OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday, September 9, 2026 4:00pm

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

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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 – September 9, 2026

DATE: September 2, 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 September meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

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

Update on the Medication Coverage Authorization Unit – Appendix B

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

Action Item – Vote to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten) and Update the Approval Criteria for the Heart Failure (HF) Medications – Appendix D

Action Item – Vote to Prior Authorize Leqembi Iqlik® (Lecanemab-irmb) – Appendix E

Action Item – Vote to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone) – Appendix F

Action Item – Vote to Prior Authorize Jobevne™ (Bevacizumab-nwgd) – Appendix G

Action Item – Vote to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate) and Update the Approval Criteria for the Miscellaneous Cancer Medications – Appendix H

Action Item – Vote to Update the Approval Criteria for the Iron Products – Appendix I

Action Item – Vote to Update the Approval Criteria for the Iron Chelating Agents – Appendix J

Action Item – Vote to Prior Authorize Amcinonide 0.1% Ointment and Update the Approval Criteria for the Topical Corticosteroids – Appendix K

Action Item – Vote to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid) and Update the Approval Criteria for the Various Systemic Antibiotics – Appendix L

Action Item – Vote to Prior Authorize Zycubo® (Copper Histidinate) – Appendix M

Action Item – Vote to Prior Authorize Morphine Oral Solution Syringes and Tapentadol Tablet, Extended-Release (ER) Tablet, and Oral Solution and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications – Appendix N

Action Item – Annual Review of Cystic Fibrosis (CF) Medications – Appendix O

Action Item – Annual Review of Amyloidosis Medications – Appendix P

Action Item – Annual Review of Bladder Control Medications – Appendix Q

Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Beizray™ (Docetaxel), Beizray™ Kit (Docetaxel/Albumin), Docivyx™ (Docetaxel), Inluriyo™ (Imlunestrant), and Veppanu™ (Vepdegestrant) – Appendix R

Annual Review of Various Ophthalmic Medications and 30-Day Notice to Prior Authorize Epioxa® HD/Epioxa® (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa™ (Veligrotug-wze) – Appendix S

Annual Review of Systemic Antihistamine Medications and 30-Day Notice to Prior Authorize Cetirizine Unit Dose Cups (UDCs) – Appendix T

Annual Review of Benign Prostatic Hyperplasia (BPH) Medications – Appendix U

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – September 9, 2026 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

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

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Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 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. July 8, 2026 DUR Board Meeting Minutes
   B. July 8, 2026 DUR Board Recommendations Memorandum
   C. August 5, 2026 DUR Board Recommendations Memorandum

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

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

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

5. **Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Utilization Update – See Appendix C**
   A. Introduction
   B. Mailing Summary
   C. Mailing Results
   D. DPP-4 Inhibitor Utilization in the SoonerCare Population FY25 to FY26

E. Conclusions
F. Recommendations

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

6. **Action Item – Vote to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten) and Update the Approval Criteria for the Heart Failure (HF) Medications – See Appendix D**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Leqembi Iqlik® (Lecanemab-irmb) – See Appendix E**
   A. Market News and Updates
   B. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone) – See Appendix F**
   A. Market News and Updates
   B. Awiqli® (Insulin Icodec-abae) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Jobevne™ (Bevacizumab-nwgd) – See Appendix G**
   A. Market News and Updates
   B. Cost Comparison: Bevacizumab Products
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate) and Update the Approval Criteria for the Miscellaneous Cancer Medications – See Appendix H**
    A. Market News and Updates
    B. Product Summaries
    C. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Update the Approval Criteria for the Iron Products – See Appendix I**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

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

12. **Action Item – Vote to Update the Approval Criteria for the Iron Chelating Agents – See Appendix J**
    A. College of Pharmacy Recommendations

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

13. **Action Item – Vote to Prior Authorize Amcinonide 0.1% Ointment and Update the Approval Criteria for the Topical Corticosteroids – See Appendix K**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

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

14. **Action Item – Vote to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid) and Update the Approval Criteria for the Various Systemic Antibiotics – See Appendix L**
    A. Market News and Updates
    B. Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Product Summary
    C. Cost Comparisons
    D. College of Pharmacy Recommendations

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

15. **Action Item – Vote to Prior Authorize Zycubo® (Copper Histidinate) – See Appendix M**
    A. Market News and Updates
    B. Zycubo® (Copper Histidinate) Product Summary
    C. College of Pharmacy Recommendations

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

16. **Action Item – Vote to Prior Authorize Morphine Oral Solution Syringes and Tapentadol Tablet, Extended-Release (ER) Tablet, and Oral Solution and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications – See Appendix N**
    A. Market News and Updates
    B. Cost Comparisons
    C. College of Pharmacy Recommendations

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

17. **Action Item – Annual Review of Cystic Fibrosis (CF) Medications – See Appendix O**
    A. Current Prior Authorization Criteria
    B. Utilization of CF Medications
    C. Prior Authorization of CF Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of CF Medications

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

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

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

19. **Action Item – Annual Review of Bladder Control Medications – See Appendix Q**
    A. Current Prior Authorization Criteria
    B. Utilization of Bladder Control Medications
    C. Prior Authorization of Bladder Control Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Bladder Control Medications

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

20. **Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Beizray™ (Docetaxel), Beizray™ Kit (Docetaxel/Albumin), Docivyx™ (Docetaxel), Inluriyo™ (Imlunestrant), and Veppanu™ (Vepdegestrant) – See Appendix R**
    A. Current Prior Authorization Criteria
    B. Utilization of Breast Cancer Medications
    C. Prior Authorization of Breast Cancer Medications
    D. Market News and Updates
    E. Product Summaries
    F. Cost Comparison: Trastuzumab Products
    G. College of Pharmacy Recommendations
    H. Utilization Details of Breast Cancer Medications

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

21. Annual Review of Various Ophthalmic Medications and 30-Day Notice to Prior Authorize Epioxa® HD/Epioxa® (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa® (Veligrotug-vvze) – See Appendix S

A. Current Prior Authorization Criteria
B. Utilization of Various Ophthalmic Medications
C. Prior Authorization of Various Ophthalmic Medications
D. Market News and Updates
E. Lumvoa® (Veligrotug-vvze) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Various Ophthalmic Medications

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

22. Annual Review of Antihistamine Medications (Systemic) and 30-Day Notice to Prior Authorize Cetirizine Oral Solution Unit Dose Cups (UDCs) – See Appendix T

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

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

23. Annual Review of Benign Prostatic Hyperplasia (BPH) Medications – See Appendix U

A. Current Prior Authorization Criteria
B. Utilization of BPH Medications
C. Prior Authorization of BPH Medications
D. College of Pharmacy Recommendations
E. Utilization Details of BPH Medications

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

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

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

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

A. Anemia Medications
B. Anticoagulants and Platelet Aggregation Inhibitors
C. Constipation and Diarrhea Medications
D. Fibromyalgia Medications
E. Myeloproliferative Neoplasm (MPN) Medications
F. Targeted Immunomodulator Agents

*Future product and class reviews subject to change.

