.02%
SUBTOTAL	**34**	**32**	**$21,304.38**	**$626.60**	**1.06**	**0.40%**
OMEPRAZOLE/SODIUM BICARBONATE PRODUCTS						
OMEPRA/BICARB CAP 40-1,100MG	9	1	$312.37	$34.71	9	0.01%
KONVOMEP SUS 2-84MG/ML	8	1	5752.28	719.035	8	0.11%
OMEPRA/BICARB CAP 20-1,100MG	1	1	$28.36	$28.36	1	0.00%
OMEPRA/BICARB POW 40-1,680MG	1	1	$400.70	$400.70	1	0.01%
SUBTOTAL	**19**	**4**	**$6,493.71**	**$341.77**	**4.75**	**0.12%**
NIZATIDINE PRODUCTS						
NIZATIDINE CAP 150MG	1	1	$162.59	$162.59	1	0.00%
SUBTOTAL	**1**	**1**	**$162.59**	**$162.59**	**1**	**0.00%**
SPECIAL PA TOTAL	**15,006**	**6,676**	**$785,684.01**	**$52.36**	**2.25**	**14.78%**
TOTAL	**224,320**	**73,954***	**$5,314,743.65**	**$ 23.69**	**3.03**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMOX = amoxicillin; BICARB = bicarbonate; BISMTH = bismuth subcitrate; CAP = capsule; CLARI = clarithromycin; DR = delayed-release; GRA = granules; LANSO = lansoprazole; INJ = injection; METR = metronidazole; ODT = orally disintegrating tablet; OMEPRA = omeprazole; PAK = packet; POW = powder; SOD = sodium; SOL = solution; STB = SoluTab®; SUS = suspension; TAB = tablet; TETRA = tetracycline
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[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 06/2026. Last accessed 06/24/2026.

Appendix K

Fiscal Year 2025 Annual Review of Epidermolysis Bullosa (EB) Medications

Oklahoma Health Care Authority
July 2026

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, 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. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
9. Filsuvez® will not be approved for concomitant use with Vyjuvek® (beremagene geperpavec-svdt) or for use on wounds treated with Zevaskyn® (prademagene zamikeracel); and
10. 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

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 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 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, 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. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
10. 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
11. A maximum approval quantity of 1 carton (2.5mL) per week will apply; and
12. 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; and
    b. Vyjuvek® must continue to be administered by an HCP. 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).

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. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
5. Prescriber must confirm that the member has been counseled and will not use other epidermolysis bullous products (e.g., Vyjuvek®, Filsuvez®) on wounds treated with Zevaskyn®; and
6. 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
7. Approval will be granted for 1 year for 1 treatment cycle.

Utilization of EB Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

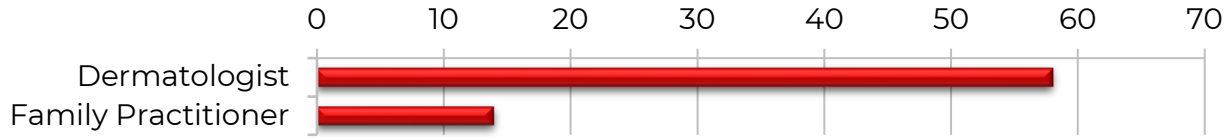
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	3	17	$536,427.97	$31,554.59	$3,030.67	404	177
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**3**	**17**	**$536,427.97**	**$31,554.59**	**$3,030.67**	**404**	**177**
Fiscal Year 2025							
FFS	3	45	$1,991,917.45	$44,264.83	$3,314.34	2,289	601
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	1	27	$682,206.75	$25,266.92	$3,609.56	68	189
2025 Total	**4**	**72**	**$2,674,124.20**	**$37,140.61**	**$3,384.97**	**2,356**	**790**
% Change	**33.30%**	**323.50%**	**398.50%**	**17.70%**	**11.70%**	**483.20%**	**346.30%**
Change	**1**	**55**	**$2,137,696.23**	**$5,586.02**	**$354.30**	**1,952**	**613**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

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

- Due to the limited number of members utilizing EB medications during fiscal year 2025, detailed demographic information could not be provided.

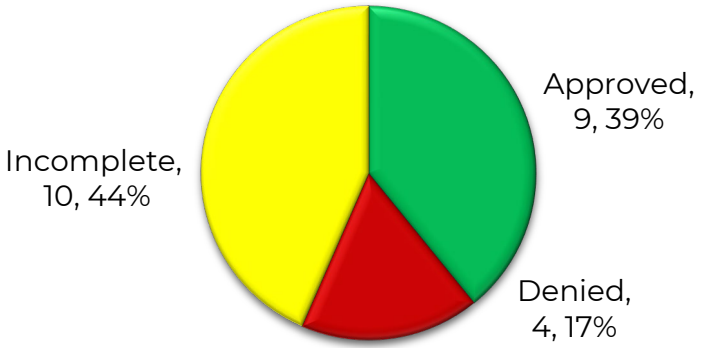
Top Prescriber Specialties of EB Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of EB Medications

There were 23 prior authorization requests submitted for EB medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	7	37%	10	53%	2	10%	**19**
Aetna	0	N/A	0	N/A	0	N/A	**0**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	2	50%	0	0%	2	50%	**4**
Total	**9**	**39%**	**10**	**44%**	**4**	**17%**	**23**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health

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

Anticipated Patent Expiration(s):

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

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

- **September 2025:** The FDA approved updates to the Vyjuvek® labeling including the following:
  - An age expansion to include treatment of patients with dystrophic epidermolysis bullosa (DEB) from birth. It was previously approved for patients 6 months of age and older with DEB.
  - Patient or caregiver administration is now allowed. It was previously only approved to be administered by a health care professional (HCP).
  - After application, patients can remove their Vyjuvek® dressings as a part of their next bandage change, rather than approximately 24 hours after application.
  - The dose increased to 1mL for patients younger than 3 years of age and 2mL for patients 3 years of age and older (from 0.8mL and 1.6mL, respectively).

Pipeline:

- **AGLE-102:** AGLE-102 is an allogeneic extracellular vesicle (EV) topical product derived from normal donor mesenchymal stem cells (MCSs)

that contains COL7 protein and COL7A1 mRNA. In preclinical models, AGLE-102 stimulated recessive DEB cells to produce COL7. It is currently being studied for the treatment of lesions in patients with recessive DEB. The Phase 1/2 clinical trial is currently recruiting patients.

- **KB803:** KB803 is a redosable, eye drop gene therapy that delivers 2 copies of the *COL7A1* transgene to the corneal epithelium, which enables local type VII collagen production in the front of the eye. KB803 is currently being studied in IOLITE, an intra-patient, double-blind, placebo-controlled, multicenter Phase 3 trial, which is looking at KB803 to treat and prevent corneal abrasions in patients with DEB. Krystal Biotech announced in June 2025 that the first patient received treatment with KB803 in their clinical trial which is ongoing.
- **SD-101 (Zorblesia™):** Zorblesia™ is a topical product being studied for treatment of skin lesions in patients with any subtype of EB. The active moiety, allantoin, has multiple actions on the skin, wound environment, and wound healing process. In May 2025, Paradigm Therapeutics announced a New Drug Application (NDA) would likely be submitted in 2025; however, there has been no update since then.

Recommendations

The College of Pharmacy recommends updating the prior authorization criteria for Vyjuvek® (beremagene geperpavec-svdt) based on the FDA approved label updates and clinical practice (changes shown in red):

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, 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~~ location (i.e., member's home, clinic) 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) or member/caregiver 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, member's home); and
    a. If member or caregiver is administering Vyjuvek®, the prescriber must attest that they will be trained on the dosing, administration, and storage of Vyjuvek®; 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~~ until the next dressing change 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. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
10. Vyjuvek® will not be approved for ~~concomitant~~ use on wounds currently treated with Filsuvez® (birch triterpenes 10% topical gel) or for use on wounds treated with Zevaskyn® (prademagene zamikeracel); and
11. A maximum approval quantity of 1 carton (2.5mL) per week will apply; and
12. 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; and
    b. Vyjuvek® must continue to be administered by an HCP or a trained member/caregiver. ~~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, member's home).

The College of Pharmacy also recommends updating the prior authorization criteria for Filsuvez® based on 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. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
9. Filsuvez® will not be approved for ~~concomitant~~ use on wounds currently treated with Vyjuvek® (beremagene geperpavec-svdt) or for use on wounds treated with Zevaskyn® (prademagene zamikeracel); and
10. 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
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 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.

Utilization Details of EB Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VYJUVEK GEL	69	3	$2,505,609.97	$36,313.19	23	93.70%
FILSUVEZ GEL 10%	3	1	$168,514.23	$56,171.41	3	6.30%
TOTAL	**72**	**4***	**$2,674,124.20**	**$37,140.61**	**18**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[2] Ernst D. Updated Vyjuvek® Label Allows for Use in Younger DEB Patients and At-Home Administration. *Medical Professionals Reference*. Available online at: https://www.empr.com/news/updated-vyjuvek-label-allows-for-use-in-younger-deb-patients-and-at-home-administration/. Issued 09/15/2025. Last accessed 06/11/2026.
[3] Vyjuvek® (Beremagene Geperpavex-svdt) Prescribing Information. Krystal Biotech, Inc. Available online at: https://www.krystallabel.com/pdf/vyjuvek-us-pi.pdf. Last revised 09/2025. Last accessed 06/11/2026.
[4] AEGLE Therapeutics. Pipeline. Available online at: https://aegletherapeutics.com/pipeline/. Last accessed 06/12/2026.
[5] MSC EVs in Dystrophic Epidermolysis Bullosa. *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT04173650. Last revised 06/25/2025. Last accessed 06/12/2026.
[6] Kyrstal Biotech, Inc. Krystal Biotech Announces First Patient Dosed in Phase 3 Clinical Trial of KB803 for the Treatment and Prevention of Corneal Abrasions in Patients with Dystrophic Epidermolysis Bullosa. Available online at: https://krystalbio.gcs-web.com/news-releases/news-release-details/krystal-biotech-announces-first-patient-dosed-phase-3-clinical. Issued 06/24/2025. Last accessed 06/12/2026.
[7] Paradigm Therapeutics, Inc. Paradigm Therapeutics. Announces Investment by Eshelman Ventures, LLC to Support Completion of Development of SD-101 (Zorblesia™), A Topical Therapy for Treatment Across the Entire Skin Surface of All Subtypes of Epidermolysis Bullosa (EB). Available online at: https://www.paradigmtherapeutics.com/news/paradigm-investment-sd101-zorblisa-eb-treatment/. Issued 05/06/2025. Last accessed 06/12/2026.
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Appendix L

Fiscal Year 2025 Annual Review of Colorectal Cancer (CRC) Medications and 30-Day Notice to Prior Authorize Jobevne™ (Bevacizumab-nwgd)

Oklahoma Health Care Authority
July 2026

Current Prior Authorization Criteria

Utilization data for Braftovi® (encorafenib), Keytruda® (pembrolizumab), Keytruda Qlex™ (pembrolizumab/berahyaluronidase alfa-pmph), Opdivo® (nivolumab), Opdivo Qvantig™ (nivolumab/hyaluronidase-nvhy), and Yervoy® (ipilimumab) and approval criteria for indications other than CRC can be found in the December 2025 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 2026 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 2025 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 April 2026 DUR packet. These medications and criteria are reviewed annually with the lung cancer medications. Utilization data for Loqtorzi® (toripalimab-tpzi) and approval criteria for indications other than CRC can be found in the August 2025 DUR packet. This medication and criteria are reviewed annually with the miscellaneous 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 colorectal cancer (CRC); and
    a. BRAF V600E mutation positive; and
    b. Used in combination with cetuximab or panitumumab; and
    c. Disease must have progressed following adjuvant therapy within 12 months; or
    d. Used following progression of any line of metastatic therapy; or
2. Diagnosis of metastatic CRC; and
    a. BRAF V600E mutation positive; and
    b. Used in combination with cetuximab and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin).

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®, Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Hercessi™, Herzuma®, or Ogivri®) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Kanjinti®, Ontruzant®, or Trazimera®). 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) and Keytruda Qlex™ (Pembrolizumab/ Berahyaluronidase Alfa-pmph) 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.

Loqtorzi® (Toripalimab-tpzi) Approval Criteria [Anal Carcinoma, Colorectal Cancer (CRC), and Small Bowel Adenocarcinoma Diagnosis]:

1. Diagnosis of anal carcinoma, CRC, or small bowel adenocarcinoma; and
2. Disease is locally unresectable, medically inoperable, advanced, or metastatic; and
3. Must meet 1 of the following:
    a. Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H); or
    b. Polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb]; and
4. No prior treatment with a checkpoint inhibitor; and
5. Used as a single agent; and
6. Dose as follows:
    a. 3mg/kg every 2 weeks.

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) and Opdivo Qvantig™ (Nivolumab/Hyaluronidase-nvhy) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite-instability high (MSI-H), mismatch repair deficient (dMMR), or has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb]; and
3. Used as a single agent or in combination with ipilimumab; and
4. Member must be 12 years of age or older; and
    a. Member must weigh ≥30kg for Opdivo Qvantig™; and

5. Opdivo Qvantig™ must not be used in combination with ipilimumab.

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 2025

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 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**
Fiscal Year 2025							
FFS	10	36	$580,642.34	$16,128.95	$576.03	2,078	1,008
Aetna	2	4	$84,501.22	$21,125.30	$754.48	162	112
Humana	4	25	$390,502.37	$15,620.09	$587.22	1,414	665
OCH	2	2	$30,548.29	$15,274.15	$545.51	120	56
2025 Total	**16**	**67**	**$1,086,194.22**	**$16,211.85**	**$590.00**	**3,774**	**1,841**
% Change	**-33.30%**	**-9.50%**	**-0.40%**	**10.00%**	**11.60%**	**-3.00%**	**-10.80%**
Change	**-8**	**-7**	**-$4,156.35**	**$1,477.38**	**$61.47**	**-116**	**-222**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Comparison of Fiscal Years: Medical Claims (All Plans)

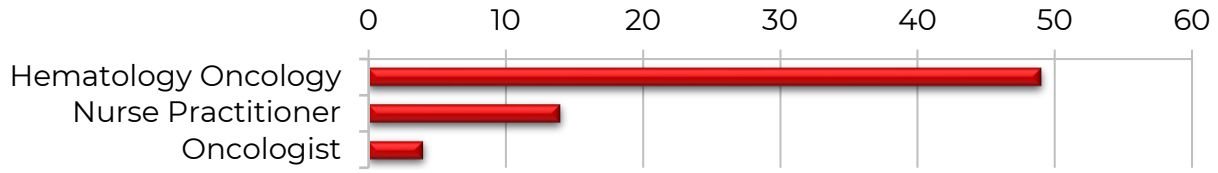
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	813	2,477	$2,556,988.28	$1,032.29	3.05
Aetna	17	33	$13,030.20	$394.85	1.94
Humana	28	43	$5,063.16	$117.75	1.54
OCH	25	36	$10,856.64	$301.57	1.44
2024 Total	**834**	**2,589**	**$2,585,938.28**	**$998.82**	**3.1**
Fiscal Year 2025					
FFS	365	1,206	$1,339,851.84	$1,110.99	3.3
Aetna	135	341	$316,807.89	$929.06	2.53
Humana	168	575	$408,332.19	$710.14	3.42
OCH	130	375	$327,383.19	$873.02	2.88
2025 Total	**740**	**2,497**	**$2,392,375.11**	**$958.10**	**3.37**
% Change	**-11.27%**	**-3.55%**	**-7.49%**	**-4.08%**	**8.71%**
Change	**-94**	**-92**	**-$193,563.17**	**-$40.72**	**0.27**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

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

- Due to the limited number of members utilizing CRC medications during fiscal year 2025, detailed demographic information could not be provided.

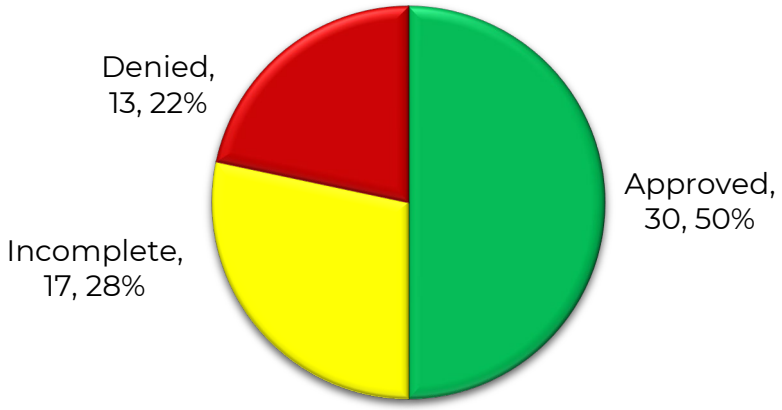
Top Prescriber Specialties of CRC Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of CRC Medications

There were 60 prior authorization requests submitted for CRC medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	22	49%	14	31%	9	20%	**45**
Aetna	1	100%	0	0%	0	0%	**1**
Humana	2	67%	0	0%	1	33%	**3**
OCH	5	45%	3	27%	3	27%	**11**
Total	**30**	**50%**	**17**	**28%**	**13**	**22%**	**60**

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

Market News and Updates[1,2]

Anticipated Patent Expirations

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

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

- **April 2025:** The FDA approved Jobevne™ (bevacizumab-nwgd), a new biosimilar to Avastin® (bevacizumab), for the treatment of the following: metastatic CRC; unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer (NSCLC); recurrent glioblastoma; metastatic renal cell carcinoma; persistent, recurrent, or metastatic cervical cancer; and epithelial ovarian, fallopian tube, or primary peritoneal cancer. Jobevne™ contains bevacizumab, which is a vascular endothelial growth factor (VEGF) inhibitor. Jobevne™ is not indicated for adjuvant treatment of colon cancer.

Cost Comparison: Bevacizumab Products

Product	Cost Per 10mg	Cost Per 28 Days*	Cost Per Year
Jobevne™ (bevacizumab-nwgd) (Q5160)	**$79.60**	**$6,368.00**	**$82,784.00**
Avastin® (bevacizumab) (J9035)	$74.36	$5,948.80	$77,334.40
Alymsys® (bevacizumab-maly) (Q5126)	$51.59	$4,127.20	$53,653.60
Vegzelma® (bevacizumab-adcd) (Q5129)	$34.65	$2,772.00	$36,036.00
Zirabev® (bevacizumab-bvzr) (Q5118)	$25.85	$2,068.00	$26,884.00
Mvasi® (bevacizumab-awwb) (Q5107)	$23.74	$1,899.20	$24,689.60

Costs do not reflect rebated prices or net costs. Costs based on payment allowance limits subject to Average Sales Price (ASP) methodology as published by the Centers for Medicare and Medicaid Services (CMS), National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 28 days is based on a dose of 5mg/kg every 2 weeks for a member weighing 80kg (400mg).
Please note: Cost information is not yet available for Avzivi® (bevacizumab-tnjn).

Recommendations

The College of Pharmacy recommends the prior authorization of Jobevne™ (bevacizumab-nwgd) with criteria similar to the other non-preferred bevacizumab products based on net costs (changes shown in red):

Alymsys® (Bevacizumab-maly), Avzivi® (Bevacizumab-tnjn), Jobevne™ (Bevacizumab-nwgd), 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.