26.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 JULY 8, 2026

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

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

Bradford Eckhart, J.D.; Deputy General Counsel	X	
Melissa Miller, State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	

OTHERS PRESENT:	
Jennifer Lauper, Bristol-Myers Squibb	Dan Calloway, Bristol-Myers Squibb
Andi Stratton, Krystal Biotech	Dominic Marchese, Krystal Biotech
Porscha Martin-Petties, Gilead	Andrew Delgado, Bristol-Myers Squibb
Courtney Walker, Novo Nordisk	David Prather, Novo Nordisk
David Mendoza, Otsuka	Deidra Williams, Humana
Laura Cordell, Sanofi	Lee Stout, Chiesi
Justin Springfield, Gilead	Kellie Vazzana, Alkermes
Kristen Winters, Centene	Bryan Steffan, Boehringer
Ashlee Waring, Organon	Scott Burns, Johnson & Johnson
Julie Rhodes, AbbVie	Andy Gorzynski, Cytokinetics
Miranda Ryzenman, Artia Solutions	Tim Melancon, Immedica
Marc Parker, VS Health Group	Kevin Chang, Sanofi
Jama Larose, Dyne Therapeutics	Wendy Lepore, MannKind
Colton Kreamer, MannKind	Irene Chung, Aetna
Lauren Ninas, MannKind	Gary Parenteau, Dexcom
Alice Chan, MannKind	Sergio Gomez, Concis
Vicky Viss, Phathom	Phillip Lohec, Viatris
Eardie Curry, Genentech	Andy Berg, Concis
Monica Mazziotti, MannKind	

PRESENT FOR PUBLIC COMMENT:	
Andrew Delgado, Bristol-Myers Squibb	Porscha Martin-Petties, Gilead
Dominic Marchese, Krystal Biotech	Courtney Walker, Novo Nordisk

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. 7 ANDREW DELGADO
2B: AGENDA ITEM NO. 8 PORSCHA MARTIN-PETTIES
2C: AGENDA ITEM NO. 13 DOMINIC MARCHESE
2D: AGENDA ITEM NO. 15 COURTNEY WALKER

ACTION: NONE REQUIRED

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

3A: JUNE 10, 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 JUNE 2026

4B: MEDICATION COVERAGE ACTIVITY FOR JUNE 2026

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **CHRONIC MEDICATION ADHERENCE (CMA) PROGRAM UPDATE**

5A: CMA PRESCRIBER MAILING SUMMARY

5B: MAILING SUMMARIES

5C: STAR RATINGS

5D: PROVIDER SUMMARY REPORT

5E: CMA TRENDS

5F: CONCLUSIONS

Materials included in agenda packet; presented by Dr. Travers

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE NEREUS™ (TRADIPITANT) AND POSFREA™ (PALONOSETRON INJECTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-EMETIC MEDICATIONS**

6A: MARKET NEWS AND UPDATES

6B: NEREUS™ (TRADIPITANT) PRODUCT SUMMARY

6C: COST COMPARISON: PALONOSETRON PRODUCTS

6D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

Dr. Holderread moved to approve; seconded by Dr. Blaiss

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE BYSANTI™ (MILSAPERIDONE) AND UPDATE THE APPROVAL CRITERIA FOR THE ATYPICAL ANTIPSYCHOTIC MEDICATIONS**

7A: MARKET NEWS AND UPDATES

7B: BYSANTI™ (MILSAPERIDONE) PRODUCT SUMMARY

7C: COST COMPARISON: ATYPICAL ANTIPSYCHOTICS FOR ADJUNCT TREATMENT OF MDD

7D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

Dr. Kupiec moved to approve; seconded by Dr. Holderread

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE HEPCLUDEX® (BULEVIRTIDE-GMOD), RELENZA® (ZANAMIVIR INHALATION POWDER), AND XOFLUZA® (BALOXAVIR) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIVIRAL MEDICATIONS**

8A: MARKET NEWS AND UPDATES

8B: HEPCLUDEX® (BULEVIRTIDE-GMOD) PRODUCT SUMMARY

8C: COST COMPARISON: ORAL INFLUENZA ANTIVIRAL MEDICATIONS

8D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

Moved to amend Sovaldi and Zepatier criteria to add "for hepatitis C treatment" to the specialist evaluation for consistency among other hepatitis C medications.

Dr. Ground moved to approve the amended criteria; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE PRIOR AUTHORIZE LOARGYS® (PEGZILARGINASE-NBLN) AND UPDATE THE APPROVAL CRITERIA FOR THE UREA CYCLE DISORDER (UCD) MEDICATIONS**

9A: MARKET NEWS AND UPDATES
9B: LOARGYS® PEGZILARGINASE-NBLN) 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

AGENDA ITEM NO. 10: **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)**

10A: INTRODUCTION
10B: PRODUCT SUMMARIES
10C: 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. 11: **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**

11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COST COMPARISON: CARBOPLATIN PRODUCTS
11D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 12: **ANNUAL REVIEW OF ANTI-ULCER MEDICATIONS**

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF ANTI-ULCER MEDICATIONS
12C: PRIOR AUTHORIZATION OF ANTI-ULCER MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF ANTI-ULCER MEDICATIONS

Materials included in agenda packet; presented by Dr. DeRemer
Dr. Kupiec moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF EB MEDICATIONS
13C: PRIOR AUTHORIZATION OF EB MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF EB MEDICATIONS

Materials included in agenda packet; presented by Dr. Moss
Moved to amend the initial approval length for both Vyjuvek and Filsuvez from 3 months to 6 months based on clinical practice.
Dr. Patatanian moved to approve the amended criteria; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF COLORECTAL CANCER (CRC) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE JOBEVNE™ (BEVACIZUMAB-NWGD)

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF CRC MEDICATIONS
14C: PRIOR AUTHORIZATION OF CRC MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: COST COMPARISON: BEVACIZUMAB PRODUCTS
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF CRC MEDICATIONS

Materials included in agenda packet; presented by Dr. Sinko
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 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)

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
15C: PRIOR AUTHORIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
15D: MARKET NEWS AND UPDATES
15E: AWIQLI® (INSULIN ICODEC-ABAE) PRODUCT SUMMARY
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)

Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 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)

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF HF MEDICATIONS
16C: PRIOR AUTHORIZATION OF HF MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: PRODUCT SUMMARIES
16F: COLLEGE OF PHARMACY RECOMMENDATIONS

16G: UTILIZATION DETAILS OF HF MEDICATIONS
Materials included in agenda packet; presented by Dr. Grimes
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 17: ANNUAL REVIEW OF ALZHEIMER'S DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LEQEMBI® IQLIK™ (LECANEMAB-IRMB)
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
17C: PRIOR AUTHORIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: COLLEGE OF PHARMACY RECOMMENDATIONS
17F: UTILIZATION DETAILS OF ALZHEIMER'S DISEASE MEDICATIONS
Materials included in agenda packet; presented by Dr. Dorsey
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 18: ANNUAL REVIEW OF TESTOSTERONE PRODUCTS
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF TESTOSTERONE PRODUCTS
18C: PRIOR AUTHORIZATION OF TESTOSTERONE PRODUCTS
18D: MARKET NEWS AND UPDATES
18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF TESTOSTERONE PRODUCTS
Non-presentation item; materials included in agenda packet by Dr. Wilson
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: 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. 20: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
NO LIVE DUR MEETING IS SCHEDULED FOR AUGUST 2026. AUGUST 2026 WILL BE A PACKET ONLY MEETING
20A: COPPER METABOLISM DISORDER MEDICATIONS
20B: IRON CHELATING AGENTS
20C: IRON PRODUCTS
20D: MISCELLANEOUS CANCER MEDICATIONS
20E: OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
20F: TOPICAL CORTICOSTEROIDS
20G: VARIOUS SYSTEMIC ANTIBIOTICS
*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. 21: ADJOURNMENT
The meeting was adjourned at 5:34pm.

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

Memorandum

Date: July 9, 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 July 8, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Chronic Medication Adherence (CMA) Program Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection) and Update the Approval Criteria for the Anti-Emetic Medications

MOTION CARRIED by unanimous approval.

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.

Recommendation 4: Vote to Prior Authorize Bysanti™ (Milsaperidone) and Update the Approval Criteria for the Atypical Antipsychotic Medications

MOTION CARRIED by unanimous approval.

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®)^			
olanzapine pamoate IM inj (Zyprexa® Relprevv™)			
paliperidone palmitate IM inj (Erzofri®)^			

Atypical Antipsychotic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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.

Recommendation 5: Vote to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder), and Xofluza® (Baloxavir) and Update the Approval Criteria for the Antiviral Medications

MOTION CARRIED by unanimous approval.

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, including the DUR Board's recommendation for clarification of the specialist evaluation *for hepatitis C treatment* to the Sovaldi® and Zepatier® criteria for consistency (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 for hepatitis C treatment 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 for hepatitis C treatment 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.

Recommendation 6: Vote to Prior Authorize Loargys® (Pegzilarginase-nbln) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications

MOTION CARRIED by unanimous approval.

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.

Recommendation 7: 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

MOTION CARRIED by unanimous approval.

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.