Utilization Details of CRC Medications: Fiscal Year 2025

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	26	8	$398,660.16	$15,333.08	3.25	36.70%
LONSURF TAB 15/6.14MG	16	6	$177,285.47	$11,080.34	2.67	16.32%
SUBTOTAL	**42**	**14**	**$575,945.63**	**$13,712.99**	**3**	**53.02%**
REGORAFENIB PRODUCTS						
STIVARGA TAB 40MG	21	5	$408,780.95	$19,465.76	4.2	37.63%
SUBTOTAL	**21**	**5**	**$408,780.95**	**$19,465.76**	**4.2**	**37.63%**
FRUQUINTINIB PRODUCTS						
FRUZAQLA CAP 5MG	4	3	$101,467.64	$25,366.91	1.33	9.34%
SUBTOTAL	**4**	**3**	**$101,467.64**	**$25,366.91**	**1.33**	**9.34%**
TOTAL	**67**	**16***	**$1,086,194.22**	**$16,211.85**	**4.19**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BEVACIZUMAB J9035 (AVASTIN)	1,660	623	$937,763.58	$564.92	2.66
BEVACIZUMAB-MALY Q5126 (ALYMSYS)	291	50	$794,114.98	$2,728.92	5.82
BEVACIZUMAB-BVZR Q5118 (ZIRABEV)	280	52	$223,078.13	$796.71	5.38
BEVACIZUMAB-AWWB Q5107 (MVASI)	198	44	$213,437.02	$1,077.96	4.5
BEVACIZUMAB-ADCD Q5129 (VEGZELMA)	68	12	$223,981.40	$3,293.84	5.67
TOTAL	**2,497**	**740**	**$2,392,375.11**	**$958.10**	**3.37**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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[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 06/2026. Last accessed 06/15/2026.
[2] Biocon Biologics Ltd. Biocon Biologics Announces U.S. FDA Approval for Jobevne™, Biosimilar Bevacizumab, Expanding Its Oncology Portfolio. Available online at: https://www.bioconbiologics.com/biocon-biologics-announces-u-s-fda-approval-for-jobevne-biosimilar-bevacizumab-expanding-its-oncology-portfolio/. Issued 04/10/2025. Last accessed 06/15/2026.

Appendix M

Fiscal Year 2025 Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy)

Oklahoma Health Care Authority
July 2026

Current Prior Authorization Criteria

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 625mg & 750mg tab
metformin/ glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	alogliptin (Nesina®)	linagliptin/metformin (generic)*
	linagliptin/metformin (Jentadueto®) – **Brand Preferred**	alogliptin/metformin (Kazano®)	saxagliptin (Onglyza®)
	linagliptin/metformin ER (Jentadueto® XR)	alogliptin/ pioglitazone (Oseni®)	saxagliptin/metformin (Kombiglyze®, Kombiglyze XR®)
	sitagliptin (Januvia®)		sitagliptin (Zituvio®)*
	sitagliptin/metformin (Janumet®)		sitagliptin/metformin (Zituvimet®)*
	sitagliptin/metformin ER (Janumet XR®)		sitagliptin/metformin ER (Zituvimet® XR)*
			sitagliptin oral solution (Brynovin®)*
DPP-4 Inhibitors/SGLT-2 Inhibitors			

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
empagliflozin/ linagliptin (Glyxambi®)			dapagliflozin/ saxagliptin (Qtern®)
			ertugliflozin/sitagliptin (Steglujan®)
Dopamine Agonists			
		bromocriptine (Cycloset®)	
Glinides			
repaglinide (Prandin®)	nateglinide (Starlix®)		
	repaglinide/ metformin (Prandimet®)		
GIP/GLP-1 Agonists			
	dulaglutide (Trulicity®)	semaglutide (Ozempic®)	exenatide (Byetta®)*
	liraglutide (Victoza®) – **Brand Preferred**	semaglutide (Rybelsus®)	liraglutide (generic)*
			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**	dapagliflozin/ metformin ER (Xigduo® XR) – **Brand Preferred**	canagliflozin (Invokana®)	dapagliflozin (generic)*
empagliflozin (Jardiance®)		canagliflozin/ metformin (Invokamet®)	dapagliflozin/ metformin ER (generic)*
empagliflozin/ metformin (Synjardy®)		canagliflozin/ metformin ER (Invokamet® XR)	ertugliflozin (Steglatro®)
empagliflozin/ metformin ER (Synjardy® XR)			ertugliflozin/metformin (Segluromet®)
			sotagliflozin (Inpefa®)*
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			
Sulfonylureas			

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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 = gastric inhibitory 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 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
5. 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
6. 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
7. Use of generic linagliptin/metformin will require a patient-specific, clinically significant reason why the member cannot use brand name Jentadueto® (linagliptin/metformin); and
8. Use of Zituvio® (sitagliptin), and Zituvimet® (sitagliptin/metformin), and Zituvimet® XR (sitagliptin/metformin) 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 or guideline supported efficacy not covered by all Tier-2 and Tier-3 GLP-1 or GIP/GLP-1 agonists. Tier structure rules for unique FDA approved indications and guideline supported efficacy will apply.

Admelog® (Insulin Lispro) 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).

Afrezza® (Insulin Human Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus (DM); and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why other rapid-acting injectable insulins are not appropriate must be provided; and
4. For the diagnosis of type 1 DM, the member must use Afrezza® with a long-acting insulin; and
5. Member must not smoke or have chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

Basaglar® (Insulin Glargine) Approval Criteria:

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

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.

Inpefa® (Sotagliflozin) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure or type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use all other lower tiered SGLT-2 inhibitors that have a similar indication must be provided.

Insulin Degludec U-100 and U-200 (Unbranded Tresiba®) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use brand name Tresiba® (the brand formulation of Tresiba® is preferred); and
3. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) must be provided.

Insulin Glargine U-300 (Unbranded Toujeo®) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use brand name Toujeo® (the brand formulation of Toujeo® is preferred); and
3. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) must be provided, and the member must be using a minimum of 100 units per day.

Kerendia® (Finerenone) Approval Criteria:

1. An FDA approved indication to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and
2. Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and

3. A patient specific, clinically significant reason why the member cannot use a sodium-glucose cotransporter-2 (SGLT-2) inhibitor must be provided; and
4. Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
5. Member must not have adrenal insufficiency; and
6. Member must not have severe hepatic impairment (Child Pugh C); and
7. Prescriber must measure serum potassium and eGFR prior to initiation of Kerendia®; and
8. Prescriber must verify serum potassium is not >5.0mEq/L prior to treatment initiation with Kerendia®; and
9. Prescriber must agree to monitor serum potassium levels 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
10. Initial authorization will be for 4 weeks, after which time serum potassium levels will be required for continued approval; and
11. A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:
    a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m^2; or
    b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m^2.

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.

Rezvoglar™ (Insulin Glargine-aglr) Approval Criteria:

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

Soliqua® 100/33 (Insulin Glargine/Lixisenatide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and

2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) with an alternative glucagon-like peptide 1 (GLP-1) receptor agonist must be provided; and
3. Current Tier-3 criteria will apply.

Symlin® (Pramlintide) Approval Criteria:

1. An FDA approved diagnosis of type 1 or type 2 diabetes; and
2. Member must be using a basal-bolus insulin regimen; and
3. Member must have failed to achieve adequate glycemic control on basal-bolus insulin regimen or is gaining excessive weight on basal-bolus insulin regimen; and
4. Member must be receiving ongoing care under the guidance of a health care professional; and
5. Members meeting any of the following criteria should not be considered for Symlin® (pramlintide) therapy:
    a. Poor compliance with insulin regimen; or
    b. Poor compliance with self-blood glucose monitoring; or
    c. Hemoglobin A1C (HbA1c) >9%; or
    d. Recurrent severe hypoglycemia requiring assistance in the past 6 months; or
    e. Presence of hypoglycemia unawareness; or
    f. Diagnosis of gastroparesis; or
    g. Required use of medications that stimulate gastrointestinal motility; or
    h. Pediatric members 15 years of age or younger.

Toujeo® (Insulin Glargine) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) must be provided, and the member must be using a minimum of 100 units of insulin glargine per day.

Tresiba® (Insulin Degludec) Approval Criteria:

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

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 (documentation must be submitted with results of autoantibody testing); and
    b. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by 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 ≥140mg/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 ≥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.

Xultophy® 100/3.6 (Insulin Degludec/Liraglutide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) with Victoza® (liraglutide) must be provided; and
3. Current Tier-3 criteria will apply.

Utilization of Anti-Diabetic Medications and Kerendia® (Finerenone): Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)
Non-Insulin Anti-Diabetic Medications and Kerendia® (Finerenone)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	36,508	170,332	$90,920,707.53	$533.79	$10.49	11,535,180	8,671,089
Aetna	4,443	8,741	$4,944,080.59	$565.62	$11.08	590,326	446,337
Humana	5,784	13,778	$7,495,221.60	$544.00	$12.00	782,830	624,789
OCH	4,697	9,357	$4,897,324.27	$523.39	$11.48	547,197	426,552
2024 Total	**39,864**	**202,208**	**$108,257,333.99**	**$535.38**	**$10.65**	**13,455,532**	**10,168,767**
Fiscal Year 2025							
FFS	19,051	88,488	$48,392,608.43	$546.88	$11.61	5,341,752	4,166,688
Aetna	8,092	37,794	$23,144,112.55	$612.38	$12.06	2,473,761	1,918,703
Humana	10,093	56,784	$35,745,345.55	$629.50	$12.97	3,377,689	2,755,643
OCH	8,381	38,724	$24,295,257.65	$627.40	$11.93	2,594,850	2,036,614
2025 Total	**39,636**	**221,790**	**$131,577,324.18**	**$593.25**	**$12.10**	**13,788,051**	**10,877,648**
% Change	**-0.60%**	**9.70%**	**21.50%**	**10.80%**	**13.60%**	**2.50%**	**7.00%**
Change	**-228**	**19,582**	**$23,319,990.19**	**$57.87**	**$1.45**	**332,519**	**708,881**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for non-insulin anti-diabetic medications and Kerendia® totaled $112,923,673.15.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

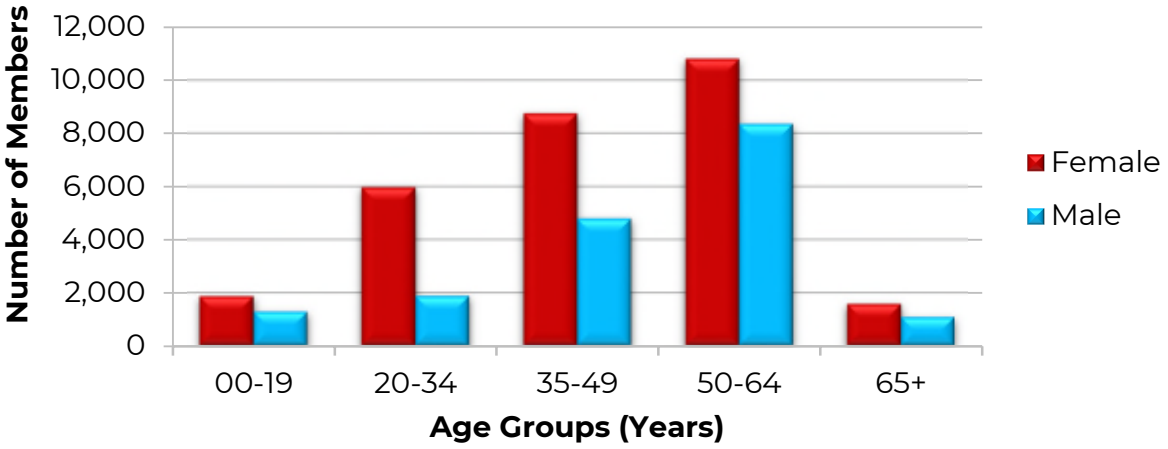
Comparison of Fiscal Years: Pharmacy Claims (All Plans)
Insulin Medications

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	14,665	73,092	$31,745,596.02	$434.32	$9.80	1,608,129	3,238,796
Aetna	1,696	3,465	$807,936.47	$233.17	$5.33	79,342	151,451
Humana	1,973	4,258	$1,017,002.77	$238.85	$5.27	94,986	192,940
OCH	1,734	3,572	$839,127.39	$234.92	$5.59	77,922	150,224
2024 Total	**15,442**	**84,387**	**$34,409,662.65**	**$407.76**	**$9.22**	**1,860,379**	**3,733,411**
Fiscal Year 2025							
FFS	8,579	38,112	$7,376,069.34	$193.54	$4.56	781,712	1,617,233
Aetna	3,021	14,755	$3,431,945.67	$232.60	$5.33	328,665	643,835
Humana	3,414	17,170	$3,823,824.18	$222.70	$4.84	389,365	789,573
OCH	3,038	14,720	$3,524,662.88	$239.45	$5.12	352,980	688,088
2025 Total	**15,406**	**84,757**	**$18,156,502.07**	**$214.22**	**$4.86**	**1,852,721**	**3,738,729**
% Change	**-0.20%**	**0.40%**	**-47.20%**	**-47.50%**	**-47.30%**	**-0.40%**	**0.10%**
Change	**-36**	**370**	**-$16,253,160.58**	**-$193.54**	**-$4.36**	**-7,658**	**5,318**

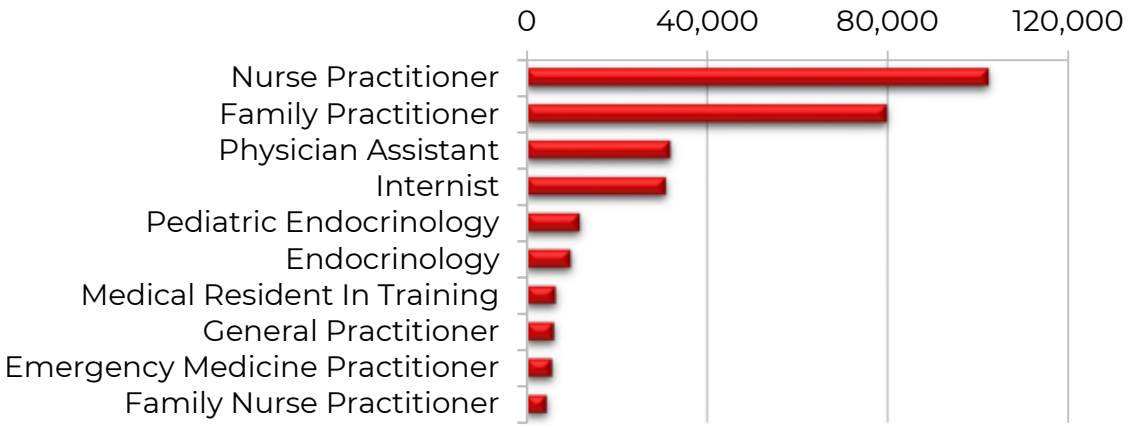
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for insulin medications totaled $12,188,248.40.[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 Anti-Diabetic Medications and Kerendia® (Finerenone): Pharmacy Claims (All Plans)



Top Prescriber Specialties of Utilizing Anti-Diabetic Medications and Kerendia® (Finerenone) by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Anti-Diabetic Medications and Kerendia® (Finerenone)

There were 24,022 prior authorization requests submitted for anti-diabetic medications and Kerendia® during fiscal year 2025. Of the 24,022 total prior authorization requests submitted, 20,791 were for non-insulin anti-diabetic medications and Kerendia® and 3,231 were for insulin medications. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	3,401	24%	7,667	53%	3,373	23%	**14,441**
Aetna	955	27%	1,426	40%	1,197	33%	**3,578**
Humana	547	38%	0	0%	896	62%	**1,443**
OCH	2,379	52%	635	14%	1,546	34%	**4,560**
Total	**7,282**	**30%**	**9,728**	**41%**	**7,012**	**29%**	**24,022**

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

Market News and Updates[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23]

Anticipated Patent Expiration(s):

- Januvia® (sitagliptin tablet): May 2027
- Janumet® XR (sitagliptin/metformin ER tablet): May 2027
- Onglyza® (saxagliptin tablet): November 2028
- Janumet® (sitagliptin/metformin tablet): January 2029
- Actoplus Met® (pioglitazone/metformin tablet): February 2029
- Invokana® (canagliflozin tablet): August 2029
- Invokamet® XR (canagliflozin/metformin ER tablet): August 2029
- Qtern® (dapagliflozin/saxagliptin tablet): June 2030
- Invokamet® (canagliflozin/metformin tablet): July 2030
- Inpefa® (sotagliflozin tablet): October 2030
- Farxiga® (dapagliflozin tablet): November 2030
- Xigduo® XR (dapagliflozin/metformin ER tablet): May 2031
- Segluromet® (ertugliflozin/metformin tablet): December 2031
- Steglatro® (ertugliflozin tablet): December 2031
- Steglujan® (ertugliflozin/sitagliptin tablet): December 2031
- Cycloset® (bromocriptine tablet): April 2032
- Ozempic® (semaglutide injection): June 2033
- Synjardy® (empagliflozin/metformin tablet): November 2034
- Jardiance® (empagliflozin tablet): December 2034
- Synjardy® XR (empagliflozin/metformin ER tablet): December 2034
- Zituvio™ (sitagliptin tablet): February 2035
- Kerendia® (finerenone tablet): July 2035
- Victoza® (liraglutide injection): July 2037
- Glyxambi® (empagliflozin/linagliptin tablet): December 2037
- Jentadueto® (linagliptin/metformin tablet): December 2037
- Jentadueto® XR (linagliptin/metformin ER tablet): December 2037
- Tradjenta® (linagliptin tablet): December 2037
- Trijardy® XR (empagliflozin/linagliptin/metformin ER tablet): December 2037
- Ozempic® (semaglutide tablet): February 2039
- Rybelsus® (semaglutide tablet): February 2039
- Brynovin™ (sitagliptin oral solution): October 2040
- Mounjaro® (tirzepatide injection): December 2041

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

- **July 2025:** Kerendia® (finerenone) was approved for a new indication to reduce the risk of cardiovascular (CV) death, hospitalization for heart failure (HF), and urgent HF visits in adult patients with HF with left ventricular ejection fraction (LVEF) ≥40%. The approval was based on results from the Phase 3 FINEARTS-HF trial, which showed that Kerendia® plus standard of care achieved a 16% relative risk reduction of the composite primary endpoint of CV death and total HF events,

defined as hospitalization for HF or an urgent HF visit, compared to placebo plus standard of care [relative risk (RR): 0.84; 95% confidence interval (CI): 0.74, 0.95; P=0.007]. The treatment effect was consistent across all prespecified subgroups including with or without sodium-glucose cotransporter-2 (SGLT-2) inhibitor use.

- **July 2025:** The FDA approved Kirsty™ (insulin aspart-xjhz) as an interchangeable biosimilar to Novolog® (insulin aspart). Kirsty™ is the first interchangeable rapid-acting insulin biosimilar product approved by the FDA and is the second biosimilar to Novolog®. Kirsty™ is available as 100 units/mL in a 10mL multiple-dose vial and in a 3mL prefilled pen.
- **October 2025:** Rybelsus® (semaglutide) was approved for a new indication to reduce the risk of major adverse CV events (MACE), including CV death, non-fatal myocardial infarction (MI) or non-fatal stroke, in adults with type 2 diabetes mellitus (T2DM) who are at high risk for these events. The approval of Rybelsus® for the new indication was based on SOUL, a randomized, double-blind, placebo-controlled trial in patients with T2DM and established CV disease and/or chronic kidney disease (CKD). The primary endpoint was the time to the first occurrence of MACE, a 3-part composite outcome which included CV death, non-fatal MI, and non-fatal stroke. MACE events occurred in 12% of patients in the Rybelsus® group vs. 13.8% of patients in the placebo group (hazard ratio: 0.86; 95% CI: 0.77, 0.96; P=0.006).
- **December 2025:** Mounjaro® (tirzepatide) was approved for an age expansion in patients 10 years of age and older with T2DM. The approval of the age expansion was based on SURPASS-PEDS, a randomized, double-blind, placebo-controlled trial in patients 10 years of age and older with T2DM with inadequate glycemic control on metformin, or basal insulin, or both. The mean change from baseline in hemoglobin A1c (HbA1c) was -1.9% and -2.2% with Mounjaro® 5mg and 10mg, respectively, vs. -0.2% with placebo (P<0.001 vs. placebo for both dosages). Mounjaro® was previously only approved in adults.
- **February 2026:** The FDA approved Ozempic® (semaglutide) tablets for the same indications as Rybelsus®. Rybelsus® was first approved by the FDA in 2019 in 3mg, 7mg, and 14mg strengths. The original strengths have been reformulated and are now being introduced as Ozempic® tablets in 1.5mg, 4mg, and 9mg strengths. The new Ozempic® tablets work similarly to Rybelsus® 3mg, 7mg, and 14mg tablets and have the same efficacy and safety profile as the original formulation offered in a smaller pill. The product has been renamed to help patients and health care professionals more easily recognize the available treatment options for T2DM that contain semaglutide.