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			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	frovatriptan tablet (Frova®)	almotriptan tablet (Axert®)	DHE autoinjector (Brekiya®)
naratriptan tablet (Amerge®)	sumatriptan/ naproxen tablet (Treximet®)	DHE nasal spray (Migranal®)	DHE injection (D.H.E. 45®)
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)		sumatriptan autoinjector pen and vial (Imitrex®)	ergotamine sublingual tablet (Ergomar®)
sumatriptan tablet (Imitrex®)		sumatriptan nasal spray (Imitrex®)	**ergotamine/caffeine suppository (Migergot®)**
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			**ergotamine/caffeine tablet (Cafergot®)**
			lasmiditan tablet (Reyvow®)
			meloxicam/rizatriptan (Symbravo®)
			rimegepant ODT (Nurtec® ODT)
			sumatriptan injection (Imitrex® STATdose System)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zavegepant nasal spray (Zavzpret™)
			zolmitriptan nasal spray (Zomig® nasal spray)

*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).
DHE = dihydroergotamine; ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

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

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

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

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

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

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

The College of Pharmacy 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.

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.

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.

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.

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

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

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

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

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone 800mg tabs (Skelaxin®)	baclofen 5mg (Lioresal®)
chlorzoxazone 500mg (Parafon Forte®)		baclofen oral granules (Lyvispah®)
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		baclofen 10mg/5mL oral soln (Ozobax® DS)
orphenadrine (Norflex®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
tizanidine tabs (Zanaflex®)		carisoprodol 250mg (Soma®)
		carisoprodol 350mg (Soma®)
		chlorzoxazone 250mg tabs
		chlorzoxazone 375mg, 750mg (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		metaxalone 400mg tabs (Skelaxin®)
		metaxalone 640mg tabs

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
		methocarbamol 1,000mg tabs (Tanlor®)
		methocarbamol oral susp (Atmeksi®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)
		tizanidine caps (Zanaflex®)
		tizanidine oral soln (Ontralfy™)

*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).
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets

Ontralfy™ (Tizanidine Oral Solution) Approval Criteria:

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

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

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

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

The College of Pharmacy recommends the prior authorization of Quiofic™ (folic acid solution) 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.

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.

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

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

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

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

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

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

Recommendation 8: 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

MOTION CARRIED by unanimous approval.

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 National Comprehensive Cancer Network (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.

Recommendation 9: Fiscal Year 2025 Annual Review of Anti-Ulcer Medications

MOTION CARRIED by unanimous approval.

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)
~~**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.

Recommendation 10: Fiscal Year 2025 Annual Review of Epidermolysis Bullosa (EB) Medications

MOTION CARRIED by unanimous approval.

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, including amending criteria #12

to allow for initial approvals for 6 months as recommended by and approved unanimously by the DUR Board (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~~ 6 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, including amending criteria #11 to allow for initial approvals for 6 months as recommended by and approved unanimously by the DUR Board (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~~ 6 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.

Recommendation 11: Fiscal Year 2025 Annual Review of Colorectal Cancer (CRC) Medications and 30-Day Notice to Prior Authorize Jobevne™ (Bevacizumab-nwgd)

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

Recommendation 12: 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)

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

Recommendation 13: 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)

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

Recommendation 14: Fiscal Year 2025 Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® Iqlik™ (Lecanemab-irmb)

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

Recommendation 15: Fiscal Year 2025 Annual Review of Testosterone Products

NO ACTION REQUIRED.

Recommendation 16: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 17: Future Business

- There is not a live DUR Board meeting scheduled for August 2026. August 2026 will be a packet-only meeting.

NO ACTION REQUIRED.

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

Memorandum

Date: August 14, 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 Packet Meeting on August 12, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: U.S. Food and Drug Administration (FDA) Safety Alerts

NO ACTION REQUIRED.

Recommendation 3: Fiscal Year 2025 Annual Review of Copper Metabolism Disorder Medications and 30-Day Notice to Prior Authorize Zycubo® (Copper Histidinate)

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

Recommendation 4: Fiscal Year 2025 Annual Review of Iron Chelating Agents

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

Recommendation 5: Fiscal Year 2025 Annual Review of Iron Products

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

Recommendation 6: Fiscal Year 2025 Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate)

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

Recommendation 7: Fiscal Year 2025 Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Morphine Oral Solution Syringes, Tapentadol Tablet, Tapentadol Extended-Release (ER) Tablet, and Tapentadol Oral Solution

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

Recommendation 8: Fiscal Year 2025 Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Amcinonide 0.1% Ointment

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

Recommendation 9: Fiscal Year 2025 Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid)

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

Recommendation 10: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

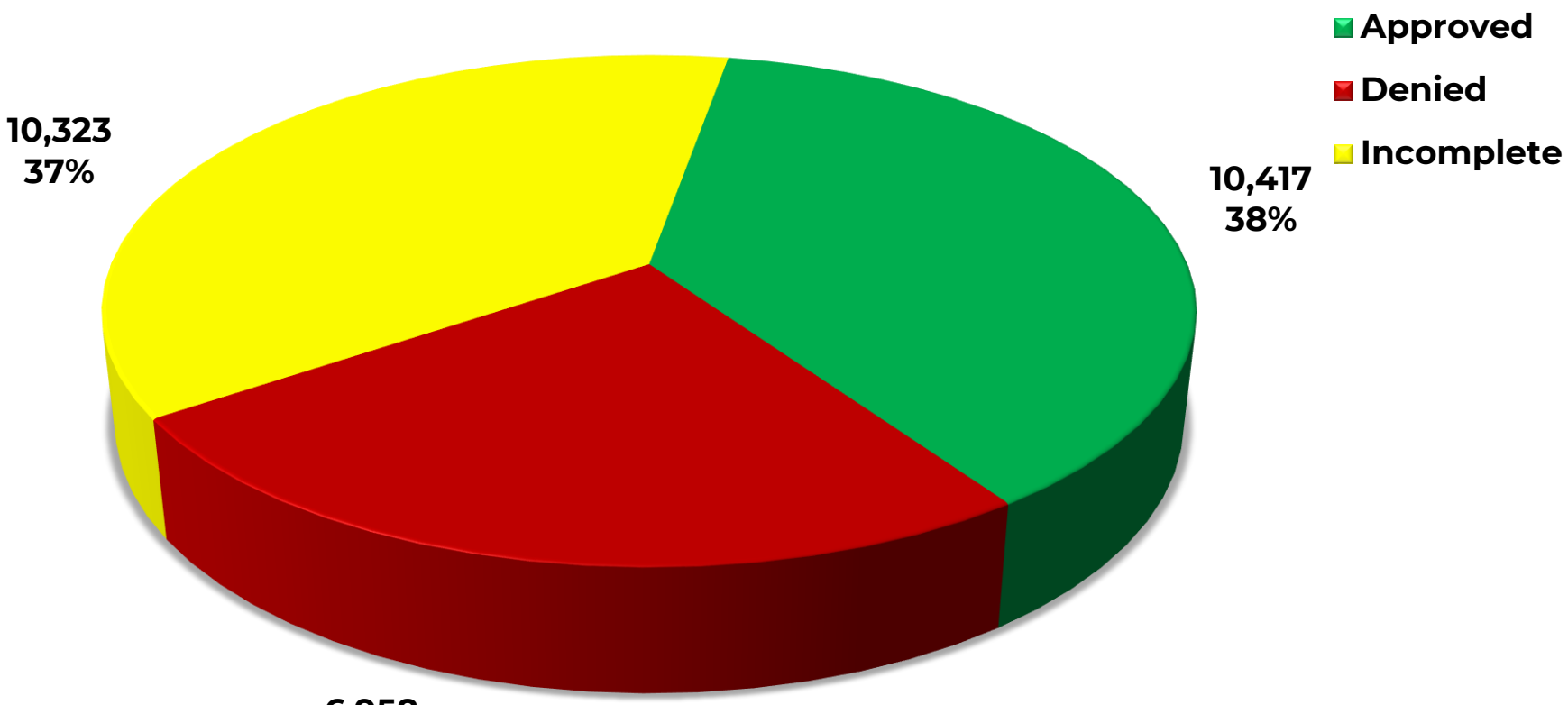
NO ACTION REQUIRED.

Recommendation 11: Future Business

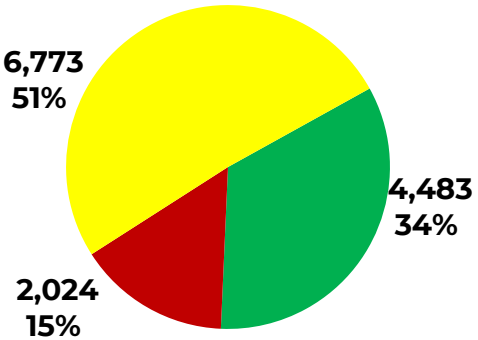
NO ACTION REQUIRED.

Appendix B

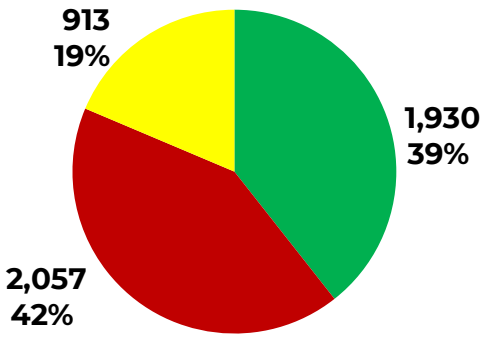
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: AUGUST 2026



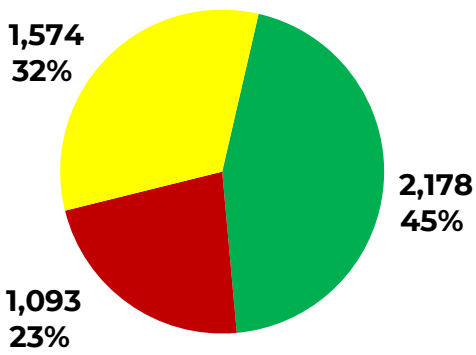
SoonerCare FFS



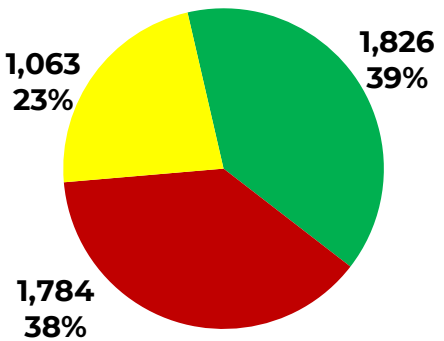
SoonerSelect Aetna



SoonerSelect Humana

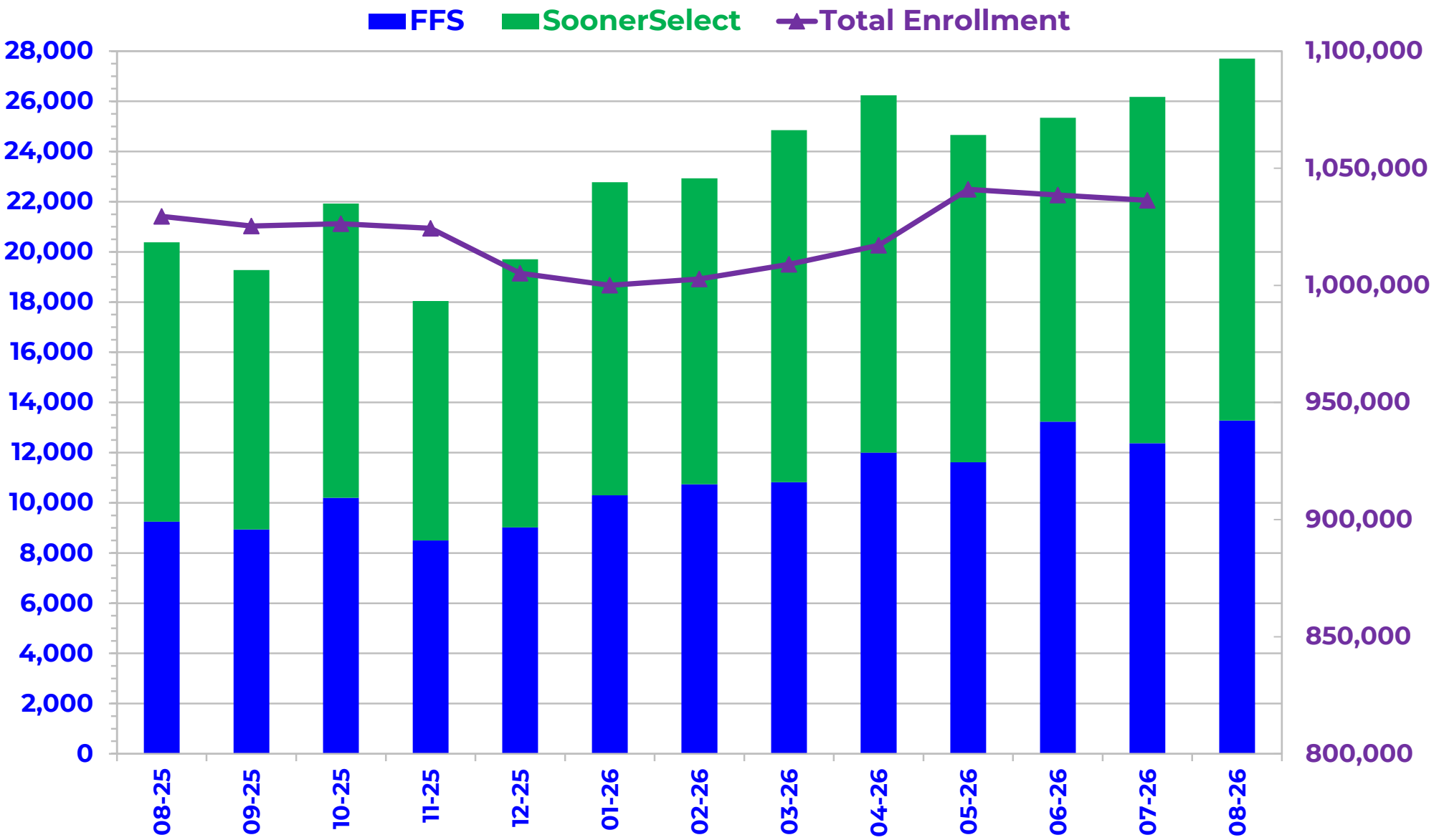


SoonerSelect OK Complete Health



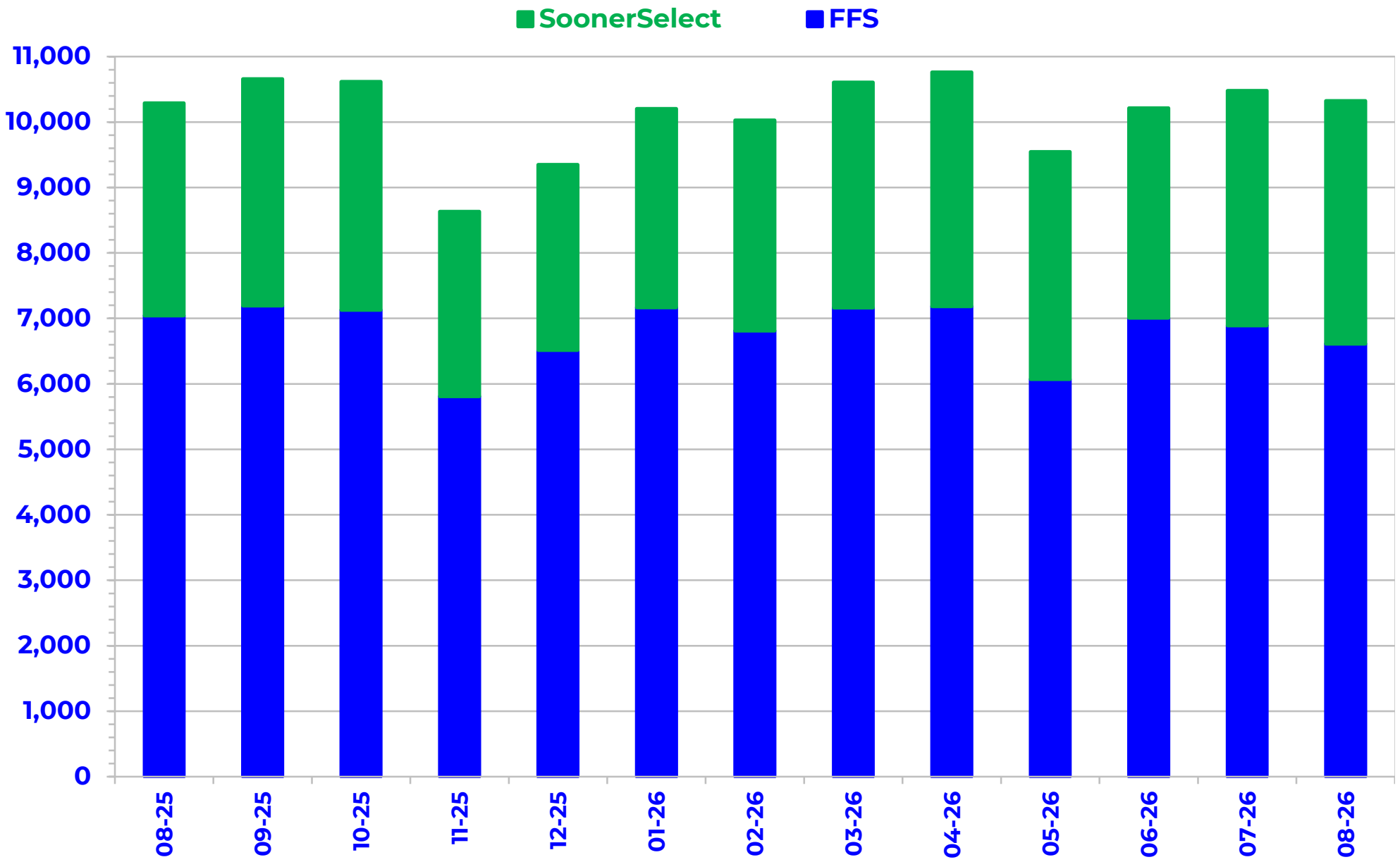
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: AUGUST 2025 – AUGUST 2026