- **March 2026:** The FDA approved Awiqli® (insulin icodec-abae) as the first and only once-weekly, long-acting basal insulin as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
- **April 2026:** The FDA approved Langlara™ (insulin glargine-aldy) as an interchangeable biosimilar to Lantus® (insulin glargine) for the treatment of adults and pediatric patients with type 1 diabetes mellitus (T1DM) and adults with T2DM. The cost of Langlara™ is not yet available.
- **April 2026:** Tzield® (teplizumab-mzwv) was approved for an expanded indication to delay the onset of Stage 3 T1DM in patients 1 year of age or older who are diagnosed with Stage 2 T1DM. The approval was supported by 1 year data from the PETITE-T1D Phase 4 trial evaluating safety and pharmacokinetics in 23 patients 1 year to younger than 8 years of age. Previously, Tzield® was approved for this indication in patients 8 years of age and older.
- **June 2026:** The FDA approved Afrezza® (insulin human) for an age expansion in patients 6 years of age and older with T1DM or T2DM. Previously, Afrezza® was only approved for use in adults.
- **June 2026:** The FDA granted accelerated approval to Tzield® (teplizumab-mzwv) to delay the decline in endogenous insulin production for pediatric patients 8 to 17 years of age recently diagnosed with Stage 3 T1DM based on evidence of reduced C-peptide decline. The approval was supported by data from the PROTECT Phase 3 trial evaluating beta cell function as assessed by significantly slowing the decrease in mean C-peptide levels (area under the curve after a four-hour, mixed-meal tolerance test; difference in least-squares mean: 0.13pmol/mL; 95% CI: 0.09, 0.17; P<0.001) at trial completion, compared to placebo, as well as data from the broader clinical development program that included over 900 patients who received Tzield®. Additionally, a *Boxed Warning* was added to the *Prescribing Information* based on cases of life-threatening viral reactivation, and Tzield® is now contraindicated in patients who are immunocompromised or who have an active viral infection.

News:

- **February 2026:** A new formulation of glipizide, available as a 15mg immediate-release tablet, has been launched. Glipizide is also available as 2.5mg, 5mg, and 10mg immediate-release tablets.
- **April 2026:** A first-time generic formulation of Farxiga® (dapagliflozin) tablets was launched.
- **May 2026:** Generic formulations of Januvia® (sitagliptin) tablets and Janumet® (sitagliptin/metformin) tablets were launched.

Guideline Update(s):

- **American Diabetes Association (ADA) Guideline Update(s):** The ADA released the *Standards of Medical Care in Diabetes 2026*, to include strategies for diagnosing and treating diabetes in children, adolescents, and adults; methods to prevent or delay diabetes and its associated comorbidities like obesity; and care recommendations to enhance health outcomes. Some notable updates and additions include:
  - Recommended use of continuous glucose monitoring at diabetes onset and anytime thereafter to improve outcomes for anyone who could benefit from its use in diabetes management
  - New guidance removing the need to meet certain treatment requirements before initiation of continuous subcutaneous (sub-Q) insulin infusion or automated insulin delivery
  - New guidance on glucose-lowering therapies in people with CKD, including use by those on dialysis
  - Additional guidance on the use of glucose-lowering therapy beyond obesity and glycemic treatment, including heart, kidney, and liver health benefits
  - Expanded guidance on screening and monitoring individuals at risk for T1DM, including the utilization of diabetes technology
  - New and updated algorithms on insulin therapy in T1DM, prevention and treatment of symptomatic HF, and CKD treatment and atherosclerotic CV disease prevention in people with T2DM

Pipeline:

- **CagriSema:** CagriSema is an investigational once-weekly sub-Q fixed-dose combination of cagrilintide, a long-acting amylin receptor agonist, and semaglutide, a long-acting glucagon-like peptide 1 (GLP-1) receptor agonist. CagriSema is being studied for the treatment of T2DM in the REIMAGINE clinical trial program in several Phase 3 trials across various stages of disease. Data from the trials was presented and showed that the primary endpoints were met and CagriSema demonstrated significant reductions in HbA1c when compared to placebo or semaglutide alone. Based on results of the REIMAGINE trials, Novo Nordisk has announced they plan to discuss the regulatory pathway for CagriSema in T2DM.
- **Mounjaro® (Tirzepatide):** Mounjaro® is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 receptor agonist currently FDA approved for the treatment of T2DM in patients 10 years of age and older. It is currently being studied in the Phase 3 SURPASS-CVOT trial comparing Mounjaro® to Trulicity® (dulaglutide) in patients with T2DM and established CVD. Mounjaro® achieved the primary endpoint of non-inferiority with an 8% lower risk of CV death, heart attack, or stroke when compared to Trulicity® (hazard ratio: 0.92; 95.3% CI: 0.83, 1.01).

Mounjaro® has been submitted to the FDA for the reduction of adverse CV outcomes in patients with T2DM but no official Prescription Drug User Fee Act (PDUFA) date has been announced.

Awiqli® (Insulin Icodec-abae) Product Summary[24,25]

Therapeutic Class: Human insulin analog

Indication(s): Adjunct to diet and exercise to improve glycemic control in adults with T2DM

How Supplied: 700 units/mL in 1mL, 1.5mL, and 3mL FlexTouch® prefilled pens

Dosing and Administration:

- Awiqli® should be injected sub-Q once weekly on any day of the week on the same day each week.
- The Awiqli® FlexTouch® pen delivers doses in 10-unit increments and can deliver up to 700 units in a single injection.
- The dose of Awiqli® should be individualized and titrated based on the patient's metabolic needs, blood glucose monitoring results, and glycemic control goal.
- Due to the long half-life of Awiqli®, adjustment of dose is not advised during acute illness nor if patients make short-term changes in their physical activity level or usual diet. In these situations, other applicable adjustments should be considered.

Efficacy: The safety and efficacy of Awiqli® were evaluated in 3 randomized, open-label, treat-to-target, active-controlled trials (Trials A, B, and C) and 1 randomized, double-blind, treat-to-target, active-controlled trial (Trial D).

- Key Inclusion Criteria:
  - Trials A and B: Insulin-naïve adults with T2DM inadequately controlled on ≥1 oral antidiabetic or GLP-1 receptor agonist
  - Trial C: Adults with T2DM treated with once- or twice-daily basal insulin with/without oral antidiabetics
  - Trial D: Adults with T2DM inadequately controlled on once-daily basal insulin with bolus insulin with/without oral antidiabetics/GLP-1 receptor agonist
- Intervention(s):
  - Trial A: Awiqli® once weekly or insulin glargine once daily
  - Trials B and C: Awiqli® once weekly or insulin degludec once daily
  - Trial D: Awiqli® once weekly or insulin glargine once daily both in combination with mealtime insulin aspart
- Primary Endpoint: Change from baseline in HbA1c at week 52 for Trial A or week 26 for Trials B, C, and D

- All trials were compared with a non-inferiority upper limit of 0.3%.
- In Trials A, B, and C, if non-inferiority was shown, there were subsequent tests for superiority in percentage of time in target range and HbA1c.

- Results: T2DM insulin-naïve patients and basal-only patients treated with Awiqli® achieved statistically significant improvement in glycemic control compared to insulin glargine or insulin degludec. T2DM patients with basal-bolus regimens achieved similar glycemic control with Awiqli® as those achieved with insulin glargine or insulin degludec.
  - Trial A: Awiqli® led to a -1.51% reduction in HbA1c compared to a -1.33% reduction in the insulin glargine group (treatment difference: -0.18%; 95% CI: -0.29%, -0.08%)
    - Awiqli® led to a statistically significant longer time in range compared to insulin glargine during the last 4 weeks of Trial A (56.52% vs. 44.57%, respectively).
  - Trial B: Awiqli® led to a -1.56% reduction in HbA1c compared to a -1.34% reduction in the insulin degludec group (treatment difference: -0.22%; 95% CI: -0.35%, -0.09%)
  - Trial C: Awiqli® led to a -0.90% reduction in HbA1c compared to a -0.71% reduction in the insulin degludec group (treatment difference: -0.19%; 95% CI: -0.32%, -0.06%)
  - Trial D: Awiqli® led to a -1.16% reduction in HbA1c, meeting the non-inferiority margin, when compared to a -1.18% reduction in the insulin glargine group (treatment difference: 0.02%; 95% CI: -0.11%, 0.15%).

Cost: The cost of Awiqli® is not yet available.

Recommendations

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

1. Prior authorization of glipizide 15mg tablet and placement into the Special Prior Authorization (PA) Tier with the following additional criteria; and
2. Designating Januvia® (sitagliptin) and Janumet® (sitagliptin/metformin) as brand preferred and moving generic sitagliptin, generic sitagliptin/metformin, and Janumet XR® (sitagliptin/metformin ER) to the Special PA Tier with the following additional criteria based on net costs; and
3. Moving Onglyza® (saxagliptin) from the Special PA Tier to Tier-3 based on net costs; and
4. Moving Nesina® (alogliptin) and Oseni® (alogliptin/pioglitazone) from Tier-3 to the Special PA Tier based on net costs; and

5. Moving Zituvio® (sitagliptin), Zituvimet® (sitagliptin/metformin), and Zituvimet® XR (sitagliptin/metformin ER) from Special PA to Tier-2 based on net costs and generic availability; and
6. Removing the brand preferred status from Farxiga® (dapagliflozin) and moving generic dapagliflozin from the Special PA Tier to Tier-1 based on net costs; and
7. Updating the GLP-1 Agonists and Glucose-Dependent Insulinotropic Polypeptide (GIP)/GLP-1 Agonists Special PA Approval Criteria based on clinical practice and for clarity.

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 625mg & 750mg tab
metformin/ glyburide (Glucovance®)			
DPP-4 Inhibitors			
	linagliptin (Tradjenta®)	~~**alogliptin (Nesina®)**~~	**alogliptin (Nesina®)**
	linagliptin/metformin (Jentadueto®) **– Brand Preferred**	alogliptin/metformin (Kazano®)	**alogliptin/ pioglitazone (Oseni®)**
	linagliptin/metformin ER (Jentadueto® XR)	~~**alogliptin/ pioglitazone (Oseni®)**~~	linagliptin/metformin (generic)*
	sitagliptin (Januvia®) **– Brand Preferred**	**saxagliptin (Onglyza®)**	~~**saxagliptin (Onglyza®)**~~
	sitagliptin (Zituvio®)		saxagliptin/metformin (Kombiglyze®, Kombiglyze XR®)
	sitagliptin/metformin (Janumet®) **– Brand Preferred**		**sitagliptin (generic Januvia®)***
	~~**sitagliptin/ metformin ER (Janumet XR®)**~~		~~**sitagliptin (Zituvio®)***~~

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
	sitagliptin/ metformin (Zituvimet®)		**sitagliptin/metformin (generic Janumet®)***
	sitagliptin/ metformin ER (Zituvimet® XR)		**sitagliptin/metformin ER (Janumet XR®)***
			~~**sitagliptin/metformin (Zituvimet®)***~~
			~~**sitagliptin/metformin ER (Zituvimet® XR)***~~
			sitagliptin oral solution (Brynovin®)*
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®)		
GIP/GLP-1 Agonists			
	dulaglutide (Trulicity®)	semaglutide (Ozempic®)	exenatide (Byetta®)*
	liraglutide (Victoza®) – **Brand Preferred**	semaglutide (Rybelsus®)	liraglutide (generic)*
			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**~~	dapagliflozin/ metformin ER (Xigduo® XR) – **Brand Preferred**	canagliflozin (Invokana®)	~~**dapagliflozin (generic)***~~
empagliflozin (Jardiance®)		canagliflozin/ metformin (Invokamet®)	dapagliflozin/ metformin ER (generic)*

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
empagliflozin/ metformin (Synjardy®)		canagliflozin/ metformin ER (Invokamet® XR)	ertugliflozin (Steglatro®)
empagliflozin/ metformin ER (Synjardy® XR)			ertugliflozin/metformin (Segluromet®)
			sotagliflozin (Inpefa®)*
SGLT-2 Inhibitors/DPP-4 Inhibitors/Biguanides			
empagliflozin/ linagliptin/ metformin ER (Trijardy® XR)			
Sulfonylureas			
glimepiride (Amaryl®)			glimepiride 3mg tablet*
glipizide (Glucotrol®)			glipizide 2.5mg immediate-release tablet*
glipizide SR (Glucotrol XL®)			**glipizide 15mg immediate-release tablet***
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 = gastric inhibitory 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 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 generic ~~dapagliflozin or~~ dapagliflozin/metformin ER will require a patient-specific, clinically significant reason why the 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
5. 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
6. 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
7. Use of glipizide 15mg 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 glipizide to achieve the 15mg dose; and
8. Use of generic linagliptin/metformin will require a patient-specific, clinically significant reason why the member cannot use brand name Jentadueto® (linagliptin/metformin); and
9. Use of generic sitagliptin (generic Januvia®) or sitagliptin/metformin (generic Janumet®) will require a patient-specific, clinically significant reason why the member cannot use brand name Januvia® (sitagliptin) or Janumet® (sitagliptin/metformin) and all available lower-tiered dipeptidyl peptidase-4 inhibitors (DPP-4 inhibitors); and
10. Use of Janumet XR® (sitagliptin/metformin ER) ~~Zituvio® (sitagliptin), and Zituvimet® (sitagliptin/metformin), and Zituvimet® XR (sitagliptin/metformin)~~ 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. Documentation of member's current A1c and goal A1c must be submitted with all requests; and
4. Member must meet 1 of the following:
    a. Member must be currently stabilized on the requested product [documentation must be provided (e.g., pharmacy records and clinical documentation of glycemic control and/or reduction in A1c while on therapy)]; or
    b. Member must have failed to achieve glycemic control and/or goal A1c reduction despite a trial at least 3 months in duration and at recommended dosing (and member must be adherent to therapy) with all available lower-tiered GLP-1 or GIP/GLP-1 agonists and have a documented clinical reason why the member cannot continue treatment with the lower tier medications; and
        i. Clinical documentation of follow-up glycemic status after trials (e.g., A1c levels, blood glucose levels) must be provided; and
        ii. For members who did not complete a 3-month trial with a lower-tiered GLP-1 or GIP/GLP-1 agonist (i.e., due to intolerable adverse effects), detailed information regarding adverse effects occurring with the lower-tiered medication(s) that are not expected to occur with the requested medication must be provided; and
5. Use of generic liraglutide will require a patient-specific, clinically significant reason why the member cannot use brand name Victoza® (liraglutide); and
6. A clinical exception will apply for medications with a unique FDA approved indication or guideline supported efficacy not covered by all Tier-2 and Tier-3 GLP-1 or GIP/GLP-1 agonists. Tier structure rules for unique FDA approved indications and guideline supported efficacy will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Awiqli® (insulin icodec-abae) with the following criteria, Kirsty™ (insulin aspart-xjhz) with criteria similar to Merilog™ (insulin aspart-szjj), and Langlara™ (insulin glargine-aldy) with criteria similar to Rezvoglar™ (insulin glargine-aglr) (changes shown in red):

Awiqli® (Insulin Icodec-abae) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use a daily basal insulin must be provided.

Kirsty™ (Insulin Aspart-xjhz) and 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.

Langlara™ (Insulin Glargine-aldy) and Rezvoglar™ (Insulin Glargine-aglr) Approval Criteria:

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

Next, the College of Pharmacy recommends removing the prior authorization from Humalog® KwikPen® U-200 (insulin lispro 200 units/mL), Lyumjev® U-100 (insulin lispro-aabc 100 units/mL), and brand name Tresiba® (insulin degludec) based on net costs and updating the Xultophy® 100/3.6 (insulin degludec/liraglutide) approval criteria based on the removal of the prior authorization from Tresiba® (changes shown in red):

Admelog® (Insulin Lispro) ~~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) or Lyumjev® U-100 (insulin lispro-aabc 100 units/mL).

~~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; and
3. A patient-specific, clinically significant reason why the member cannot use Humalog® Kwikpen® U-200 (insulin lispro 200 units/mL).

~~Tresiba® (Insulin Degludec) Approval Criteria:~~

~~1. An FDA approved diagnosis of diabetes mellitus; and~~

~~2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine) or Semglee® (insulin glargine-yfgn) must be provided.~~

Xultophy® 100/3.6 (Insulin Degludec/Liraglutide) Approval Criteria:

1. An FDA approved diagnosis of type 2 diabetes mellitus; and
2. A patient-specific, clinically significant reason why the member cannot use Lantus® (insulin glargine), ~~or~~ Semglee® (insulin glargine-yfgn), or brand name Tresiba® (insulin degludec) with Victoza® (liraglutide) must be provided; and
3. Current Tier-3 criteria will apply.

Next, the College of Pharmacy recommends updating the Afrezza® (insulin human inhalation powder) approval criteria based on the FDA approved age expansion (changes shown in red):

Afrezza® (Insulin Human Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of diabetes mellitus (DM); and
2. Member must be 6 ~~18~~ years of age or older; and
3. A patient-specific, clinically significant reason why other rapid-acting injectable insulins are not appropriate must be provided; and
4. For the diagnosis of type 1 DM, the member must use Afrezza® with a long-acting insulin; and
5. Member must not smoke or have chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

Additionally, the College of Pharmacy recommends updating the Kerendia® (finerenone) approval criteria based on the new FDA approved indication and clinical practice (changes shown in red):

Kerendia® (Finerenone) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. To reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure (HF) in adult members with chronic kidney disease (CKD) associated with type 2 diabetes mellitus (T2DM); and
        i. Member must be receiving a maximum tolerated dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or have a contraindication to use; and
        ii. Member has albuminuria (urine albumin-to-creatinine ratio ≥30mg/g) despite maximum tolerated dosing of an ACE or ARB; or

b. To reduce the risk of cardiovascular death, hospitalization for HF, and urgent HF visits in adult members with HF with left ventricular ejection fraction (LVEF) ≥40%; and
    i. Member is currently receiving guideline-directed management and therapy (GDMT) appropriate to their stage of HF or has a contraindication or documented intolerance to GDMT; and
2. Member is currently stabilized on a sodium-glucose cotransporter-2 (SGLT-2) inhibitor or a patient specific, clinically significant reason why the member cannot use an SGLT-2 inhibitor must be provided; and
3. Member must not be receiving concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir); and
4. Member must not have adrenal insufficiency; and
5. Member must not have severe hepatic impairment (Child Pugh C); and
6. Prescriber must measure serum potassium and eGFR and verify the member meets the following prior to initiation of Kerendia®; and
    a. Serum potassium ≤5mEq/L; and
    b. eGFR ≥25mL/min/1.73m^2; and
~~7. Prescriber must verify serum potassium is not >5.0mEq/L prior to treatment initiation with Kerendia®; and~~
8. Prescriber must agree to monitor serum potassium levels 4 weeks after a dose adjustment and throughout treatment and adjust the dose accordingly per package labeling; and
~~9. Initial authorization will be for 4 weeks, after which time serum potassium levels will be required for continued approval; and~~
10. A quantity limit of 30 tablets per 30 days will apply. The member's eGFR should be provided for initiation of treatment to ensure the correct recommended dose per package labeling. The following initial dose will be approved based on eGFR:
    a. Kerendia® 10mg once daily in members with eGFR 25 to <60mL/min/1.73m^2; or
    b. Kerendia® 20mg once daily in members with eGFR ≥60mL/min/1.73m^2; and
11. A maximum approvable dose will apply based on indication per the package labeling:
    a. CKD associated with T2DM: 20mg once daily; or
    b. HF with LVEF ≥40%: 40mg once daily; and
12. 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 and that serum potassium levels and eGFR are monitored periodically and the dose is adjusted accordingly per the package labeling. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends updating the Tzield® (teplizumab-mzwv) approval criteria based on the new FDA approvals and label updates (changes shown in red):

Tzield® (Teplizumab-mzwv) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Stage 2 Type 1 diabetes mellitus (DM). Diagnosis must be confirmed by the following:
        i. Laboratory testing confirming the presence of ≥2 pancreatic islet autoantibodies (documentation must be submitted with results of autoantibody testing); and
        ii. Documented evidence of dysglycemia without overt hyperglycemia as demonstrated by 1 of the following (results of lab testing must be submitted):
            1. Fasting plasma glucose ≥100mg/dL and <126mg/dl; or
            2. 2-hour plasma glucose ≥140 mg/dL and <200mg/dl; or
            3. Hemoglobin A1c ≥5.7% and <6.5% or ≥10% increase in A1c; or
            4. 30-, 60-, or 90-minute value ≥200mg/dl on 2 separate occasions; ~~and~~ or
    b. Recently diagnosed Stage 3 Type 1 DM. Diagnosis must be confirmed by the following:
        i. Member was diagnosed within the last 8 weeks; and
        ii. Laboratory testing confirming the presence of ≥1 pancreatic islet autoantibody (documentation must be submitted with results of autoantibody testing); and
        iii. Peak C-peptide ≥0.2pmol/mL (results of lab testing must be submitted); and
2. Member must be:
    a. ~~8 years~~ 1 year of age or older for Stage 2 Type 1 DM; or
    b. 8 to 17 years of age for Stage 3 Type 1 DM; and
3. ~~Prescriber must confirm that member's clinical history does not suggest a diagnosis of Type 2 DM; and~~
4. Prescriber must confirm that the member's diagnosis is of autoimmune origin and does not suggest insulin resistance due to obesity, type 2 diabetes mellitus (T2DM), or dysglycemia due to other forms of diabetes including but not limited to genetic forms of diabetes, maturity-onset diabetes of the young (MODY), latent autoimmune diabetes in adults (LADA), or diabetes secondary to medications or surgery; and
5. Tzield® must be prescribed by an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
6. ~~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~~

7. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Tzield®; and
8. Prescriber must confirm that the member does not have any contraindications for use of Tzield®; and
9. Prescriber must verify that Tzield® treatment will be interrupted and/or discontinued when appropriate, as per the package labeling [e.g., prolonged severe lymphopenia, viral reactivation, liver enzymes >5 times the upper limit of normal (ULN), or bilirubin >3 times ULN, severe cytokine release syndrome, serious infections]; and
10. 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
11. 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
12. A quantity limit of 28mL per 14 days will apply; and
13. Approvals will be for the following:
    a. Stage 2 T1DM: (1) 14-day cycle per member per lifetime; or
    b. Stage 3 T1DM: (2) 12-day cycles per member per lifetime.