SoonerCare FFS Prior Authorization Activity

8/1/2026 Through 8/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	6	1	1	4	359
Amphetamines	1,100	532	82	486	353
Analgesics - Anti-Inflammatory	280	90	34	156	343
Analgesics - Nonnarcotic	10	0	1	9	0
Analgesics - Opioid	373	126	41	206	148
Androgens - Anabolic	83	4	25	54	357
Anorectal and Related Products	1	0	0	1	0
Anorexiants Non-Amphetamine	3	0	2	1	0
Anthelmintics	6	0	2	4	0
Anti-Infective Agents - Misc.	58	9	12	37	94
Anti-Obesity Agents	657	87	281	289	102
Antianxiety Agents	39	3	2	34	360
Antiarrhythmics	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	750	109	100	541	490
Antibiotics	55	14	3	38	223
Anticoagulants	17	2	2	13	359
Anticonvulsants	308	112	23	173	383
Antidepressants	372	84	50	238	498
Antidiabetics	2,145	588	326	1,231	367
Antidiarrheal/Probiotic Agents	2	0	0	2	0
Antidotes and Specific Antagonists	1	1	0	0	360
Antiemetics	50	3	8	39	124
Antifungals	9	2	1	6	19
Antihistamines	27	7	9	11	310
Antihyperlipidemics	101	14	25	62	334
Antihypertensives	43	5	5	33	744
Antimalarials	6	1	1	4	360
Antimyasthenic/Cholinergic Agents	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	257	168	9	80	195
Antiparkinson and Related Therapy Agents	11	2	0	9	180
Antipsychotics/Antimanic Agents	797	518	49	230	611
Antivirals	29	5	2	22	43
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	336	192	23	121	962
Beta Blockers	16	3	0	13	846
Calcium Channel Blockers	14	1	3	10	87
Cardiovascular Agents - Misc.	114	42	18	54	443
Contraceptives	75	32	8	35	400
Corticosteroids	15	3	3	9	242
Cough/Cold/Allergy	1	0	1	0	0
Dermatologicals	734	181	164	389	257
Diagnostic Products	60	20	7	33	151
Dietary Products/Dietary Management Products	2	0	1	1	0
Digestive Aids	7	3	1	3	359
Diuretics	21	8	3	10	724
Dopamine and Norepinephrine Reuptake Inhibitors (DRNIs)	2	1	0	1	1,086

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	217	95	24	98	237
Estrogens	30	3	6	21	359
Gastrointestinal Agents - Misc.	465	108	98	259	279
Genitourinary Agents - Misc.	7	4	0	3	542
Gout Agents	11	2	3	6	269
Hematological Agents - Misc.	23	5	5	13	287
Hematopoietic Agents	50	15	12	23	165
Histamine H3-Receptor Antagonist/Inverse Agonists	1	1	0	0	359
Hypnotics/Sedatives/Sleep Disorder Agents	57	6	12	39	268
Laxatives	18	8	1	9	187
Medical Devices and Supplies	427	73	96	258	289
Migraine Products	596	144	143	309	234
Minerals and Electrolytes	21	2	0	19	356
Miscellaneous Therapeutic Classes	105	39	19	47	314
Multivitamins	5	3	0	2	359
Musculoskeletal Therapy Agents	73	5	16	52	234
Nasal Agents - Systemic and Topical	24	1	5	18	360
Neuromuscular Agents	104	44	21	39	347
Ophthalmic Agents	79	9	12	58	246
Other*	49	28	1	20	218
Otic Agents	68	29	5	34	12
Passive Immunizing and Treatment Agents	20	7	1	12	333
Progestins	15	4	2	9	325
Psychotherapeutic and Neurological Agents - Misc.	327	88	58	181	229
Respiratory Agents - Misc.	35	21	1	13	350
Stimulants - Misc.	252	125	14	113	351
Thyroid Agents	10	0	8	2	0
Ulcer Drugs/Antispasmodics/Anticholinergics	147	22	28	97	591
Urinary Antispasmodics	68	9	8	51	603
Vaccines	5	1	0	4	87
Vaginal and Related Products	14	0	3	11	0
Vasopressors	5	0	1	4	0
Vitamins	62	0	45	17	0
Total	**12,385**	**3,874**	**1,976**	**6,535**	
Overrides					
Brand	21	11	1	9	362
Compound	22	20	0	2	8
Dosage Change	187	149	0	38	19
High Dose	1	1	0	0	358
Ingredient Duplication	1	0	0	1	0
Lost/Broken Rx	68	57	1	10	20
MAT Override	3	3	0	0	116
NDC vs Age	102	75	14	13	557
NDC vs Sex	7	6	1	0	332
Nursing Home Issue	55	50	0	5	13
Opioid MME Limit	54	14	5	35	142

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Opioid Quantity	19	6	6	7	178
Other	29	17	1	11	40
Prescriber Temp Unlock	1	1	0	0	3
Quantity vs Days Supply	252	165	12	75	336
STBS/STBSM	19	9	6	4	48
Step Therapy Exception	2	0	1	1	0
Stolen	6	5	0	1	42
Third Brand Request	46	20	0	26	18
Overrides Total	**895**	**609**	**48**	**238**	
Total Regular PAs + Overrides	**13,280**	**4,483**	**2,024**	**6,773**	

Denial Reasons	
Unable to verify required trials.	6,392
Does not meet established criteria.	2,081
Lack required information to process request.	545
Other PA Activity	
Duplicate Requests	1,791
Letters	63,367
No Process	2
Helpdesk Initiated Prior Authorizations	342
PAs Missing Information	267
Pharmacotherapy	91
Changes to Existing PAs	773