Utilization Details of Anti-Diabetic Medications and Kerendia® (Finerenone): Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GLP-1/GIP AGONIST PRODUCTS						
TIER-2 PRODUCTS						
TRULICITY INJ 0.75MG/0.5ML	12,485	4,531	$13,225,218.21	$1,059.29	2.76	10.05%
TRULICITY INJ 1.5MG/0.5ML	12,355	3,789	$13,528,995.07	$1,095.02	3.26	10.28%
TRULICITY INJ 3MG/0.5ML	8,996	2,447	$9,996,154.64	$1,111.18	3.68	7.60%
TRULICITY INJ 4.5MG/0.5ML	6,707	1,453	$7,728,809.82	$1,152.35	4.62	5.87%
VICTOZA INJ 18MG/3ML	1,783	731	$1,402,697.19	$786.71	2.44	1.07%
BYETTA INJ 5MCG	84	45	$76,914.06	$915.64	1.87	0.06%
BYETTA INJ 10MCG	31	16	$25,615.67	$826.31	1.94	0.02%
TIER-2 SUBTOTAL	**42,441**	**13,012**	**$45,984,404.66**	**$1,083.49**	**3.26**	**34.95%**
TIER-3 PRODUCTS						
OZEMPIC INJ 8MG/3ML	8,393	1,462	$8,043,796.82	$958.39	5.74	6.11%
OZEMPIC INJ 2MG/3ML	6,431	2,269	$6,171,000.98	$959.57	2.83	4.69%
OZEMPIC INJ 4MG/3ML	6,153	1,731	$5,896,623.72	$958.33	3.55	4.48%
RYBELSUS TAB 7MG	337	101	$324,919.20	$964.15	3.34	0.25%
RYBELSUS TAB 14MG	299	69	$285,752.07	$955.69	4.33	0.22%
RYBELSUS TAB 3MG	201	90	$192,116.72	$955.80	2.23	0.15%
BYDUREON BC INJ 2MG/0.85ML	53	18	$45,907.36	$866.18	2.94	0.03%
TIER-3 SUBTOTAL	**21,867**	**5,740**	**$20,960,116.87**	**$958.53**	**3.81**	**15.93%**
SPECIAL PA PRODUCTS						
MOUNJARO INJ 5MG/0.5ML	2,580	888	$2,698,172.73	$1,045.80	2.91	2.05%
MOUNJARO INJ 7.5MG/0.5ML	2,456	751	$2,568,994.49	$1,046.01	3.27	1.95%
MOUNJARO INJ 10MG/0.5ML	2,039	618	$2,141,754.42	$1,050.39	3.3	1.63%
MOUNJARO INJ 15MG/0.5ML	1,988	329	$2,091,077.24	$1,051.85	6.04	1.59%
MOUNJARO INJ 2.5MG/0.5ML	1,782	785	$1,865,249.44	$1,046.72	2.27	1.42%
LIRAGLUTIDE INJ 18MG/3ML	1,451	627	$918,957.59	$633.33	2.31	0.70%
MOUNJARO INJ 12.5MG/0.5ML	1,398	388	$1,463,609.55	$1,046.93	3.6	1.11%
EXENATIDE INJ 10MCG	3	2	$2,359.68	$786.56	1.5	0.00%
EXENATIDE INJ 5MCG	1	1	$782.56	$782.56	1	0.00%
SPECIAL PA SUBTOTAL	**13,698**	**4,389**	**$13,750,957.70**	**$1,003.87**	**3.12**	**10.45%**
GLP-1/GIP AGONIST TOTAL	**78,006**	**23,141**	**$80,695,479.23**	**$1,034.48**	**3.37**	**61.33%**
BIGUANIDE PRODUCTS						
TIER-1 PRODUCTS						
METFORMIN TAB 500MG	29,758	11,349	$334,648.15	$11.25	2.62	0.25%
METFORMIN TAB 1,000MG	19,943	6,968	$239,728.80	$12.02	2.86	0.18%
METFORMIN TAB 500MG ER	19,038	7,879	$240,756.87	$12.65	2.42	0.18%
METFORMIN TAB 750MG ER	1,986	821	$28,294.65	$14.25	2.42	0.02%
METFORMIN TAB 850MG	1,112	459	$12,595.35	$11.33	2.42	0.01%
TIER-1 SUBTOTAL	**71,837**	**27,476**	**$856,023.82**	**$11.92**	**2.61**	**0.65%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPECIAL PA PRODUCTS						
METFORMIN OSM TAB 1,000 ER	115	36	$2,387.19	$20.76	3.19	0.00%
METFORMIN SOL 500MG/5ML	89	18	$21,022.19	$236.20	4.94	0.02%
METFORMIN MOD TAB 1,000 ER	23	12	$736.42	$32.02	1.92	0.00%
METFORMIN OSM TAB 500MG ER	22	15	$392.83	$17.86	1.47	0.00%
METFORMIN MOD TAB 500MG ER	18	9	$527.86	$29.33	2	0.00%
METFORMIN TAB 625MG	1	1	$1,972.43	$1,972.43	1	0.00%
SPECIAL PA SUBTOTAL	**268**	**91**	**$27,038.92**	**$100.89**	**2.95**	**0.02%**
BIGUANIDE TOTAL	**72,105**	**27,567**	**$883,062.74**	**$12.25**	**2.62**	**0.67%**
SGLT-2 INHIBITOR PRODUCTS						
TIER-1 PRODUCTS						
JARDIANCE TAB 25MG	12,316	3,817	$14,640,698.98	$1,188.75	3.23	11.13%
JARDIANCE TAB 10MG	11,501	4,287	$12,624,807.96	$1,097.71	2.68	9.59%
FARXIGA TAB 10MG	11,223	3,287	$10,651,855.37	$949.11	3.41	8.10%
FARXIGA TAB 5MG	2,364	821	$2,115,652.67	$894.95	2.88	1.61%
TIER-1 SUBTOTAL	**37,404**	**12,212**	**$40,033,014.98**	**$1,070.29**	**3.06**	**30.43%**
TIER-3 PRODUCTS						
INVOKANA TAB 300MG	192	44	$176,228.84	$917.86	4.36	0.13%
INVOKANA TAB 100MG	146	45	$143,795.13	$984.90	3.24	0.11%
TIER-3 SUBTOTAL	**338**	**89**	**$320,023.97**	**$946.82**	**3.8**	**0.24%**
SPECIAL PA PRODUCTS						
DAPAGLIFLOZIN TAB 10MG	563	487	$313,609.33	$557.03	1.16	0.24%
DAPAGLIFLOZIN TAB 5MG	117	106	$61,886.11	$528.94	1.1	0.05%
STEGLATRO TAB 15MG	25	8	$8,862.45	$354.50	3.13	0.01%
STEGLATRO TAB 5MG	4	3	$1,419.23	$354.81	1.33	0.00%
SPECIAL PA SUBTOTAL	**709**	**604**	**$385,777.12**	**$544.11**	**1.17**	**0.29%**
SGLT-2 INHIBITOR TOTAL	**38,451**	**12,905**	**$40,738,816.07**	**$1,059.50**	**2.98**	**30.96%**
SULFONYLUREA PRODUCTS						
TIER-1 PRODUCTS						
GLIPIZIDE TAB 10MG	3,779	1,339	$52,263.64	$13.83	2.82	0.04%
GLIPIZIDE TAB 5MG	3,503	1,378	$40,529.95	$11.57	2.54	0.03%
GLIPIZIDE ER TAB 10MG	2,007	796	$47,835.05	$23.83	2.52	0.04%
GLIMEPIRIDE TAB 4MG	1,591	552	$21,108.26	$13.27	2.88	0.02%
GLYBURIDE TAB 5MG	1,560	516	$26,578.76	$17.04	3.02	0.02%
GLIPIZIDE ER TAB 5MG	1,485	680	$25,055.86	$16.87	2.18	0.02%
GLIMEPIRIDE TAB 2MG	1,211	475	$14,006.36	$11.57	2.55	0.01%
GLIMEPIRIDE TAB 1MG	491	216	$5,396.43	$10.99	2.27	0.00%
GLIPIZIDE ER TAB 2.5MG	489	234	$8,868.11	$18.14	2.09	0.01%
GLYBURIDE TAB 2.5MG	351	139	$5,499.33	$15.67	2.53	0.00%
GLYBURIDE TAB 1.25MG	38	19	$594.86	$15.65	2	0.00%
GLYBURIDE MCR TAB 3MG	34	9	$574.10	$16.89	3.78	0.00%
GLYBURIDE MCR TAB 6MG	11	5	$313.99	$28.54	2.2	0.00%
GLYBURIDE MCR TAB 1.5MG	7	3	$153.21	$21.89	2.33	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 SUBTOTAL	**16,557**	**6,361**	**$248,777.91**	**$15.03**	**2.6**	**0.19%**
SPECIAL PA PRODUCTS						
GLIPIZIDE TAB 2.5MG	40	15	$2,231.16	$55.78	2.67	0.00%
SPECIAL PA SUBTOTAL	**40**	**15**	**$2,231.16**	**$55.78**	**2.67**	**0.00%**
SULFONYLUREA TOTAL	**16,597**	**6,376**	**$251,009.07**	**$15.12**	**2.6**	**0.19%**
DPP-4 INHIBITOR PRODUCTS						
TIER-2 PRODUCTS						
JANUVIA TAB 100MG	3,023	846	$2,412,115.63	$797.92	3.57	1.83%
TRADJENTA TAB 5MG	1,345	298	$877,784.30	$652.63	4.51	0.67%
JANUVIA TAB 50MG	857	275	$686,621.91	$801.19	3.12	0.52%
JANUVIA TAB 25MG	413	151	$294,533.40	$713.16	2.74	0.22%
TIER-2 SUBTOTAL	**5,638**	**1,570**	**$4,271,055.24**	**$757.55**	**3.59**	**3.25%**
TIER-3 PRODUCTS						
ALOGLIPTIN TAB 25MG	42	14	$10,073.47	$239.84	3	0.01%
ALOGLIPTIN TAB 12.5MG	28	8	$5,056.85	$180.60	3.5	0.00%
ALOGLIPTIN TAB 6.25MG	9	2	$2,077.70	$230.86	4.5	0.00%
NESINA TAB 12.5MG	2	1	$803.22	$401.61	2	0.00%
TIER-3 SUBTOTAL	**81**	**25**	**$18,011.24**	**$222.36**	**3.24**	**0.01%**
SPECIAL PA PRODUCTS						
SAXAGLIPTIN TAB 5MG	83	19	$15,667.27	$188.76	4.37	0.01%
SAXAGLIPTIN TAB 2.5MG	9	4	$1,078.48	$119.83	2.25	0.00%
ONGLYZA TAB 5MG	6	4	$4,568.58	$761.43	1.5	0.00%
SITAGLIPTIN TAB 50MG	6	2	$548.46	$91.41	3	0.00%
SITAGLIPTIN TAB 100MG	5	3	$937.05	$187.41	1.67	0.00%
SITAGLIPTIN TAB 25MG	2	2	$342.82	$171.41	1	0.00%
SPECIAL PA SUBTOTAL	**111**	**34**	**$23,142.66**	**$208.49**	**3.26**	**0.02%**
DPP-4 INHIBITOR TOTAL	**5,830**	**1,629**	**$4,312,209.14**	**$739.66**	**3.58**	**3.28%**
TZD PRODUCTS						
TIER-1 PRODUCTS						
PIOGLITAZONE TAB 30MG	1,955	724	$33,819.31	$17.30	2.7	0.03%
PIOGLITAZONE TAB 15MG	1,821	751	$28,520.57	$15.66	2.42	0.02%
PIOGLITAZONE TAB 45MG	1,092	378	$20,640.60	$18.90	2.89	0.02%
TZD TOTAL	**4,868**	**1,853**	**$82,980.48**	**$17.05**	**2.63**	**0.06%**
SGLT-2 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
SYNJARDY XR TAB 12.5-1,000MG	454	127	$401,581.79	$884.54	3.57	0.31%
SYNJARDY XR TAB 25-1,000MG	448	132	$506,346.19	$1,130.24	3.39	0.38%
SYNJARDY TAB 12.5-1,000MG	405	133	$492,590.94	$1,216.27	3.05	0.37%
SYNJARDY TAB 5-1,000MG	99	43	$126,872.87	$1,281.54	2.3	0.10%
SYNJARDY XR TAB 10-1,000MG	68	25	$79,684.94	$1,171.84	2.72	0.06%
SYNJARDY XR TAB 5-1,000MG	44	18	$36,115.87	$820.82	2.44	0.03%
SYNJARDY TAB 12.5-500MG	40	16	$46,534.24	$1,163.36	2.5	0.04%
SYNJARDY TAB 5-500MG	34	18	$33,339.28	$980.57	1.89	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 SUBTOTAL	**1,592**	**512**	**$1,723,066.12**	**$1,082.33**	**3.11**	**1.31%**
TIER-2 PRODUCTS						
XIGDUO XR TAB 10-1,000MG	296	75	$273,181.96	$922.91	3.95	0.21%
XIGDUO XR TAB 5-1,000MG	176	46	$145,976.09	$829.41	3.83	0.11%
XIGDUO XR TAB 10-500MG	11	5	$7,512.15	$682.92	2.2	0.01%
XIGDUO XR TAB 2.5-1,000MG	2	1	$598.25	$299.13	2	0.00%
XIGDUO XR TAB 5-500MG	2	2	$3,435.02	$1,717.51	1	0.00%
TIER-2 SUBTOTAL	**487**	**129**	**$430,703.47**	**$884.40**	**3.78**	**0.33%**
TIER-3 PRODUCTS						
INVOKAMET XR TAB 150-1,000MG	21	3	$13,409.39	$638.54	7	0.01%
INVOKAMET XR TAB 50-1,000MG	18	3	$10,543.06	$585.73	6	0.01%
INVOKAMET TAB 150-1,000MG	15	7	$15,693.37	$1,046.22	2.14	0.01%
TIER-3 SUBTOTAL	**54**	**13**	**$39,645.82**	**$734.18**	**4.15**	**0.03%**
SPECIAL PA PRODUCTS						
SEGLUROMET TAB 7.5-1,000MG	15	2	$5,332.51	$355.50	7.5	0.00%
DAPA/METFOR ER TAB 10-1,000MG	14	9	$9,544.41	$681.74	1.56	0.01%
DAPA/METFOR ER TAB 5-1,000MG	8	7	$5,572.57	$696.57	1.14	0.00%
SPECIAL PA SUBTOTAL	**37**	**18**	**$20,449.49**	**$552.69**	**2.06**	**0.02%**
SGLT-2 INHIBITOR/BIGUANIDE COMBINATION TOTAL	**2,170**	**672**	**$2,213,864.90**	**$1,020.21**	**3.23**	**1.68%**
DPP-4 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS						
TIER-2 PRODUCTS						
JANUMET TAB 50-1,000MG	868	302	$778,345.02	$896.71	2.87	0.59%
JANUMET XR TAB 50-1,000MG	233	74	$163,530.05	$701.85	3.15	0.12%
JENTADUETO TAB 2.5-1,000MG	188	75	$239,093.76	$1,271.78	2.51	0.18%
JANUMET XR TAB 100-1,000MG	171	52	$157,089.14	$918.65	3.29	0.12%
JANUMET TAB 50-500MG	136	41	$100,635.44	$739.97	3.32	0.08%
JANUMET XR TAB 50-500MG	14	3	$4,810.40	$343.60	4.67	0.00%
JENTADUETO TAB 2.5-850MG	10	1	$5,146.89	$514.69	10	0.00%
JENTADUETO TAB XR 5-1,000MG	4	2	$6,116.66	$1,529.17	2	0.00%
JENTADUETO TAB XR 2.5-1,000MG	3	3	$1,803.91	$601.30	1	0.00%
TIER-2 SUBTOTAL	**1,627**	**553**	**$1,456,571.27**	**$895.25**	**2.94**	**1.11%**
TIER-3 PRODUCTS						
ALOG/METFOR TAB 12.5-1,000MG	3	1	$619.23	$206.41	3	0.00%
TIER-3 SUBTOTAL	**3**	**1**	**$619.23**	**$206.41**	**3**	**0.00%**
SPECIAL PA PRODUCTS						
KOMBIGLYZE XR TAB 5-1,000MG	3	2	$2,081.56	$693.85	1.5	0.00%
SAXA/METFOR TAB 5-1,000MG	3	2	$1,471.64	$490.55	1.5	0.00%
SAXA/METFOR TAB 2.5-1,000MG	2	1	$676.18	$338.09	2	0.00%
SITA/METFOR TAB 50-500MG	1	1	$171.41	$171.41	1	0.00%
SPECIAL PA SUBTOTAL	**9**	**6**	**$4,400.79**	**$488.98**	**1.5**	**0.00%**
DPP-4 INHIBITOR/BIGUANIDE COMBINATION TOTAL	**1,639**	**560**	**$1,461,591.29**	**$891.76**	**2.93**	**1.11%**
SGLT-2 INHIBITOR/DPP-4 INHIBITOR/BIGUANIDE COMBINATION PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
TRIJARDY XR TAB 25-5-1,000MG	226	43	$136,741.26	$605.05	5.26	0.10%
TRIJARDY XR TAB 12.5-2.5-1,000MG	156	43	$88,563.40	$567.71	3.63	0.07%
TRIJARDY XR TAB 10-5-1,000MG	83	22	$60,643.11	$730.64	3.77	0.05%
TRIJARDY XR TAB 5-2.5-1,000MG	32	6	$15,320.58	$478.77	5.33	0.01%
SGLT-2/DPP-4/BIGUANIDE COMBINATION TOTAL	**497**	**114**	**$301,268.35**	**$606.17**	**4.36**	**0.23%**
SGLT-2 INHIBITOR/DPP-4 INHIBITOR COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
GLYXAMBI TAB 25-5 MG	277	44	$163,672.46	$590.88	6.3	0.12%
GLYXAMBI TAB 10-5 MG	167	34	$96,728.64	$579.21	4.91	0.07%
TIER-1 SUBTOTAL	**444**	**78**	**$260,401.10**	**$586.49**	**5.69**	**0.20%**
SPECIAL PA PRODUCTS						
STEGLUJAN TAB 15-100MG	13	1	$7,124.97	$548.07	13	0.01%
SPECIAL PA SUBTOTAL	**13**	**1**	**$7,124.97**	**$548.07**	**13**	**0.01%**
SGLT-2/DPP-4 INHIBITOR COMBINATION TOTAL	**457**	**79**	**$267,526.07**	**$585.40**	**5.78**	**0.20%**
SULFONYLUREA/BIGUANIDE COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
GLYB/METFOR TAB 5-500MG	104	30	$1,885.66	$18.13	3.47	0.00%
GLIP/METFOR TAB 5-500MG	101	42	$4,410.00	$43.66	2.4	0.00%
GLIP/METFOR TAB 2.5-500MG	55	30	$2,849.78	$51.81	1.83	0.00%
GLYB/METFOR TAB 2.5-500MG	20	9	$525.17	$26.26	2.22	0.00%
GLYB/METFOR TAB 1.25-250MG	6	1	$109.20	$18.20	6	0.00%
GLIP/METFOR TAB 2.5-250MG	6	2	$264.06	$44.01	3	0.00%
SULFONYLUREA/BIGUANIDE COMBINATION TOTAL	**292**	**114**	**$10,043.87**	**$34.40**	**2.56**	**0.01%**
FINERENONE PRODUCTS						
KERENDIA TAB 10MG	228	46	$154,070.60	$675.75	4.96	0.12%
KERENDIA TAB 20MG	52	11	$34,126.23	$656.27	4.73	0.03%
FINERENONE TOTAL	**280**	**57**	**$188,196.83**	**$672.13**	**4.91**	**0.14%**
ALPHA-GLUCOSIDASE INHIBITOR PRODUCTS						
TIER-1 PRODUCTS						
ACARBOSE TAB 25MG	128	46	$3,773.02	$29.48	2.78	0.00%
ACARBOSE TAB 50MG	61	21	$2,094.70	$34.34	2.9	0.00%
ACARBOSE TAB 100MG	56	17	$2,479.64	$44.28	3.29	0.00%
TIER-1 SUBTOTAL	**245**	**84**	**$8,347.36**	**$34.07**	**2.92**	**0.01%**
TIER-3 PRODUCTS						
MIGLITOL TAB 50MG	1	1	$166.17	$166.17	1	0.00%
TIER-3 SUBTOTAL	**1**	**1**	**$166.17**	**$166.17**	**1**	**0.00%**
ALPHA-GLUCOSIDASE INHIBITOR TOTAL	**246**	**85**	**$8,513.53**	**$34.61**	**2.89**	**0.01%**
GLINIDE PRODUCTS						
TIER-1 PRODUCTS						
REPAGLINIDE TAB 1MG	50	14	$1,311.05	$26.22	3.57	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
REPAGLINIDE TAB 2MG	38	8	$1,055.78	$27.78	4.75	0.00%
REPAGLINIDE TAB 0.5MG	28	10	$519.64	$18.56	2.8	0.00%
TIER-1 SUBTOTAL	**116**	**32**	**$2,886.47**	**$24.88**	**3.63**	**0.00%**
TIER-2 PRODUCTS						
NATEGLINIDE TAB 60MG	26	13	$1,036.70	$39.87	2	0.00%
NATEGLINIDE TAB 120MG	21	7	$972.45	$46.31	3	0.00%
TIER-2 SUBTOTAL	**47**	**20**	**$2,009.15**	**$42.75**	**2.35**	**0.00%**
GLINIDE TOTAL	**163**	**52**	**$4,895.62**	**$30.03**	**3.13**	**0.00%**
GLP-1 AGONIST/INSULIN COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
SOLIQUA INJ 100U/33MCG	67	19	$54,769.84	$817.46	3.53	0.04%
XULTOPHY INJ 100U/3.6MCG	67	14	$75,245.60	$1,123.07	4.79	0.06%
GLP-1 AGONIST/INSULIN COMBINATION TOTAL	**134**	**33**	**$130,015.44**	**$970.26**	**4.06**	**0.10%**
DPP-4 INHIBITOR/TZD COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
ALOG/PIOG TAB 25-30MG	10	1	$1,752.45	$175.25	10	0.00%
ALOG/PIOG TAB 25-45MG	9	1	$2,629.69	$292.19	9	0.00%
DPP-4 INHIBITOR/TZD COMBINATION TOTAL	**19**	**2**	**$4,382.14**	**$230.64**	**9.5**	**0.00%**
TZD/BIGUANIDE PRODUCTS						
TIER-3 PRODUCTS						
PIOG/METFOR TAB 15-500MG	14	2	$375.41	$26.82	7	0.00%
PIOG/METFOR TAB 15-850MG	4	1	$122.51	$30.63	4	0.00%
TZD/BIGUANIDE TOTAL	**18**	**3**	**$497.92**	**$27.66**	**6**	**0.00%**
AMYLINOMIMETIC PRODUCTS						
SPECIAL PA PRODUCTS						
SYMLIN PEN 120 INJ 1,000MCG	11	3	$16,908.44	$1,537.13	3.67	0.01%
SYMLIN PEN 60 INJ 1,000MCG	3	2	$4,998.75	$1,666.25	1.5	0.00%
AMYLINOMIMETIC TOTAL	**14**	**5**	**$21,907.19**	**$1,564.80**	**2.8**	**0.02%**
SULFONYLUREA/TZD COMBINATION PRODUCTS						
TIER-3 PRODUCTS						
PIOG/GLIM TAB 30-4MG	2	1	$571.75	$285.88	2	0.00%
PIOG/GLIM TAB 30-2MG	1	1	$318.37	$318.37	1	0.00%
SULFONYLUREA/TZD COMBINATION TOTAL	**3**	**2**	**$890.12**	**$296.71**	**1.5**	**0.00%**
DOPAMINE AGONIST PRODUCTS						
TIER-3 PRODUCTS						
CYCLOSET TAB 0.8MG	1	1	$174.18	$174.18	1	0.00%
DOPAMINE AGONIST TOTAL	**1**	**1**	**$174.18**	**$174.18**	**1**	**0.00%**
TOTAL	**221,790**	**39,636***	**$131,577,324.18**	**$593.25**	**5.6**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ALOG = alogliptin; DAPA = dapagliflozin; DPP-4 = dipeptidyl peptidase-4; ER, XL, XR = extended-release; GIP = glucose-dependent insulinotropic polypeptide; GLIM = glimepiride; GLIP = glipizide; GLP-1 = glucagon-like peptide 1; GLYB = glyburide; INJ = injection; MCR = micronized; METFOR = metformin; MOD = modified release; OSM = osmotic; PIOG = pioglitazone; SAXA = saxagliptin; SGLT-2 = sodium-glucose cotransporter-2; SITA = sitagliptin; SOL = solution; TZD = thiazolidinedione; TAB = tablet; U = unit
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Utilization Details of Insulin Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INSULIN GLARGINE PRODUCTS						
LANTUS SOLO INJ 100U/ML	30,976	10,217	$4,269,224.09	$137.82	3.03	23.51%
LANTUS INJ 100U/ML	4,217	1,348	$508,660.28	$120.62	3.13	2.80%
INS GLAR YFGN INJ 100U/ML	2,551	1,443	$268,403.46	$105.21	1.77	1.48%
TOUJEO MAX INJ 300U/ML	624	151	$532,854.67	$853.93	4.13	2.93%
INS GLAR YFGN SOL 100U/ML	485	270	$51,679.39	$106.56	1.8	0.28%
SEMGLEE INJ 100U/ML	481	341	$207,809.56	$432.04	1.41	1.14%
TOUJEO SOLO INJ 300U/ML	395	116	$258,839.66	$655.29	3.41	1.43%
BASAGLAR KWIK INJ 100U/ML	296	163	$126,688.89	$428.00	1.82	0.70%
INS GLARGINE INJ 100U/ML	56	32	$11,209.75	$200.17	1.75	0.06%
SEMGLEE INJ 100U/ML	18	17	$11,081.89	$615.66	1.06	0.06%
INS GLARGINE MAX INJ 300U/ML	15	7	$4,334.70	$288.98	2.14	0.02%
REZVOGLAR KWIK INJ 100U/ML	7	5	$588.48	$84.07	1.4	0.00%
INS GLARGINE SOL 100U/ML	7	6	$880.53	$125.79	1.17	0.00%
INS GLARGINE INJ 300U/ML	4	3	$617.07	$154.27	1.33	0.00%
BASAGLAR TEMPO INJ 100U/ML	1	1	$325.81	$325.81	1	0.00%
SUBTOTAL	**40,133**	**14,120**	**$6,253,198.23**	**$155.81**	**2.84**	**34.44%**
INSULIN ASPART PRODUCTS						
NOVOLOG FLEX INJ 100U/ML	5,517	2,123	$1,176,993.60	$213.34	2.6	6.48%
INSULIN ASP FLEX INJ 100U/ML	4,457	1,736	$841,975.99	$188.91	2.57	4.64%
NOVOLOG FLEX RELI INJ 100U/ML	3,016	1,216	$389,348.23	$129.09	2.48	2.14%
NOVOLOG INJ 100U/ML	2,683	699	$622,350.50	$231.96	3.84	3.43%
INS ASP INJ 100U/ML	2,177	687	$535,213.67	$245.85	3.17	2.95%
NOVOLOG RELI INJ 100U/ML	845	270	$172,695.18	$204.37	3.13	0.95%
FIASP FLEX INJ 100U/ML	219	53	$141,542.22	$646.31	4.13	0.78%
NOVOLOG PENFILL INJ 100U/ML	176	52	$40,339.89	$229.20	3.38	0.22%
INS ASP PENFILL INJ 100U/ML	66	21	$12,483.09	$189.14	3.14	0.07%
FIASP INJ 100U/ML	45	16	$33,820.39	$751.56	2.81	0.19%
FIASP PENFILL INJ 100U/ML	34	8	$15,512.88	$456.26	4.25	0.09%
FIASP PUMPCART INJ 100U/ML	23	7	$16,190.67	$703.94	3.29	0.09%
SUBTOTAL	**19,258**	**6,888**	**$3,998,466.31**	**$207.63**	**2.8**	**22.02%**
INSULIN LISPRO PRODUCTS						
HUMALOG KWIK INJ 100U/ML	7,997	2,692	$1,860,918.15	$232.70	2.97	10.25%
HUMALOG INJ 100U/ML	5,098	1,184	$1,029,543.73	$201.95	4.31	5.67%
HUMALOG JR INJ 100U/ML	582	169	$116,505.90	$200.18	3.44	0.64%
HUMALOG KWIK INJ 200U/ML	489	93	$891,869.40	$1,823.86	5.26	4.91%
INS LISP KWIK JR INJ 100U/ML	316	84	$68,416.35	$216.51	3.76	0.38%
INS LISP INJ 100U/ML	152	113	$31,943.00	$210.15	1.35	0.18%
HUMALOG INJ 100U/ML	138	42	$39,188.90	$283.98	3.29	0.22%
LYUMJEV INJ 100U/ML	112	23	$96,549.15	$862.05	4.87	0.53%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INS LISP INJ 100U/ML	85	48	$7,761.08	$91.31	1.77	0.04%
LYUMJEV KWIK INJ 200U/ML	38	8	$76,853.23	$2,022.45	4.75	0.42%
LYUMJEV KWIK INJ 100U/ML	35	15	$24,923.96	$712.11	2.33	0.14%
HUMALOG TEMPO INJ 100U/ML	18	10	$4,042.71	$224.60	1.8	0.02%
ADMELOG SOLO INJ 100U/ML	2	2	$583.35	$291.68	1	0.00%
ADMELOG INJ 100U/ML	1	1	$105.62	$105.62	1	0.00%
SUBTOTAL	**15,063**	**4,484**	**$4,249,204.53**	**$282.10**	**3.36**	**23.40%**
INSULIN DEGLUDEC PRODUCTS						
TRESIBA FLEX INJ 100U/ML	1,515	467	$709,930.59	$468.60	3.24	3.91%
TRESIBA FLEX INJ 200U/ML	1,360	326	$1,080,011.44	$794.13	4.17	5.95%
INS DEGLUDEC FLEX INJ 200U/ML	85	34	$21,838.30	$256.92	2.5	0.12%
INS DEGLUDEC FLEX INJ 100U/ML	84	44	$13,957.58	$166.16	1.91	0.08%
TRESIBA INJ 100U/ML	9	6	$3,659.25	$406.58	1.5	0.02%
INS DEGLUDEC INJ 100U/ML	2	2	$260.08	$130.04	1	0.00%
SUBTOTAL	**3,055**	**879**	**$1,829,657.24**	**$598.91**	**3.48**	**10.08%**
INSULIN DETEMIR PRODUCTS						
LEVEMIR FLEX INJ 100U/ML	1,625	878	$371,353.12	$228.52	1.85	2.05%
LEVEMIR INJ 100U/ML	654	256	$152,056.87	$232.50	2.55	0.84%
LEVEMIR INJ FLEXTOUCH 100U/ML	3	3	$647.93	$215.98	1	0.00%
SUBTOTAL	**2,282**	**1,137**	**$524,057.92**	**$229.65**	**2.01**	**2.89%**
REGULAR INSULIN PRODUCTS						
HUMULIN R INJ 100U/ML	532	168	$46,549.28	$87.50	3.17	0.26%
HUMULIN R KWIK INJ 500U/ML	450	98	$524,052.66	$1,164.56	4.59	2.89%
NOVOLIN R FLEX 100U/ML	298	136	$26,635.72	$89.38	2.19	0.15%
NOVOLIN R INJ 100U/ML	243	96	$20,355.52	$83.77	2.53	0.11%
NOVOLIN R RELI INJ 100U/ML	163	71	$10,105.28	$62.00	2.3	0.06%
HUMULIN R INJ 500U/ML	49	10	$74,654.33	$1,523.56	4.9	0.41%
AFREZZA POWDER 4-8-12U	9	2	$28,765.53	$3,196.17	4.5	0.16%
AFREZZA POWDER 8-12U	2	1	$9,101.78	$4,550.89	2	0.05%
SUBTOTAL	**1,746**	**582**	**$740,220.10**	**$423.95**	**3**	**4.08%**
REGULAR/NPH INSULIN COMBINATION PRODUCTS						
NOVOLIN 70/30 FLEX INJ 100U/ML	329	107	$46,696.62	$141.94	3.07	0.26%
HUMULIN 70/30 KWIK INJ 100U/ML	301	90	$78,335.93	$260.25	3.34	0.43%
HUMULIN 70/30 INJ 100U/ML	196	52	$23,002.17	$117.36	3.77	0.13%
NOVOLIN 70/30 INJ 100U/ML	192	65	$26,147.36	$136.18	2.95	0.14%
NOVOLIN 70/30 RELI INJ 100U/ML	113	44	$9,379.53	$83.00	2.57	0.05%
SUBTOTAL	**1,131**	**358**	**$183,561.61**	**$162.30**	**3.16**	**1.01%**
NPH INSULIN PRODUCTS						
NOVOLIN N INJ 100U/ML	293	121	$29,899.65	$102.05	2.42	0.16%
HUMULIN N INJ 100U/ML	252	95	$23,374.83	$92.76	2.65	0.13%
HUMULIN N KWIK INJ 100U/ML	236	111	$47,251.62	$200.22	2.13	0.26%
NOVOLIN N RELI INJ 100U/ML	151	53	$9,572.92	$63.40	2.85	0.05%
NOVOLIN N INJ 100U/ML	115	60	$14,410.26	$125.31	1.92	0.08%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**1,047**	**440**	**$124,509.28**	**$118.92**	**2.38**	**0.69%**
INSULIN ASPART/NPH COMBINATION PRODUCTS						
NOVOLOG MIX FLEX INJ 100U/ML	272	84	$59,199.29	$217.64	3.24	0.33%
INS ASP PROT FLEX INJ 100U/ML	160	54	$43,345.42	$270.91	2.96	0.24%
NOVOLOG MIX FLEX RELI 100U/ML	97	32	$17,935.88	$184.91	3.03	0.10%
NOVOLOG MIX INJ 100U/ML	56	17	$16,105.62	$287.60	3.29	0.09%
INS ASP 70/30 INJ 100U/ML	15	12	$2,240.27	$149.35	1.25	0.01%
NOVOLOG 70/30 RELI INJ 100U/ML	9	7	$806.32	$89.59	1.29	0.00%
SUBTOTAL	**609**	**206**	**$139,632.80**	**$229.28**	**2.96**	**0.77%**
INSULIN GLULISINE PRODUCTS						
APIDRA SOLO INJ 100U/ML	188	57	$55,053.81	$292.84	3.3	0.30%
APIDRA INJ 100U/ML	60	14	$10,333.21	$172.22	4.29	0.06%
SUBTOTAL	**248**	**71**	**$65,387.02**	**$263.66**	**3.49**	**0.36%**
INSULIN LISPRO/NPH COMBINATION PRODUCTS						
HUMALOG 75/25 KWIK INJ 100U/ML	106	31	$28,142.12	$265.49	3.42	0.15%
HUMALOG 75/25 SUS 100U/ML	30	7	$7,237.29	$241.24	4.29	0.04%
HUMALOG 50/50 KWIK INJ 100U/ML	28	7	$8,771.13	$313.25	4	0.05%
INS LISP 75/25 KWIK INJ 100U/ML	21	5	$4,456.49	$212.21	4.2	0.02%
SUBTOTAL	**185**	**50**	**$48,607.03**	**$262.74**	**3.7**	**0.27%**
TOTAL	**84,757**	**15,406***	**$18,156,502.07**	**$214.22**	**5.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ASP = aspart; FLEX = FlexPen; GLAR = glargine; INJ = injection; INS = insulin; JR = junior; KWIK = KwikPen; LISP = lispro; POW = powder; PROT = protamine; RELI = Relion; SOL = solution; SOLO = Solostar; SUS = suspension; U = unit
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix N

Fiscal Year 2025 Annual Review of Heart Failure (HF) Medications and 30-Day Notice to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten)

Oklahoma Health Care Authority
July 2026

Current Prior Authorization Criteria

Camzyos® (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or non-dihydropyridine calcium channel blockers; and
7. Member must not be taking concurrent strong CYP2C19 inhibitors (e.g., fluvoxamine, fluconazole), moderate to strong CYP2C19 inducers (e.g., rifampin), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and
8. If the member is taking moderate to strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or weak to moderate CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole), the prescriber must verify that the Camzyos® dose will be adjusted according to the package labeling; and
9. Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos®; and
10. 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 4 months after the final dose of Camzyos®; and

11. Prescriber, pharmacy, and member must be enrolled in the Camzyos® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment; and
13. Subsequent approvals will be for the duration of 1 year.

Corlanor® (Ivabradine) Tablet and Oral Solution Approval Criteria:

1. A diagnosis of 1 of the following:
    a. To reduce the risk of hospitalization for worsening heart failure (HF) in adult members with stable, symptomatic chronic HF with reduced left ventricular ejection fraction (LVEF); or
    b. For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in members 6 months of age and older; or
    c. For the treatment of inappropriate sinus tachycardia (IST); and
2. For a diagnosis of worsening HF in adults:
    a. Prescriber must verify that the member has LVEF ≤35%; and
    b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥70 beats per minute (bpm); and
    c. Member must be on maximal/maximally tolerated doses of beta blockers or have a contraindication to beta blockers; and
3. For a diagnosis of DCM in members 6 months of age or older:
    a. Prescriber must verify that the member has LVEF ≤45%; and
    b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate (HR) as follows:
        i. Age 6 to 12 months, HR ≥105 bpm; or
        ii. Age 1 to 3 years, HR ≥95 bpm; or
        iii. Age 3 to 5 years, HR ≥75 bpm; or
        iv. Age 5 to 18 years, HR ≥70 bpm; and
    c. Prescriber must verify that dose titration will be followed according to package labeling; and
    d. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Authorization of Corlanor® solution for members >40kg requires a patient-specific, clinically significant reason why Corlanor® tablets cannot be used; and
5. For Corlanor® tablets, a quantity limit of 60 tablets per 30 days will apply; and
6. For Corlanor® solution, a quantity limit of 280mL (56 ampules) per 28 days will apply.