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

SoonerSelect Aetna Prior Authorization Activity

8/1/2026 Through 8/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	852	664	149	39	361
Analgesics - Anti-Inflammatory	167	126	25	16	340
Analgesics - Nonnarcotic	12	0	10	2	0
Analgesics - Opioid	134	62	33	39	122
Androgens - Anabolic	70	4	63	3	365
Anorectal and Related Products	6	0	6	0	0
Anthelmintics	4	0	4	0	0
Antianginal Agents	3	0	0	3	0
Antianxiety Agents	39	7	11	21	339
Antiasthmatic and Bronchodilator Agents	172	28	93	51	278
Antibiotics	22	2	4	16	20
Anticoagulants	9	3	0	6	184
Anticonvulsants	74	22	30	22	320
Antidepressants	278	78	96	104	414
Antidiabetics	654	207	349	98	319
Antiemetics	20	3	5	12	133
Antifungals	3	1	0	2	61
Antihistamines	19	4	14	1	366
Antihyperlipidemics	31	8	11	12	256
Antihypertensives	44	5	4	35	365
Anti-Infective Agents - Misc.	13	4	3	6	25
Antineoplastics and Adjunctive Therapies	32	15	2	15	198
Anti-Obesity Agents	347	58	278	11	99
Antiparkinson and Related Therapy Agents	7	0	3	4	0
Antipsychotics/Antimanic Agents	222	55	113	54	336
Antivirals	1	0	1	0	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	97	78	13	6	619
Beta Blockers	19	0	3	16	0
Calcium Channel Blockers	15	2	2	11	365
Cardiovascular Agents - Misc.	49	15	25	9	333
Contraceptives	23	1	21	1	365
Corticosteroids	14	9	5	0	315
Dermatologicals	320	127	151	42	223
Diagnostic Products	33	16	7	10	748
Dietary Products/Dietary Management Products	2	1	0	1	365
Digestive Aids	1	0	0	1	0
Diuretics	21	3	1	17	198
Endocrine and Metabolic Agents - Misc.	38	19	17	2	204
Estrogens	17	0	6	11	0
Gastrointestinal Agents - Misc.	93	32	50	11	198
Genitourinary Agents - Misc.	2	1	1	0	365
Gout Agents	3	1	2	0	365

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hematological Agents - Misc.	8	2	0	6	365
Hematopoietic Agents	20	11	6	3	235
Histamine H3-Receptor Antagonist/Inverse Agonists	1	1	0	0	365
Hypnotics/Sedatives/Sleep Disorder Agents	28	5	19	4	297
Laxatives	18	2	7	9	62
Medical Devices and Supplies	105	22	67	16	479
Migraine Products	258	82	158	18	258
Minerals and Electrolytes	11	3	0	8	228
Miscellaneous Therapeutic Classes	29	21	7	1	334
Multivitamins	1	1	0	0	365
Musculoskeletal Therapy Agents	64	5	20	39	77
Nasal Agents - Systemic and Topical	14	2	8	4	365
Neuromuscular Agents	14	13	0	1	313
Ophthalmic Agents	39	5	18	16	238
Other	13	2	2	9	229
Otic Agents	20	2	14	4	24
Passive Immunizing and Treatment Agents	1	1	0	0	184
Progestins	1	0	1	0	0
Psychotherapeutic and Neurological Agents - Misc.	39	14	18	7	259
Respiratory Agents - Misc.	3	2	1	0	275
Stimulants - Misc.	89	55	30	4	358
Ulcer Drugs/Antispasmodics/Anticholinergics	79	6	24	49	429
Urinary Antispasmodics	11	3	4	4	365
Vaccines	3	3	0	0	146
Vaginal and Related Products	2	1	0	1	77
Vitamins	46	5	41	0	230
****Total**	**4,900**	**1,930**	**2,057**	**913**	

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

Overrides					
Brand	3	3	0	0	274
Other	913	0	0	913	0
Quantity Level Limit	29	29	0	0	232
Step Therapy Met	1	1	0	0	184
Overrides Total	**946**	**33**	**0**	**913**	

Denial Reason	
Benefit	161
Experimental/Investigational	160
Lack Required Infomation to Process Request	112
Medical Necessity	1,613
Other	11
Other PA Activity	
Duplicate Requests	39
Letters	6,091
No Process	267
Changes to existing PAs	0
PAs missing info	14

*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

8/1/2026 Through 8/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	7	3	0	4	254
Analgesics - Anti-Inflammatory	73	57	5	11	342
Analgesics - Nonnarcotic	6	3	1	2	73
Analgesics - Opioid	69	41	24	4	292
Androgens - Anabolic	77	11	48	18	93
Anorectal and Related Products	1	0	0	1	0
Anthelmintics	2	1	0	1	365
Antianxiety Agents	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	126	61	49	16	252
Antibiotics	5	0	0	5	0
Anticonvulsants	18	9	3	6	375
Antidepressants	63	37	11	15	399
Antidiabetics	463	153	202	108	207
Antiemetics	13	1	1	11	456
Antifungals	2	1	0	1	365
Antihistamines	1	0	0	1	0
Antihyperlipidemics	30	20	6	4	341
Antihypertensives	5	1	1	3	365
Anti-Infective Agents - Misc.	6	2	0	4	365
Antineoplastics and Adjunctive Therapies	48	27	0	21	237
Anti-Obesity Agents	319	91	92	136	141
Antiparkinson and Related Therapy Agents	5	2	1	2	731
Antipsychotics/Antimanic Agents	27	20	3	4	279
Antivirals	3	1	1	1	92
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	10	4	3	3	315
Calcium Channel Blockers	3	3	0	0	365
Cardiovascular Agents - Misc.	41	22	8	11	337
Contraceptives	25	7	11	7	187
Corticosteroids	3	0	0	3	0
Dermatologicals	246	143	57	46	235
Diagnostic Products	62	52	5	5	567
Digestive Aids	4	4	0	0	365
Diuretics	3	2	0	1	274
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	0	1	0
Endocrine and Metabolic Agents - Misc.	50	32	4	14	229
Estrogens	13	8	1	4	320
Gastrointestinal Agents - Misc.	117	55	34	28	258
Genitourinary Agents - Misc.	1	1	0	0	365
Gout Agents	1	0	1	0	0
Hematological Agents - Misc.	5	5	0	0	365
Hematopoietic Agents	16	6	2	8	197
Histamine H3-Receptor Antagonist/Inverse Agonists	2	0	0	2	0
Hypnotics/Sedatives/Sleep Disorder Agents	9	1	8	0	184
Laxatives	8	0	7	1	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
Medical Devices and Supplies	136	128	3	5	1,073
Migraine Products	149	105	33	11	223
Minerals and Electrolytes	1	0	0	1	0
Miscellaneous Therapeutic Classes	20	14	1	5	308
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	23	5	8	10	243
Nasal Agents - Systemic and Topical	3	0	3	0	0
Neuromuscular Agents	43	25	1	17	316
Ophthalmic Agents	34	12	8	14	159
Other	1	0	0	1	0
Otic Agents	1	0	0	1	0
Passive Immunizing and Treatment Agents	3	0	0	3	0
Psychotherapeutic and Neurological Agents - Misc.	24	17	5	2	233
Respiratory Agents - Misc.	19	12	1	6	277
Stimulants - Misc.	19	13	4	2	325
Ulcer Drugs/Antispasmodics/Anticholinergics	18	4	8	6	365
Urinary Antispasmodics	19	1	15	3	30
Vaginal and Related Products	2	0	0	2	0
Vitamins	84	9	0	75	148
Total	**2,591**	**1,234**	**679**	**678**	
Overrides					
Dosage Change	116	40	58	18	125
Ingredient Duplication	202	112	62	28	156
NDC vs Age	518	367	24	127	258
NDC vs Sex	5	1	0	4	73
Opioid MME Limit	11	9	0	2	320
Opioid Quantity	5	5	0	0	457
Other	346	79	83	184	115
Quantity vs Days Supply	235	155	35	45	245
STBS/STBSM	601	60	100	441	37
Step Therapy Exception	211	116	48	47	208
Third Brand Request	4	0	4	0	0
Overrides Total	**2,254**	**944**	**414**	**896**	
Total Regular PAs + Overrides	**4,845**	**2,178**	**1,093**	**1,574**	
Denial Reasons					
Alternatives Not Met					337
Medical Necessity					756