Entresto® (Sacubitril/Valsartan) Approval Criteria:

1. An FDA approved diagnosis of chronic heart failure [New York Heart Association (NYHA) Class II, III, or IV]; and
2. A quantity limit of 60 tablets per 30 days will apply.

Entresto® Sprinkle (Sacubitril/Valsartan) Approval Criteria:

1. An FDA approved diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction; and
2. Member must be 1 to 10 years of age; and
3. Member must weigh <50kg; and
4. A recent weight (within the last 3 months) must be provided on the prior authorization request to ensure proper weight-based dosing and to authorize the appropriate amount of drug required according to package labeling; and
5. A quantity limit of 240 capsules per 30 days will apply.

Furoscix® (Furosemide On-Body Injection) Approval Criteria:

1. An FDA approved indication for the treatment of edema in members with chronic heart failure or chronic kidney disease (CKD), including nephrotic syndrome; and
2. Member must be 18 years of age or older; and
3. Furoscix® must be prescribed by, or in consultation with, a cardiologist, nephrologist, or a provider trained in managing acute decompensated heart failure (ADHF) or CKD; and
4. Member is currently showing signs of edema; and
5. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or
    c. Torsemide oral tablets; and
6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix, as determined by:
    a. Oxygen saturation ≥90% on exertion; and
    b. Respiratory rate <24 breaths per minute; and
    c. Resting heart rate <100 beats per minute; and
    d. Systolic blood pressure >100mmHg; and
8. Member must have an adequate environment for at-home administration, have been trained on the proper use of Furoscix®, and be able to detect and respond to the device alarms; and

9. Member must not have any contraindications for use of Furoscix® including anuria or hepatic cirrhosis; and
10. Member must not have conditions that require immediate hospitalization; and
11. Approvals will be issued per incident of fluid overload; and
12. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of fluid overload.

Verquvo® (Vericiguat) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death and hospitalization for heart failure (HF) in adults with all of the following:
    a. Chronic symptomatic HF [New York Heart Association (NYHA) Class II, III, or IV]; and
    b. Reduced left ventricular ejection fraction (LVEF) <45%; and
    c. Already receiving guideline-directed medical therapy for HF, as documented in member's pharmacy claims history; and
2. Member has evidence of worsening HF (decompensation) demonstrated by at least 1 of the following:
    a. Hospitalization for HF within the past 6 months; or
    b. Received outpatient intravenous (IV) diuretics within the past 3 months; and
3. Member must be 18 years of age or older; and
4. Member must not be taking concomitant soluble guanylate cyclase (sGC) stimulators (e.g., riociguat); and
5. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during treatment and for 1 month after the final dose of Verquvo®; and
6. Prescriber must agree to titrate to the target maintenance dose according to package labeling, as tolerated by the member; and
7. Initial approvals will be for the duration of 6 months. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 30 tablets per 30 days will apply.

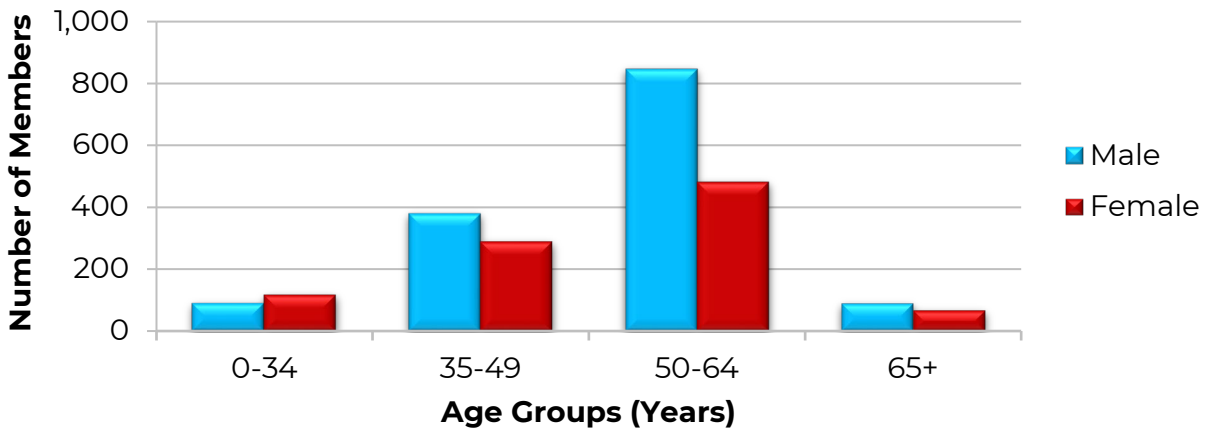
Utilization of HF Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

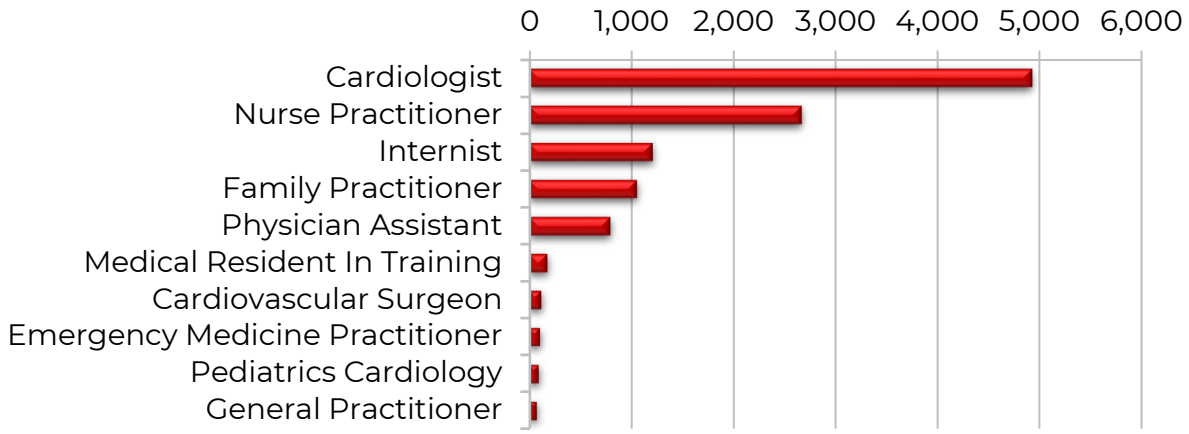
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	2,096	9,769	$6,192,617.30	$633.90	$21.23	574,723	291,687
Aetna	243	451	$308,350.99	$683.71	$23.41	27,298	13,169
Humana	302	632	$464,225.86	$734.53	$24.75	36,213	18,754
OCH	249	422	$283,293.91	$671.31	$22.47	24,016	12,609
2024 Total	**2,262**	**11,274**	**$7,248,488.06**	**$642.94**	**$21.56**	**662,250**	**336,219**
Fiscal Year 2025							
FFS	1,342	5,608	$3,599,676.40	$641.88	$21.61	323,298	166,594
Aetna	423	1,962	$1,492,519.55	$760.71	$25.16	119,242	59,322
Humana	529	2,511	$1,864,019.27	$742.34	$24.92	144,624	74,789
OCH	455	1,992	$1,457,668.72	$731.76	$24.55	116,359	59,383
2025 Total	**2,369**	**12,073**	**$8,413,883.94**	**$696.92**	**$23.37**	**703,523**	**360,088**
% Change	**4.7%**	**7.1%**	**16.1%**	**8.4%**	**8.4%**	**6.2%**	**7.1%**
Change	**107**	**799**	**$1,165,395.88**	**$53.98**	**$1.81**	**41,273**	**23,869**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024

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



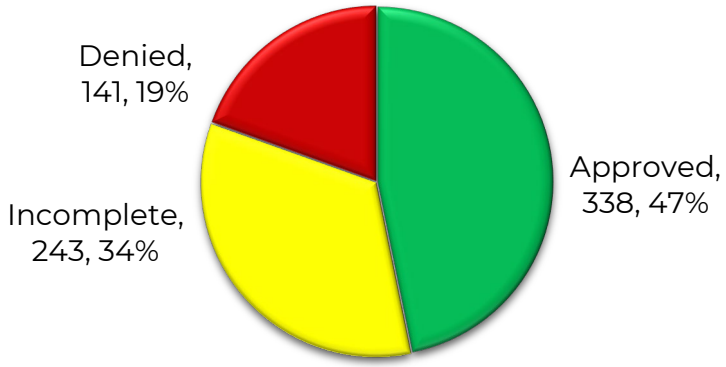
Top Prescriber Specialties of HF Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of HF Medications

There were 722 prior authorization requests submitted for HF medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	178	25%	221	31%	53	7%	**452**
Aetna	28	4%	11	2%	8	1%	**47**
Humana	55	8%	0	0%	24	3%	**79**
OCH	77	11%	11	2%	56	8%	**144**
Total	**338**	**47%**	**243**	**34%**	**141**	**19%**	**722**

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

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

Anticipated Patent Expiration(s):

- Corlanor® (ivabradine oral solution): December 2026
- Corlanor® (ivabradine tablet): June 2027
- Verquvo® (vericiguat tablet): November 2032
- Furoscix® (furosemide on-body infusor): April 2034
- Camzyos® (mavacamten capsule) April 2036
- Entresto® (sacubitril/valsartan tablet): May 2036
- Entresto® Sprinkle (sacubitril/valsartan capsule, pellets): February 2037
- Myqorzo™ (aficamten) July 2042
- Enbumyst™ (bumetanide nasal spray) May 2045

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

- **April 2025:** The FDA approved reduced dosing to 2.5mg orally once daily with Camzyos® (mavacamten) when used in combination with moderate CYP2C19 inhibitors or strong CYP3A4 inhibitors.
- **September 2025:** The FDA approved Enbumyst™ (bumetanide nasal spray) for the treatment of edema associated with congestive HF, hepatic, and renal disease, including nephrotic syndrome in adults.
- **October 2025:** The FDA approved Lasix® ONYU (furosemide on-body infusor) for the treatment of edema in adult patients with chronic HF.
- **December 2025:** The FDA approved Myqorzo™ (aficamten) for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.
- **December 2025:** The FDA expanded the approval of Furoscix® (furosemide injection) for the treatment of edema from adults only to include pediatric patients weighing ≥43kg.
- **January 2026:** The FDA approved a new dosing regimen for Verquvo® (vericiguat tablet) for a starting dose of 5mg once daily or 2.5mg once daily for patients at risk of symptomatic hypotension.

Pipeline:

- **Revascor® (Rexlemestrocel-L):** Revascor® is an investigational donor bone marrow intracardiac injection for patients with advanced and/or end-stage HF with reduced ejection fraction (HFrEF). The injection contains 150 million mesenchymal precursor cells (MPCs). In 2023, DREAM-HF, the phase 3, randomized, double-blind, sham-controlled trial was completed in ischemic or nonischemic patients with New York Heart Association (NYHA) functional class II or III HFrEF. DREAM-HF results showed left ventricular ejection fraction (LVEF) improvement and reduction in myocardial infarction and stroke when added to standard of care but failed to reduce the frequency of HF hospitalizations. A confirmatory trial may be needed to evaluate the benefits in this population. The FDA granted Revascor® both Orphan-

Drug Designation (ODD) and Regenerative Medicine Advanced Therapy (RMAT) for congenital heart disease. The manufacturer, Mesoblast, intends to file for a Biologics License Application (BLA) for patients with end-stage ischemic HFrEF implanted with a left ventricular assist device (LVAD) and expects potential FDA approval in 2027.

- **Vicadrostat/Empagliflozin:** Vicadrostat/empagliflozin is an investigational selective aldosterone synthase inhibitor/sodium-glucose cotransporter 2 (SGLT-2) inhibitor combination currently being studied in a 43-month Phase 3, double-blind, randomized, parallel-group superiority trial, EASi-HF Reduced, for the treatment of symptomatic heart failure NYHA II-IV. Participants with LVEF <40% will be randomized to vicadrostat and empagliflozin or placebo and empagliflozin. The primary endpoint is time to CV death, hospitalization for heart failure, or urgent heart failure visit. The estimated completion date is February 2029. This combination is also being studied in patients with HF with preserved ejection fraction (HFpEF), in patients with chronic kidney disease, and for cardiovascular (CV) risk reduction in patients with hypertension, type 2 diabetes, and CV disease.
- **Ziltivekimab:** Ziltivekimab is an investigational subcutaneous human monoclonal antibody IL-6 antagonist for patients with systemic inflammation and HF with mildly reduced or preserved ejection fraction. Two Phase 3 randomized, quadruple, parallel, placebo-controlled trials are currently ongoing, ATHENA and HERMES, with estimated completion dates of October 2026 and July 2027, respectively. The primary endpoint in HERMES is time to CV death, urgent visit for HF, or hospitalization for HF. The primary endpoint in ATHENA is a 12-month mean change in Kansas City Cardiomyopathy Questionnaire clinical summary score.

Enbumyst™ (Bumetanide Nasal Spray) Product Summary[13,14,15]

Therapeutic Class: Loop diuretic

Indication(s): Treatment of edema associated with congestive heart failure, hepatic disease, and renal disease, including the nephrotic syndrome, in adults

How Supplied: 0.5mg/0.1mL of bumetanide contained in a single-use nasal spray device with 12 devices per carton

Dosing and Administration:

- The recommended dose of Enbumyst™ is 0.5mg to 2mg per incident of edema administered via nasal inhalation.
- The dosage of Enbumyst™ is patient specific and depends on patient response to treatment.

- The maximum daily dosage is 2mg/day.
- Enbumyst™ is not intended for chronic treatment, and it is recommended to utilize oral diuretics for long term management.

Efficacy: The safety and efficacy of Enbumyst™ were evaluated in a Phase 1 open-label, randomized, controlled, crossover trial utilizing bumetanide tablets. Enbumyst™ was determined to have comparable pharmacokinetic and pharmacodynamic effects to bumetanide tablets; thus, the FDA granted approval of this novel dosage form via the 505(b)(2) pathway.

Cost Comparison:

Product	Cost Per Unit	Cost Per Day*
Enbumyst™ (bumetanide 0.5mg/0.1mL) nasal spray	**$99.75**	**$399.00**
bumetanide 2mg tablet	$0.17	$0.85

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), Specialty Pharmaceutical Allowable Cost (SPAC), or State Maximum Allowable Costs (SMAC).
*Cost per day is based on the FDA approved maximum recommended daily dose of 2mg/day for Enbumyst™ and 10mg/day for bumetanide tablets.
Unit = each tablet or single-use cartridge

Lasix® ONYU (Furosemide On-Body Infusor) Product Summary[16,17,18]

Therapeutic Class: Loop diuretic

Indication(s): Treatment of edema in adult patients with chronic HF

How Supplied: Lasix® ONYU is supplied as an 80mg/2.67mL single-dose prefilled cartridge co-packaged with a single-use Disposable Unit. A Reusable Unit is packaged separately and is required for administration.

- The Disposable Unit is a single-use component that holds the prefilled cartridge and contains a 29-gauge needle and retraction device.
- The Reusable Unit is billed separately and can be used up to 48 times.

Dosing and Administration:

- The on-body infusor delivers 80mg of furosemide over 5 hours (i.e., 30mg is delivered over the first hour followed by 12.5 mg per hour over 4 hours) and can be administered once or twice daily as needed.
- To prepare for use of the on-body infusor, the prefilled cartridge should be placed into the Disposable Unit. Once assembled, the Disposable Unit and the Reusable Unit should be slid together until the blue Status Light illuminates on the Reusable Unit.
- Lasix® ONYU should be administered via subcutaneous injection and given within 7 hours of assembly.
- The device contains visual and auditory alarms that indicate when the full dose has been successfully administered.

- Lasix® ONYU is not intended for chronic treatment, and it is recommended to utilize oral diuretics for long term management.

Efficacy: The safety and tolerability of Lasix® ONYU were evaluated in two Phase 1 open-label, single-dose trials, Study 1, a randomized, active-comparator, crossover trial and Study 2, a prospective, single-center, single-arm, single-dose trial utilizing conventional intravenous (IV) furosemide. Lasix® ONYU was determined to have comparable pharmacokinetic and pharmacodynamic effects to conventional IV furosemide; thus, the FDA granted approval of this novel dosage form via the 505(b)(2) pathway.

Cost Comparison:

Product	Cost Per Unit	Cost Per 80mg Dose*
Lasix® ONYU (furosemide on-body infusor) 80mg/2.67mL	**$475.00Δ**	**$475.00**
Furoscix® (furosemide on-body injection) 80mg/10mL	$980.59	$980.59
furosemide injection 10mg/mL vial	$0.17	$1.36

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 80mg dose is based on the single-use nature of Lasix® ONYU and Furoscix® as these products are not approved for chronic usage or maintenance dosing.
ΔThe cost does not include the Reuseable Unit Delivery Device, which can be used for up to 48 infusions.
Unit = each mL or single-use cartridge

Myqorzo™ (Aficamten) Product Summary[19,20]

Therapeutic Class: Cardiac myosin inhibitor

Indication(s): Treatment of adults with symptomatic obstructive HCM to improve functional capacity and symptoms

How Supplied: 5 mg, 10 mg, 15mg, or 20mg film-coated tablets

Dosing and Administration:
- The recommended starting dose of Myqorzo™ is 5mg orally once daily.
- Myqorzo™ should be titrated by 5mg every 2-8 weeks until a maintenance dose is achieved. The maintenance dose is individualized based on the patient's LVEF and Valsalva left ventricular outflow tract gradient (LVOT-G) criteria (refer to the full *Prescribing Information* for dose adjustment recommendations).
- The FDA maximum daily dose is 20mg once daily.

Efficacy: The safety and efficacy of Myqorzo™ were studied in a Phase 3, randomized, double-blind, placebo-controlled 24-week trial, SEQUOIA-HCM.
- Key Inclusion Criteria:
  - 18-85 years of age with obstructive HCM
  - Body mass index <35kg/m^2

    - LVEF ≥60%
    - Left ventricular outflow tract gradients ≥30 mmHg at rest and ≥50 mmHg after the Valsalva maneuver
    - NYHA functional class II or III HF
    - Decreased exercise capacity (peak oxygen uptake ≤90% based on gender and age)
    - Women of childbearing potential must have a negative pregnancy test
    - Men and women must agree to use contraception during and 4 weeks after trial
- Interventions:
    - Patients were randomized 1:1 to Myqorzo™ 5mg or placebo once daily
    - Doses were escalated at weeks 2, 4, and 6 weeks, based on echocardiogram testing, to a maximum of 20mg
- Primary Endpoints: Change in oxygen uptake from baseline to week 24
- Results: At 24 weeks, the mean change in the peak oxygen uptake was 1.8mL/kg/min [95% confidence interval (CI): 1.2, 2.3] in the Myqorzo™ group and 0.0mL/kg/min (95% CI: −0.5, 0.5) in the placebo group (mean group difference: 1.7mL/kg/min; 95% CI: 1, 2.4; P<0.001).

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 days*	Cost Per Year
Myqorzo™ (aficamten) 20mg tablet	**$296.99**	**$8,909.70**	**$106,916.40**
Camzyos® (mavacamten) 15mg capsule	$291.07	$8,732.10	$104,785.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days is based on the FDA approved maximum recommended dose of 20mg once daily for Myqorzo™ and 15mg once daily for Camzyos™.
Unit = each tablet or capsule

Recommendations

The College of Pharmacy recommends the prior authorization of Enbumyst™ (bumetanide nasal spray), Lasix® ONYU (furosemide on-body infusor), and Myqorzo™ (aficamten) with the following criteria (shown in red):

Enbumyst™ (Bumetanide Nasal Spray) Approval Criteria:

1. An FDA approved indication of the treatment of edema associated with congestive heart failure, hepatic disease, or renal disease, including nephrotic syndrome; and
2. Member must be 18 years of age or older; and
3. Member is currently showing signs of edema; and

4. Member must not currently have significant nasal mucosal or structural abnormalities, such as acute episodes of rhinitis or congestion due to any cause; and
5. Enbumyst™ must be prescribed by, or in consultation with, a specialist in the area of the patient's diagnosis (e.g., cardiologist, nephrologist, hepatologist, gastroenterologist); and
6. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or
    c. Torsemide oral tablets; and
7. Prescriber must verify the member will discontinue oral diuretics during the treatment with Enbumyst™ and will transition back to oral diuretic maintenance therapy when practical; and
8. Prescriber must verify the member or caregiver will be counseled on the proper administration of Enbumyst™; and
9. Approvals will be issued per incident of edema; and
    a. A quantity limit of 36 nasal spray devices per 36 days will apply; or
    b. For requests exceeding the quantity limit, clinical documentation supporting the need for additional supply must be provided for a quantity limit override; and
10. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of edema.