*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

8/1/2026 Through 8/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	360	174	133	53	1,069
Analgesics - Anti-Inflammatory	108	56	38	14	936
Analgesics - Nonnarcotic	12	0	9	3	0
Analgesics - Opioid	252	88	118	46	239
Androgens - Anabolic	70	2	51	17	1,095
Anorectal and Related Products	6	0	2	4	0
Anorexiants Non-Amphetamine	4	0	0	4	0
Anthelmintics	7	0	6	1	0
Antianginal Agents	1	0	0	1	0
Antianxiety Agents	27	5	19	3	611
Antiasthmatic and Bronchodilator Agents	270	105	112	53	564
Antibiotics	26	16	5	5	240
Anticoagulants	1	0	1	0	0
Anticonvulsants	70	26	34	10	1,014
Antidepressants	193	70	93	30	947
Antidiabetics	727	345	235	147	870
Antiemetics	16	2	4	10	131
Antifungals	5	1	3	1	365
Antihistamines	10	2	5	3	621
Antihyperlipidemics	27	5	18	4	1,095
Antihypertensives	19	8	11	0	443
Anti-Infective Agents - Misc.	15	5	7	3	154
Antimalarials	1	1	0	0	139
Antimyasthenic/Cholinergic Agents	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	85	46	14	25	465
Anti-Obesity Agents	326	72	96	158	433
Antiparkinson and Related Therapy Agents	2	0	1	1	0
Antipsychotics/Antimanic Agents	198	83	70	45	897
Antivirals	3	1	1	1	126
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	120	66	40	14	1,048
Beta Blockers	11	5	4	2	520
Calcium Channel Blockers	8	6	0	2	654
Cardiovascular Agents - Misc.	28	10	13	5	1,095
Chemicals	1	0	0	1	0
Contraceptives	25	10	12	3	453
Corticosteroids	8	1	1	6	90
Dermatologicals	295	100	130	65	604
Diagnostic Products	34	12	16	6	974
Dietary Products/Dietary Management Products	1	1	0	0	365
Digestive Aids	1	1	0	0	1,095
Diuretics	5	1	3	1	142
Endocrine and Metabolic Agents - Misc.	57	20	26	11	1,052
Estrogens	23	12	7	4	218

*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
Gastrointestinal Agents - Misc.	104	33	61	10	738
Genitourinary Agents - Misc.	1	1	0	0	1,095
Gout Agents	6	1	4	1	1,095
Hematological Agents - Misc.	7	5	1	1	493
Hematopoietic Agents	31	6	12	13	65
Hypnotics/Sedatives/Sleep Disorder Agents	21	5	12	4	267
Laxatives	16	5	1	10	289
Medical Devices and Supplies	171	92	42	37	881
Migraine Products	252	100	106	46	744
Minerals and Electrolytes	5	0	4	1	0
Miscellaneous Therapeutic Classes	30	23	3	4	740
Multivitamins	3	0	0	3	0
Musculoskeletal Therapy Agents	40	4	23	13	181
Nasal Agents - Systemic and Topical	19	2	12	5	130
Neuromuscular Agents	45	19	13	13	355
Ophthalmic Agents	59	26	10	23	361
Other	51	8	3	40	329
Otic Agents	44	9	26	9	212
Passive Immunizing and Treatment Agents	1	1	0	0	122
Progestins	1	1	0	0	1,243
Psychotherapeutic and Neurological Agents - Misc.	63	14	24	25	836
Respiratory Agents - Misc.	8	2	3	3	1,095
Stimulants - Misc.	141	75	49	17	921
Thyroid Agents	9	5	0	4	619
Ulcer Drugs/Antispasmodics/Anticholinergics	43	16	21	6	615
Urinary Antispasmodics	29	12	12	5	329
Vaccines	3	0	2	1	0
Vaginal and Related Products	7	2	2	3	611
Vasopressors	1	1	0	0	147
Vitamins	3	0	0	3	0
****Total**	**4,673**	**1,826**	**1,784**	**1,063**	

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

Denial Reasons	
Medical Necessity	1,784

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

Appendix C

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

Oklahoma Health Care Authority
September 2026

Introduction[1,2,3]

In the United States, it is estimated that over 40 million people have a diagnosis of diabetes, with 1.5 million diagnosed every year. In Oklahoma, approximately 385,000 adults have been diagnosed with diabetes, resulting in an estimated cost of $5.2 billion each year.

Type 2 diabetes (T2D) accounts for 90-95% of all diabetes cases, and the 2026 American Diabetes Association (ADA) *Standards of Medical Care in Diabetes* guidelines recommend pharmacologic therapy should be started at the time T2D is diagnosed, without delay, unless there are contraindications. Medication plans should have adequate efficacy to achieve and maintain individualized treatment goals with respect to glucose lowering, reduction of cardiovascular (CV) and kidney disease risks, weight management, and impacts on other health conditions and treatment burden.

DPP-4 inhibitors have been approved by the U.S. Food and Drug Administration (FDA) for T2D since 2006, and there are currently 4 FDA-approved DPP-4 inhibitors available (i.e., sitagliptin, saxagliptin, linagliptin, alogliptin), as well as combination products with metformin and sodium-glucose cotransporter-2 (SGLT-2) inhibitors. The 2026 ADA guidelines continue to reaffirm the 2025 guideline recommendations and updates regarding DPP-4 inhibitor use, including the following:

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

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

Based on the 2026 ADA pharmacological treatment flow chart, metformin continues to be a 1st-line recommended option, and GLP-1 and GIP/GLP-1 RAs and SGLT-2 inhibitors are now listed as preferred options based on their efficacy for glucose lowering and additional indications, while DPP-4 inhibitors have become a lower recommended treatment option.

Mailing Summary

In August 2025, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) sent an educational letter to 164 providers regarding 748 unique members utilizing a DPP-4 inhibitor and 44 members with concurrent use of a DPP-4 inhibitor and a GLP-1 RA or GIP/GLP-1 RA based on their SoonerCare pharmacy claims history. The number of members associated with these top 164 providers ranged from 1 to 34 members per provider.

Members were included in the mailing for DPP-4 utilization if they had a paid claim for a DPP-4 inhibitor during the specified time period (01/01/2025 to 06/30/2025). For concurrent use with a GLP-1 RA or GIP/GLP-1 RA, members were flagged if they had overlapping paid claims with a DPP-4 inhibitor for ≥90 days.

Mailing Results

Since the mailing in August 2025, a post-mailing claims analysis was performed in August 2026 for the 748 unique members and 164 providers to assess the impact of the mailing. Members who no longer have SoonerCare coverage or became dual eligible since the mailing were excluded from this analysis; therefore, the analysis includes 657 unique members who were utilizing a DPP-4 inhibitor prior to the mailing and 38 members with concurrent use of a GLP-1 RA or GIP/GLP-1 RA for ≥90 days. The results of the pharmacy claims analysis can be seen in Table 1.

Table 1: Members with DPP-4 Inhibitor Utilization and Concurrent DPP-4 Inhibitor and GLP-1 RA or GIP/GLP-1 RA Utilization				
	Pre-Mailing	Post-Mailing	Change	% Change
Total number of members with DPP-4 inhibitor paid claim	657	472	-185	-28.16%
Total number of members with concurrent DPP-4 inhibitor and GLP-1 RA or GIP/GLP-1 RA utilization for ≥90 days	38	28	-10	-26.32%

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

Since the mailing, 181 unique members who were included for DPP-4 inhibitor utilization now have a paid claim for a GLP-1 RA or GIP/GLP-1 RA, and 81 of those members are no longer utilizing a DPP-4 inhibitor. At the time of the analysis, 100 of those 181 members had concurrent use of a DPP-4 inhibitor and a GLP-1 RA or GIP/GLP-1 RA, with 38 members having concurrent use ≥90 days. The addition of the 38 members leads to a total of 66 members with concurrent use ≥90 days post-mailing.

DPP-4 Inhibitor Utilization in the SoonerCare Population: Fiscal Year (FY) 2025 (FY25) to FY 2026 (FY26)

Due to the observed increase in concurrent use of a DPP-4 inhibitor and a GLP-1 RA or GIP/GLP-1 RA since the initial mailing, a new claims analysis was performed to identify members utilizing DPP-4 inhibitors during FY25 and FY26 and to assess the extent of concurrent use with GLP-1 RAs or GIP/GLP-1 RAs. Members were included in the claims analysis for DPP-4 utilization if they had a paid claim for a DPP-4 inhibitor during either fiscal year. For concurrent use with a GLP-1 RA or GIP/GLP-1 RA, members were flagged if they had overlapping paid claims with a DPP-4 inhibitor for ≥90 days or ≥180 days. The results can be seen in Table 2 below.