Lasix® ONYU (Furosemide On-Body Infusor) Approval Criteria:

1. An FDA approved indication for the treatment of edema in members with chronic heart failure; and
2. Member must be 18 years of age or older; and
3. Must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of edema; and
5. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or
    c. Torsemide oral tablets; and
6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Lasix® ONYU and will transition back to oral diuretic maintenance therapy when practical; and

7. Prescriber must verify the member or caregiver will be trained on the proper use of Lasix® ONYU and is able to detect and respond to the device alarms; and
8. Member must not have any contraindications for use of Lasix® ONYU; and
9. Member must not have conditions that require immediate hospitalization; and
10. The following quantity limits will apply:
    a. Approval quantities for the kit (i.e., co-packaged prefilled-cartridge and disposable unit) will be issued per incident of edema; and
    b. 1 Reusable Unit (drug delivery device) per year; or
        i. For requests exceeding this limit, approval of an additional Reusable Unit will be granted upon verification that the previously dispensed Reusable Unit has reached its lifespan of 48 uses, as indicated in package labeling; and
        ii. Only 1 Reusable Unit will be approved at a time; and
11. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of edema.

Myqorzo™ (Aficamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55% to initiate therapy; and
    a. Prescriber must agree to assess the member's clinical status and LVEF during treatment and adjust or interrupt the Myqorzo™ dose accordingly; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or non-dihydropyridine calcium channel blockers; and
7. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments or increased monitoring according to package labeling, prior to and during treatment with Myqorzo™; and
8. Prescriber, pharmacy, and member must be enrolled in the Myqorzo™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. A quantity limit of 30 tablets per 30 days will apply; and

10. Initial approvals will be for the duration of 6 months. Subsequent approvals, for the duration of 1 year, may be granted if the prescriber attests that the member is tolerating and responding well to treatment.

The College of Pharmacy also recommends updating the approval criteria for Camzyos® (mavacamten), Furoscix® (furosemide on-body infusor), and Verquvo® (vericiguat) based on recent FDA approvals (changes shown in red):

Camzyos® (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or non-dihydropyridine calcium channel blockers; and
7. ~~Member must not be taking concurrent strong CYP2C19 inhibitors (e.g., fluvoxamine, fluconazole), moderate to strong CYP2C19 inducers (e.g., rifampin), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and~~
8. ~~If the member is taking moderate to strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin) or weak to moderate CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole), the prescriber must verify that the Camzyos® dose will be adjusted according to the package labeling; and~~
9. Prescriber must evaluate the potential for drug interactions, including the need for dose adjustments, according to package labeling, prior to and during treatment with Camzyos®; and
10. Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos®; and
11. 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 4 months after the final dose of Camzyos®; and
12. Prescriber, pharmacy, and member must be enrolled in the Camzyos® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
13. A quantity limit of 30 capsules per 30 days will apply; and

14. Initial approvals will be for the duration of 6 months. Subsequent ~~Further~~ approvals, for the duration of 1 year, may be granted if the prescriber attests ~~documents~~ that the member is tolerating and responding well to treatment.~~; and~~
~~15. Subsequent approvals will be for the duration of 1 year.~~

Furoscix® (Furosemide On-Body Injection) Approval Criteria:

1. An FDA approved indication for the treatment of edema in members with chronic heart failure or chronic kidney disease (CKD), including nephrotic syndrome; and
~~2. Member must be 18 years of age or older; and~~
3. Member must weigh ≥43kg; and
4. Furoscix® must be prescribed by, or in consultation with, a cardiologist, nephrologist, or a provider trained in managing acute decompensated heart failure (ADHF) or CKD; and
5. Member is currently showing signs of edema; and
6. Member has been established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or
    c. Torsemide oral tablets; and
7. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
~~8. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:~~
    ~~a. Oxygen saturation ≥90% on exertion; and~~
    ~~b. Respiratory rate <24 breaths per minute; and~~
    ~~c. Resting heart rate <100 beats per minute; and~~
    ~~d. Systolic blood pressure >100mmHg; and~~
~~9. Member must have an adequate environment for at-home administration, have been trained on the proper use of Furoscix®, and be able to detect and respond to the device alarms; and~~
10. Prescriber must verify the member or caregiver will be trained on the proper use of Furoscix® and is able to detect and respond to the device alarms; and
11. Member must not have any contraindications for use of Furoscix® ~~including anuria or hepatic cirrhosis;~~ and
12. Member must not have conditions that require immediate hospitalization; and
13. Approvals will be issued per incident of edema ~~fluid overload~~; and

14. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of edema ~~fluid overload~~.

Verquvo® (Vericiguat) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death and hospitalization for heart failure (HF) in adults with all of the following:
   a. Chronic symptomatic HF [New York Heart Association (NYHA) Class II, III, or IV]; and
   b. Reduced left ventricular ejection fraction (LVEF) <45%; and
   c. Already receiving guideline-directed medical therapy for HF, as documented in member's pharmacy claims history; and
2. Member has evidence of worsening HF (decompensation) demonstrated by at least 1 of the following:
   a. Hospitalization for HF within the past 6 months; or
   b. Received outpatient intravenous (IV) diuretics within the past 3 months; and
3. Member must be 18 years of age or older; and
4. Member must not be taking concomitant soluble guanylate cyclase (sGC) stimulators (e.g., riociguat); and
5. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during treatment and for 1 month after the final dose of Verquvo®; and
6. Prescriber must attest that the member will be assessed for symptomatic hypotension before initiation and during treatment per package labeling; and
7. Prescriber must verify that the dose will be adjusted per package labeling for members at increased risk for symptomatic hypotension; and
8. Prescriber must agree to titrate to the target maintenance dose according to package labeling, as tolerated by the member; and
9. Initial approvals will be for the duration of 6 months. Compliance will be checked for continued approval every 6 months; and
10. A quantity limit of 30 tablets per 30 days will apply.

Utilization Details of HF Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SACUBITRIL/VALSARTAN PRODUCTS						
ENTRESTO TAB 24/26MG	5,996	1,419	$3,817,742.04	$636.71	4.23	45.37%
ENTRESTO TAB 49/51MG	3,238	720	$2,136,231.85	$659.74	4.5	25.39%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ENTRESTO TAB 97/103MG	2,221	421	$1,489,846.50	$670.80	5.28	17.71%
SUBTOTAL	**11,455**	**2,560**	**$7,443,820.39**	**$649.86**	**4.47**	**88.47%**
IVABRADINE PRODUCTS						
IVABRADINE TAB 5MG	211	81	$34,727.25	$164.58	2.6	0.41%
CORLANOR TAB 5MG	104	33	$56,155.20	$539.95	3.15	0.67%
IVABRADINE TAB 7.5MG	90	24	$18,560.04	$206.22	3.75	0.22%
CORLANOR SOL 5MG/5ML	34	6	$21,252.19	$625.06	5.67	0.25%
CORLANOR TAB 7.5MG	21	9	$12,434.50	$592.12	2.33	0.15%
SUBTOTAL	**460**	**153**	**$143,129.18**	**$311.15**	**3.01**	**1.71%**
MAVACAMTEN PRODUCTS						
CAMZYOS CAP 5MG	44	12	$358,485.33	$8,147.39	3.67	4.26%
CAMZYOS CAP 2.5MG	25	3	$209,139.40	$8,365.58	8.33	2.49%
CAMZYOS CAP 10MG	19	4	$140,134.08	$7,375.48	4.75	1.67%
CAMZYOS CAP 15MG	8	2	$67,472.77	$8,434.10	4	0.8%
SUBTOTAL	**96**	**21**	**$775,231.58**	**$8,075.33**	**4.57**	**9.21%**
VERICIGUAT PRODUCTS						
VERQUVO TAB 5MG	26	5	$14,195.51	$545.98	5.2	0.17%
VERQUVO TAB 10MG	22	7	$14,661.01	$666.41	3.14	0.17%
VERQUVO TAB 2.5MG	12	7	$7,664.57	$638.71	1.71	0.09%
SUBTOTAL	**60**	**19**	**$36,521.09**	**$608.68**	**3.16**	**0.43%**
SUBCUTANEOUS FUROSEMIDE PRODUCTS						
FUROSCIX KIT 80MG/10ML	2	1	$15,181.70	$7,590.85	2	0.18%
SUBTOTAL	**2**	**1**	**$15,181.70**	**$7,590.85**	**2**	**0.18%**
TOTAL	**12,073**	**2,369***	**$8,413,883.94**	**$696.92**	**5.1**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members
CAP = capsule; SOL = solution; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix O

Fiscal Year 2025 Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® Iqlik™ (Lecanemab-irmb)

Oklahoma Health Care Authority
July 2026

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.

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 28; 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.

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 of Alzheimer's Disease Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	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**
Fiscal Year 2025							
FFS	964	6,000	$86,464.11	$14.41	$0.42	312,894	204,532
Aetna	80	308	$10,287.20	$33.40	$0.76	19,213	13,556
Humana	104	433	$6,549.70	$15.13	$0.35	26,545	18,902
OCH	70	221	$3,683.88	$16.67	$0.29	17,693	12,853
2025 Total	**1,167**	**6,962**	**$106,984.89**	**$15.37**	**$0.43**	**376,345**	**249,843**
% Change	**22.80%**	**14.30%**	**16.80%**	**2.20%**	**4.90%**	**12.80%**	**11.80%**
Change	**217**	**873**	**$15,393.84**	**$0.33**	**$0.02**	**42,684**	**26,437**

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 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

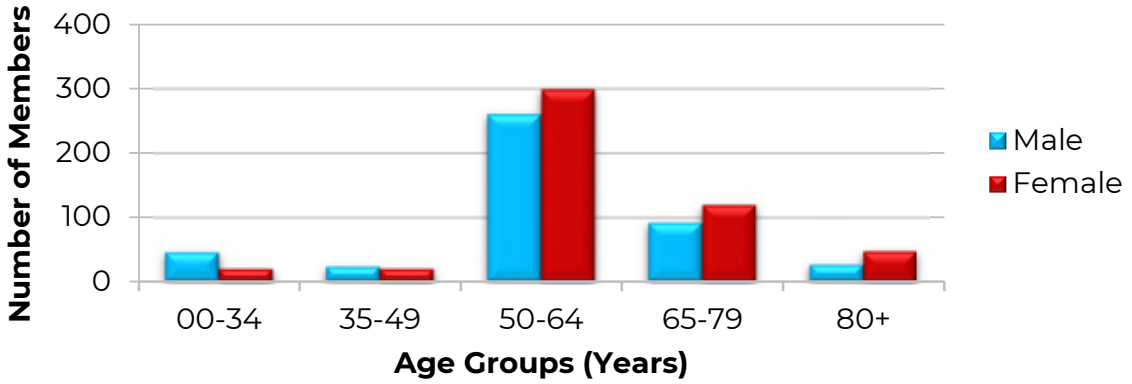
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	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**
Fiscal Year 2025					
FFS	1	16	$13,158.80	$822.43	16
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2025 Total	**1**	**16**	**$13,158.80**	**$822.43**	**16**
% Change	**0.00%**	**-27.27%**	**-55.51%**	**-38.82%**	**-27.27%**
Change	**0**	**-6**	**-$16,417.20**	**-$521.93**	**-6**

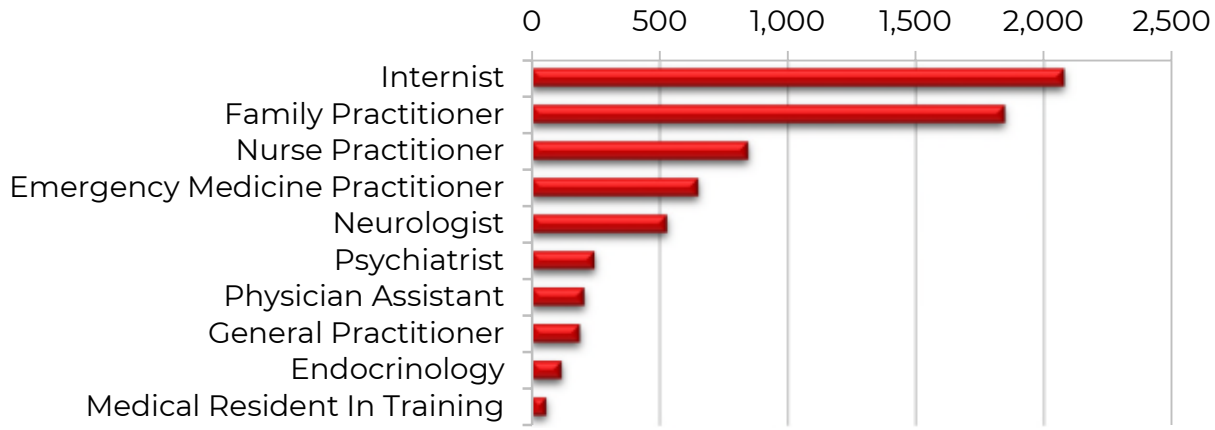
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = OK Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for Alzheimer's disease medications totaled $16,499.07[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 448 prior authorization requests submitted for Alzheimer's disease medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

[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.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	198	48%	81	20%	130	32%	**409**
Aetna	4	33%	4	33%	4	33%	**12**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	9	33%	2	7%	16	59%	**27**
Total	**211**	**47%**	**87**	**19%**	**150**	**34%**	**448**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health

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

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):

- **August 2025:** The FDA approved Leqembi® Iqlik™ (lecanemab-irmb), a subcutaneous (sub-Q) maintenance injection for the treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease. The sub-Q formulation provides an alternative to the previously approved intravenous (IV) infusion and is intended to reduce administration burden for patients and caregivers. Approval was supported by pharmacokinetic and exposure data demonstrating that the sub-Q formulation provides comparable drug exposure to the IV formulation. The recommended maintenance dose is 360mg administered once weekly by sub-Q injection after completion of the IV initiation phase. The approval expands administration options for patients receiving lecanemab therapy. In addition to this new formulation of lecanemab, the FDA also issued a Drug Safety Communication to require label updates regarding

additional magnetic resonance imaging (MRI) monitoring prior to the 3rd infusion for patients taking lecanemab.

Pipeline:

- **Leqembi® Iqlik™ (Lecanemab-irmb):** Leqembi® Iqlik™ is being studied as a starting dose for the treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease. Currently Leqembi® Iqlik™ is only approved for maintenance dosing following 18 months of the lecanemab IV infusion. A supplemental Biologic License Application (sBLA) was submitted and accepted by the FDA and a Prescription Drug User Fee Act (PDUFA) date of May 24, 2026 was set. The sBLA is supported by data evaluating the sub-Q administration of lecanemab across a range of doses and data showed that once-weekly administration of 500mg sub-Q achieved equivalent exposure to once every 2 weeks IV administration and similar clinical and biomarker benefits. The sub-Q administration demonstrated a safety profile similar to IV administration, with less than 2% incidence of systemic injection or infusion-related reactions. The FDA requested additional information that they determined would lead to a major amendment to the sBLA and extended the review period and set a new PDUFA date of August 24, 2026.

Recommendations

The College of Pharmacy recommends the prior authorization of Leqembi® Iqlik™ (lecanemab-irmb) with criteria similar to Leqembi® (lecanemab-irmb), including updates to the MRI monitoring criteria based on the Drug Safety Communication and corresponding label updates (changes shown in red):

Leqembi® and Leqembi® Iqlik™ (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. Lecanemab-irmb ~~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 lecanemab-irmb ~~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 lecanemab-irmb ~~Leqembi®~~; and prior to the 3rd, 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 lecanemab-irmb ~~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. Requests for the Leqembi® intravenous (IV) formulation will require the following:

a. 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
b. 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
c. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
d. For a maintenance dose of 10mg/kg every 4 weeks, prescriber must verify the member has received treatment with Leqembi® at a dose of 10mg/kg every 2 weeks for 18 months; and

15. Requests for the Leqembi® Iqlik™ subcutaneous (sub-Q) formulation will require the following:
    a. Member has received treatment with the IV formulation at a dose of 10mg/kg every 2 weeks for 18 months; and
    b. Member or caregiver has been trained by a health care professional on the sub-Q administration and proper storage of Leqembi® Iqlik™; 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 for the IV formulation and 7.2mL per 28 days for the sub-Q formulation; and
20. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

Utilization Details of Alzheimer's Disease Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MEMANTINE PRODUCTS						
MEMANTINE TAB HCL 10MG	3,030	544	$45,178.87	$14.91	5.57	42.23%
MEMANTINE TAB HCL 5MG	1,159	302	$17,755.69	$15.32	3.84	16.60%
MEMANTINE HCL CAP 28MG ER	90	9	$2,271.57	$25.24	10	2.12%
MEMANTINE HCL CAP 7MG ER	11	2	$255.35	$23.21	5.5	0.24%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MEMANTINE HCL SOL 2MG/ML	4	1	$683.06	$170.77	4	0.64%
MEMANTINE TITRA PACK 5-10MG	3	3	$79.55	$26.52	1	0.07%
SUBTOTAL	**4,297**	**861**	**$66,224.09**	**$15.41**	**4.99**	**61.90%**
DONEPEZIL PRODUCTS						
DONEPEZIL TAB 10MG	1,384	320	$17,301.01	$12.50	4.33	16.17%
DONEPEZIL TAB 5MG	1,126	309	$13,631.78	$12.11	3.64	12.74%
DONEPEZIL TAB 23MG	4	2	$123.98	$31.00	2	0.12%
DONEPEZIL ODT 5MG	2	1	$65.54	$32.77	2	0.06%
SUBTOTAL	**2,516**	**632**	**$31,122.31**	**$12.37**	**3.98**	**29.09%**
RIVASTIGMINE PRODUCTS						
RIVASTIGMINE CAP 3MG	30	6	$730.16	$24.34	5	0.68%
RIVASTIGMINE CAP 1.5MG	21	8	$465.82	$22.18	2.63	0.44%
RIVASTIGMINE CAP 4.5MG	10	4	$209.49	$20.95	2.5	0.20%
RIVASTIGMINE PATCH 9.5MG/24HR	7	1	$422.61	$60.37	7	0.40%
RIVASTIGMINE CAP 6MG	6	1	$136.37	$22.73	6	0.13%
RIVASTIGMINE PATCH 4.6MG/24HR	2	2	$126.02	$63.01	1	0.12%
SUBTOTAL	**76**	**22**	**$2,090.47**	**$27.51**	**3.45**	**1.95%**
GALANTAMINE PRODUCTS						
GALANTAMINE TAB 8MG	27	4	$798.29	$29.57	6.75	0.75%
GALANTAMINE TAB 4MG	25	5	$525.46	$21.02	5	0.49%
GALANTAMINE CAP 16MG ER	11	1	$432.80	$39.35	11	0.40%
SUBTOTAL	**63**	**10**	**$1,756.55**	**$27.88**	**6.3**	**1.64%**
MEMANTINE/DONEPEZIL COMBINATION PRODUCTS						
MEMAN/DONEP CAP 28-10MG	5	1	$2,872.31	$574.46	5	2.68%
NAMZARIC CAP 7-10MG	2	1	$1,154.31	$577.16	2	1.08%
NAMZARIC CAP 14-10MG	1	1	$578.40	$578.40	1	0.54%
NAMZARIC CAP 21-10MG	1	1	$580.09	$580.09	1	0.54%
NAMZARIC CAP 28-10MG	1	1	$606.36	$606.36	1	0.57%
SUBTOTAL	**10**	**5**	**$5,791.47**	**$579.15**	**2**	**5.41%**
TOTAL	**6,962**	**1,167***	**$106,984.89**	**$15.37**	**5.97**	**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; MEMAN/DONEP = memantine/ donepezil; ODT = oral disintegrating tablet; SOL = solution; TAB = tablet; TITRA = titration
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LECANEMAB-IRMB INJ J0174	16	1	$13,158.80	$822.43	16
TOTAL	**16**	**1**	**$13,158.80**	**$822.43**	**16**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[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 06/2026. Last accessed 06/16/2026.
[2] Leqembi® Iqlik™ (Lecanemab-irmb) Prescribing Information. Eisai Inc. Available online at: https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf?hash=fd09a407-669b-4124-a068-0adcbbc8bfbd. Last revised 08/2025. Last accessed 06/26/2026.
[3] U.S. FDA. FDA to Recommend Additional, Earlier MRI Monitoring for Patients with Alzheimer's Disease Taking Leqembi® (Lecanemab). Available online at: https://www.fda.gov/drugs/drug-safety-communications/fda-recommend-additional-earlier-mri-monitoring-patients-alzheimers-disease-taking-leqembi-lecanemab. Issued 08/28/2025. Last accessed 06/26/2026
[4] Biogen. FDA Accepts Leqembi® Iqlik™ (Lecanemab-irmb) Supplemental Biologics License Application as a Subcutaneous Starting Dose for the Treatment of Early Alzheimer's Disease under Priority Review. Available online at: https://investors.biogen.com/news-releases/news-release-details/fda-accepts-leqembir-iqliktm-lecanemab-irmb-supplemental. Issued 01/25/2026. Last accessed 06/26/2026.
[5] Eisai. Update on FDA Priority Review of Leqembi® Iqlik™ (Lecanemab-irmb) Subcutaneous Injection as a Starting Dose for Early Alzheimer's Disease. Available online at: https://www.eisai.com/news/2026/pdf/enews202625pdf.pdf. Issued 05/08/2026. Last accessed 06/26/2026.

Appendix P

Fiscal Year 2025 Annual Review of Testosterone Products

Oklahoma Health Care Authority
July 2026

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, tube (Androgel®, Testim®, Vogelxo®)	testosterone cypionate IM inj (Azmiro™)
testosterone topical gel 1.62% pump (Androgel®)	testosterone topical gel 1% pump (Vogelxo®)	testosterone nasal gel (Natesto®)
	testosterone topical gel 2% pump (Fortesta®)	testosterone pellets (Testopel®)
	testosterone topical solution (Axiron®)	testosterone undecanoate IM inj (Aveed®)
		testosterone undecanoate oral cap (Jatenzo®, 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 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	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**
Fiscal Year 2025							
FFS	188	735	$36,758.69	$50.01	$1.49	19,591	24,692
Aetna	332	1,120	$56,839.89	$50.75	$2.02	20,622	28,123
Humana	533	1,573	$83,062.39	$52.81	$1.66	18,062	49,994
OCH	463	1,215	$62,086.35	$51.10	$1.86	14,091	33,355
2025 Total	**1,456**	**4,643**	**$238,747.32**	**$51.42**	**$1.75**	**72,366**	**136,164**
% Change	**15.70%**	**50.70%**	**34.70%**	**-10.60%**	**-3.30%**	**62.80%**	**39.00%**
Change	**198**	**1,563**	**$61,544.09**	**-$6.11**	**-$0.06**	**27,924**	**38,182**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

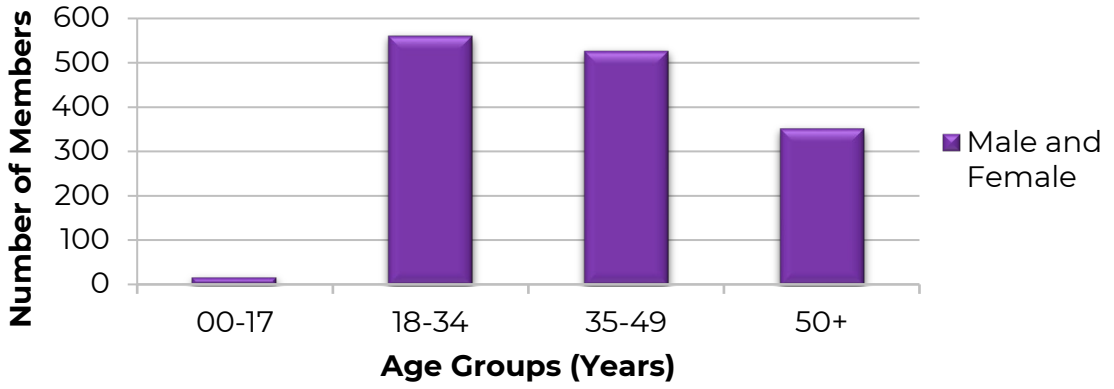
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	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**
Fiscal Year 2025					
FFS	5	9	$25.00	$2.78	1.8
Aetna	34	175	$415.87	$2.38	5.15
Humana	52	191	$223.55	$1.17	3.67
OCH	34	164	$328.34	$2.00	4.82
2025 Total	**124**	**539**	**$992.76**	**$1.84**	**4.35**
% Change	**264.71%**	**557.32%**	**739.47%**	**27.78%**	**80.50%**
Change	**90**	**457**	**$874.50**	**$0.40**	**1.94**

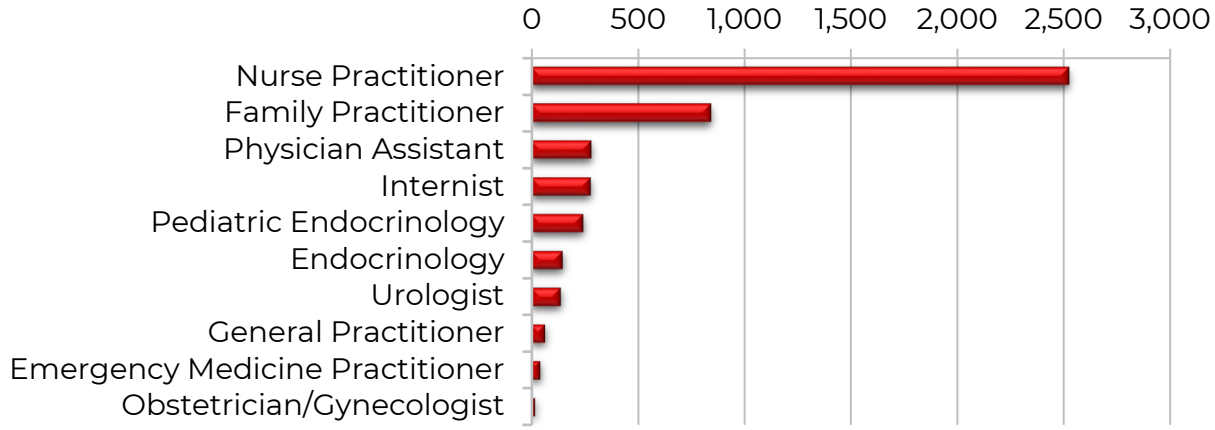
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for testosterone products totaled $32,511.28[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 Testosterone Products: Pharmacy Claims (All Plans)



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

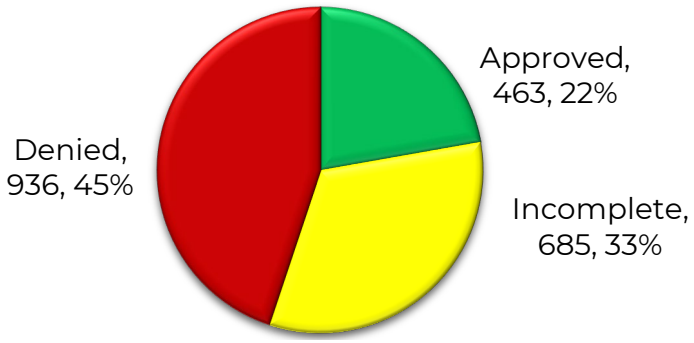


Prior Authorization of Testosterone Products

There were 2,084 prior authorization requests submitted for testosterone products during fiscal year 2025. All testosterone products require prior authorization regardless of tier status in order to evaluate diagnosis and submitted labs. The following charts show the status of the submitted petitions for fiscal year 2025.

[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.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	211	24%	453	51%	219	25%	**883**
Aetna	77	19%	180	45%	144	36%	**401**
Humana	104	28%	0	0%	263	72%	**367**
OCH	71	16%	52	12%	310	72%	**433**
Total	**463**	**22%**	**685**	**33%**	**936**	**45%**	**2,084**

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

Market News and Updates[1]

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

Recommendations

The College of Pharmacy does not recommend any changes to the Testosterone Products Product Based Prior Authorization (PBPA) category at this time.

Utilization Details of Testosterone Products: Fiscal Year 2025

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	4,007	1,266	$167,846.26	$41.89	3.17	70.30%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TESTOST CYP INJ 100MG/ML	61	37	$3,522.49	$57.75	1.65	1.48%
TESTOST ENAN INJ 200MG/ML	23	14	$1,746.71	$75.94	1.64	0.73%
XYOSTED INJ 50MG/0.5ML	17	4	$10,442.45	$614.26	4.25	4.37%
XYOSTED INJ 75MG/0.5ML	9	3	$5,608.97	$623.22	3	2.35%
XYOSTED INJ 100MG/0.5ML	7	3	$4,325.00	$617.86	2.33	1.81%
DEPO-TESTOST INJ 200MG/ML	2	2	$138.67	$69.34	1	0.06%
DEPO-TESTOST INJ 100MG/ML	1	1	$74.04	$74.04	1	0.03%
SUBTOTAL	**4,127**	**1,330**	**$193,704.59**	**$46.94**	**3.1**	**81.13%**
TESTOSTERONE TOPICAL PRODUCTS						
TESTOSTERONE GEL 1.62% PUMP	292	105	$14,353.62	$49.16	2.78	6.01%
TESTOSTERONE GEL 1% (50MG)	198	50	$23,621.71	$119.30	3.96	9.89%
TESTOSTERONE GEL 1% PUMP	8	7	$1,507.79	$188.47	1.14	0.63%
TESTOSTERONE GEL 1.62% (20.25MG)	7	2	$2,211.35	$315.91	3.5	0.93%
TESTOSTERONE GEL 1.62% (40.5MG)	5	3	$842.92	$168.58	1.67	0.35%
TESTOSTERONE GEL 1% (25MG)	2	2	$203.84	$101.92	1	0.09%
ANDROGEL GEL 1.62% PUMP	2	2	$1,205.12	$602.56	1	0.50%
TESTOSTERONE SOL 30MG/ACT	1	1	$85.74	$85.74	1	0.04%
SUBTOTAL	**515**	**172**	**$44,032.09**	**$85.50**	**2.99**	**18.44%**
TESTOSTERONE ORAL PRODUCTS						
JATENZO CAP 237MG	1	1	$1,010.64	$1,010.64	1	0.42%
SUBTOTAL	**1**	**1**	**$1,010.64**	**$1,010.64**	**1**	**0.42%**
TOTAL	**4,643**	**1,456***	**$238,747.32**	**$51.42**	**3.19**	**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 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TESTOSTERONE CYPIONATE INJ J1071	539	124	$992.76	$1.84	4.35
TOTAL	**539**	**124**	**$992.76**	**$1.84**	**4.35**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[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 06/2026. Last Accessed 06/16/2026.

Appendix Q

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 17, 2026

FDA Approves First Single-Dose Generic Treatment for Influenza

The FDA approved the first generic of Xofluza® (baloxavir marboxil) tablets, the first single-dose treatment for acute uncomplicated influenza and prophylaxis in patients 5 years of age and older. Generic baloxavir marboxil tablets may be used for:

- Treatment of acute uncomplicated influenza in patients 5 years of age and older who have been symptomatic for no more than 48 hours, and who are otherwise healthy or at high risk of developing influenza-related complications; and
- Post-exposure prophylaxis of influenza in patients 5 years of age and older following contact with an individual who has influenza.

Baloxavir marboxil tablets are contraindicated in patients with a known history of hypersensitivity reactions to baloxavir marboxil or any of its ingredients. Baloxavir marboxil carries warnings such as increased incidence of treatment-emergent resistance in patients younger than 5 years of age. The most common side effects include diarrhea, bronchitis, nausea, sinusitis, and headaches. Healthcare providers should review the full prescribing information for complete safety and dosing information.

Xofluza® is a registered trademark of Genentech, Inc. FDA approved Norwich Pharmaceuticals, Inc.'s application for generic baloxavir marboxil tablets.

FDA NEWS RELEASE

For Immediate Release: June 16, 2026

FDA Broadens Access to Over-the-Counter Naloxone Nasal Spray for Opioid Overdose

The FDA approved another over-the-counter (OTC) intranasal naloxone product, Rextovy™, a 4mg naloxone hydrochloride nasal spray for the emergency treatment of opioid overdose. Consumers may directly purchase this product without a prescription in places such as pharmacies, convenience stores, and online.

Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. Rextovy™ is an additional life-saving medication approved by the FDA to reverse an opioid overdose to be sold directly to consumers and contains the same active ingredient as other naloxone nasal sprays. The availability of multiple

approved formulations expands access and market availability, encourages competition that may reduce costs, and offers alternative sourcing options. The number of overdose deaths has dramatically decreased since the first FDA approval of an OTC naloxone nasal spray in 2023, but drug overdose persists as a major public health issue in the U.S., primarily driven by synthetic opioids like illicit fentanyl. In the 12-month period ending in August 2023, 111,451 overdose deaths were reported; in the 12-month period ending in December 2025, 68,632 overdose deaths were reported.

When using Rextovy™, some people may experience symptoms when they regain consciousness following overdose reversal, such as shaking, sweating, nausea, or anger. The product is safe to use even when it is uncertain whether opioids are present in the person's system. The product's packaging includes pictorial directions with five clear steps, including calling 911 after giving the first dose.

The FDA granted the nonprescription approval to Amphastar Pharmaceuticals, Inc.

FDA NEWS RELEASE

For Immediate Release: June 15, 2026

FDA Approves New Indication for Tzield® (Teplizumab) for Certain Pediatric Patients with Recently Diagnosed Stage 3 Type 1 Diabetes

The FDA granted accelerated approval to Tzield® (teplizumab) for a new indication, to delay the decline of insulin production in pediatric patients ages 8 through 17 years who have been recently diagnosed with Stage 3 type 1 diabetes (T1D). This approval marks the first FDA-approved treatment for this indication and represents an important advancement for children living with type 1 diabetes and their families.

Tzield® was previously approved to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients 1 year of age and older with Stage 2 type 1 diabetes. The newly approved indication is for the use of Tzield® to help delay the decline in insulin production in certain pediatric patients who have recently been diagnosed with Stage 3 disease.

The FDA granted this application under the FDA's accelerated approval pathway. The approval was based on evidence from an adequate and well-controlled clinical trial that Tzield® demonstrated a statistically significant effect on C-peptide, a surrogate endpoint reasonably likely to predict clinical benefit. A required post-approval study is ongoing to verify clinical benefit.

Healthcare professionals and patients should review the prescribing information for important safety information. The approved labeling includes a boxed warning regarding serious and life-threatening cases of viral reactivation, including Epstein-Barr virus (EBV) and cytomegalovirus (CMV) reactivation, reported with Tzield®. The most common side effects of the drug are vomiting, rash, increased liver transaminase, and headache. Tzield® is

associated with leukopenia, lymphopenia, and neutropenia that can increase the risk for certain infections.

FDA NEWS RELEASE

For Immediate Release: June 12, 2026

FDA Clears First Over-the-Counter Continuous Glucose Monitor for Children

The FDA cleared for marketing the first over-the-counter (OTC) continuous glucose monitor (CGM) for children, Dexcom Inc.'s Stelo Glucose Biosensor System, an integrated CGM (iCGM) indicated for people 2 years of age and older who do not use insulin. The FDA previously cleared the Stelo Glucose Biosensor System OTC for individuals 18 years and older in March 2024.

Prediabetes is increasingly impacting children in the United States, placing millions at heightened risk for progressing to Type 2 diabetes. OTC CGMs can play a critical role in addressing this public health concern for pediatric users who do not use insulin. By providing real-time glucose data, these devices can help pediatric patients and their caregivers build greater glycemic awareness, track patterns in response to meals and exercise, and make informed adjustments to support healthier long-term outcomes and quality of life.

The product is indicated for children, including those with diabetes, who receive oral medication to manage their condition and people who want to understand how diet, exercise, and other lifestyle changes affect their glucose levels. The Stelo Glucose Biosensor System uses a wearable sensor, paired with an application installed on a compatible smartphone, or other smart device, such as a parent's or caregiver's smartphone, to continuously measure, record, analyze and display glucose values. Each sensor lasts for up to 15 days before it must be replaced, although sensor wear time may be shorter in pediatric users than in adults due to several interconnected physiological and behavioral factors. The app displays glucose measurements and trends every 15 minutes. Users and their caregivers should consult their health care provider before making any medication adjustments based on the device's output.

Dexcom and the FDA used previous clinical study data from both pediatrics and adults, along with real-world data on current iCGM use among both groups, to understand expected device performance in pediatric users over the full 15-day wear period. Participants in the previous study reported mild adverse events including local infection, skin irritation, and pain or discomfort.

For children, the device should be used under the supervision of an adult caregiver. Importantly, this system is not for people with problematic hypoglycemia because it is not designed to alert users when this potentially dangerous condition occurs. This system is also not for people on dialysis.

People with a history of disordered eating or eating disorders should talk with their health care provider before using Stelo.

FDA NEWS RELEASE
For Immediate Release: June 9, 2026
FDA Expands Sunscreen Options for the First Time in 20 Years

The FDA added bemotrizinol to the list of permitted sunscreen active ingredients, marking a significant milestone in the FDA's efforts to advance sunscreen innovation. Bemotrizinol is the first new active ingredient added to the over-the-counter (OTC) sunscreen monograph since the late 1990s.

The new ingredient has been marketed as a sunscreen ingredient in Europe and many countries around the world for years. Bemotrizinol provides protection against both ultraviolet A and B rays and has low levels of absorption through the skin into the body. The FDA considers bemotrizinol to be generally recognized as safe and effective (GRASE) for use in sunscreens by adults and children 6 months of age and older.

Bemotrizinol is the first new active ingredient added to an OTC monograph under the streamlined process established by the CARES Act.

FDA NEWS RELEASE
For Immediate Release: June 2, 2026
FDA Issues Draft Guidance to Help Accelerate Cell and Gene Therapies for Patients

The FDA issued draft guidance to help developers bring promising gene therapies to patients more efficiently by making greater use of existing scientific and regulatory knowledge.

When finalized, the guidance will outline how sponsors can use publicly available information and established platform knowledge, including chemistry, manufacturing, and controls (CMC) data, nonclinical study results, and clinical information, to streamline regulatory submissions for human gene therapy products that use genome editing in human somatic cells.

This draft guidance supports the development of a wide range of cell and gene therapy products, including those that use genome editing, and is part of a broader set of complementary FDA actions in this area.

For sponsors developing genome editing therapies, it complements the FDA's Plausible Mechanism Framework, providing the scientific tools and data-sharing strategies that allow sponsors to efficiently establish the evidentiary foundation this approach requires. It also works in tandem with the FDA's recently issued draft guidance, Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing, which recommends methods for evaluating off-target editing risks. This new draft guidance explains how sponsors can use existing public and platform knowledge to streamline regulatory submissions across multiple stages of product development. Together with the FDA’s other

recent actions, it provides developers across the cell and gene therapy field with a clear, science-based path for building on existing knowledge and experience, while maintaining the rigorous standards needed to ensure patient safety.

In all cases, sponsors should provide a scientific rationale demonstrating the applicability of the data being leveraged to their specific product and development context. The FDA encourages sponsors to engage early in product development, even before submitting an Investigational New Drug (IND) application, for example through Initial Targeted Engagement for Regulatory Advice on CBER/CDER Products (INTERACT) and pre-IND meetings, to discuss their specific development strategies.

Current Drug Shortages Index (as of June 25, 2026):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bacitracin Ophthalmic Ointment	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***

Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Furosemide Oral Solution	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Isocarboxazid Tablet	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***

Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***