Table 2: SoonerCare DPP-4 Inhibitor Utilization During FY25 and FY26				
	FY25	FY26	Change	% Change
Total number of members with DPP-4 inhibitor paid claim	1,780	1,820	40	2.25%
Total number of members with concurrent DPP-4 inhibitor and GLP-1 RA or GIP/GLP-1 RA utilization for ≥90 days	142	157	15	10.56%
Total number of members with concurrent DPP-4 inhibitor and GLP-1 RA or GIP/GLP-1 RA utilization for ≥180 days	72	88	16	22.22%

DPP-4 = dipeptidyl peptidase-4; FY = fiscal year; GIP = glucose-dependent insulinotropic polypeptide; GLP-1 RA = glucagon-like peptide 1 receptor agonist
Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Conclusions

The results of the mailing showed a 28% decrease in DPP-4 inhibitor claims and a 26% decrease in concurrent DPP-4 and GLP-1 RA or GIP/GLP-1 RA use among the members who were initially flagged for concurrent use and inclusion in the mailing. Despite this, there was a 74% increase in concurrent use among other members who were initially only using a DPP-4 inhibitor. There have also been moderate increases from FY25 to FY26 for both criteria. It is important to note that the analysis is based on paid SoonerCare pharmacy claims and does not include whether a member received their medications through a non-SoonerCare source (i.e., private insurance, free clinics, samples). These results indicate a need for additional provider and member education regarding the importance of the utilization of guideline-recommended T2D medications with the best efficacy to ensure the best possible outcomes for SoonerCare members with T2D.

Recommendations

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

[1] American Diabetes Association (ADA). The Burden of Diabetes in Oklahoma. Available online at: https://diabetes.org/sites/default/files/2026-02/oklahoma-diabetes-02-15-26.pdf. Issued 02/2026. Last accessed 08/17/2026.

[2] ADA Professional Practice Committee. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes – 2026. *Diabetes Care* 2026; 49(1): S27–S49. doi: 10.2337/dc26-S002.

[3] ADA Professional Practice Committee. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2026. *Diabetes Care* 2026; 49(1): S183–S215. doi: 10.2337/dc26-S009.

Appendix D

Vote to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten) and Update the Approval Criteria for the Heart Failure (HF) Medications

Oklahoma Health Care Authority
September 2026

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

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.

Enbumyst™ (Bumetanide Nasal Spray) Product Summary[7,8,9]

Therapeutic Class: Loop diuretic

Indication(s): Treatment of edema associated with congestive HF, 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	$0.15	$0.75

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[10,11,12]

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	$1,019.81	$1,019.81
furosemide injection 10mg/mL vial	$0.18	$1.44

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[13,14]

Therapeutic Class: Cardiac myosin inhibitor

Indication(s): Treatment of adults with symptomatic obstructive HCM to improve functional capacity and symptoms

How Supplied: 5mg, 10mg, 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 left ventricular ejection fraction (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%
- LVOT-G gradients ≥30mmHg at rest and ≥50mmHg after the Valsalva maneuver
- New York Heart Association (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
    a. Prescriber must agree to assess the member's clinical status and LVEF during treatment and adjust or interrupt the Camzyos® 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. ~~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.

[1] Camzyos™ (Mavacamten) Prescribing Information. Bristol Myers Squibb. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214998s000lbl.pdf. Last revised 04/2025. Last accessed 08/18/2026.
[2] Corstasis Therapeutics. Corstasis Therapeutics Announces FDA Approval of Enbumyst™ (Bumetanide Nasal Spray) for the Treatment of Edema Associated with Congestive Heart Failure, Liver Disease and Kidney Disease. *Business Wire.* Available online at: https://www.businesswire.com/news/home/20250915243998/en/Corstasis-Therapeutics-Announces-FDA-Approval-of-ENBUMYST-bumetanide-nasal-spray-for-the-Treatment-of-Edema-Associated-with-Congestive-Heart-Failure-Liver-Disease-and-Kidney-Disease. Issued 09/15/2025. Last accessed 08/18/2026.
[3] SQ Innovation. SQ Innovation Announces FDA Approval of Lasix® ONYU for Treatment of Edema in Heart Failure. Available online at: https://sqinnovation.com/fda-approval/. Issued 10/08/2025. Last accessed 08/18/2026.
[4] U.S. FDA. FDA Approves Drug to Improve Functional Capacity and Symptoms in Adults with Rare Inherited Heart Condition. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-drug-improve-functional-capacity-and-symptoms-adults-rare-inherited-heart-condition. Issued 12/23/2025. Last accessed 08/18/2026.
[5] Finch, Joshua. FDA Approves Furosemide On-Body Infusor for Pediatric Patients Weighing 43kg or More. *Contemporary Pediatrics.* Available online at: https://www.contemporarypediatrics.com/view/fda-approves-furosemide-on-body-infusor-for-pediatric-patients-weighing-43-kg-or-more. Issued 12/23/2025. Last accessed 08/18/2026.
[6] Verquvo® (Vericiguat Tablet) Prescribing Information. Merck. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214377s000lbl.pdf. Last revised 01/2026. Last accessed 08/18/2026.
[7] Enbumyst™ (Bumetanide Nasal Spray) Prescribing Information. Corstasis Therapeutics. Available online at: https://pi.esperion.com/enbumyst/enbumyst-pi.pdf. Last revised 09/2025. Last accessed 08/18/2026.
[8] Ambrosy A, Bensimhon D, Bernstein G, et al. Randomized Study Comparing a Novel Intranasal Formulation of Bumetanide with Oral and Intravenous Formulations. *Circulation* 2025; 151:737–740. doi: 10.1161/CIRCULATIONAHA.124.072949.
[9] Bensimhon D, Weintraub W, Peacock W, et al. Reduced Heart Failure-Related Healthcare Costs with Furoscix Versus In-Hospital Intravenous Diuresis in Heart Failure Patients: The FREEDOM-HF Study. *Future Cardiology* 2023; 385-396. doi: 10.2217/fca-2023-0071.
[10] Lasix® ONYU (Furosemide On-Body Infusor) Prescribing Information. SQ Innovation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217294s000lbl.pdf. Last revised 10/2025. Last accessed 08/18/2026.
[11] SQ Innovation. Instructions for Use Lasix® ONYU. Available online at: https://www.lasix-onyu.com/wp-content/uploads/2025/10/instructions-for-use.pdf. Last accessed 08/18/2026.
[12] Osmanska J, Brooksbank K, Docherty K, et al. A Novel, Small-volume Subcutaneous Furosemide Formulation Delivered by an Abdominal Patch Infusor Device in Patients with Heart Failure: Results of Two Phase I Studies. *Eur Heart J Cardiovas Pharmacother* 2024; 10(1):35-44. doi: 10.1093/ehjcvp/pvad073.
[13] Myqorzo™ (Aficamten) Prescribing Information. Cytokinetics. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219083s000lbl.pdf. Last revised 12/2025. Last accessed 08/18/2026.
[14] Maron M, Masri A, Nassif M, et al. Aficamten for Symptomatic Obstructive Hypertrophic Cardiomyopathy. *N Engl J Med* 2024; 390(20):1849-1861. doi: 10.1056/NEJMoa2401424.

Appendix E

Vote to Prior Authorize Leqembi Iqlik® (Lecanemab-irmb)

Oklahoma Health Care Authority
September 2026

Market News and Updates[1,2]

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.
- **July 2026:** The FDA approved a supplemental Biologics License Application (sBLA) for Leqembi Iqlik® (lecanemab-irmb) as an initiation dose for early Alzheimer's disease. Leqembi Iqlik® is administered sub-Q via an autoinjector as an alternative to IV dosing. The initiation dose is 500mg once weekly as two 250mg injections, each delivered in approximately 15 seconds. Leqembi Iqlik® may also be used for maintenance dosing at 360mg once weekly after 18 months of IV or sub-Q treatment. Patients may receive Leqembi® as an IV infusion or sub-Q injection and may switch between the two formulations at any time.

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~~ after 1 month, 2 months, 3 months, and 6 months of treatment, and as clinically indicated ~~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 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. Verification that lecanemab-irmb will be shipped via cold chain supply to the administering location (i.e., member's home, clinic) and storage and handling requirements will be followed as per the package labeling; and
15. Requests for Leqembi® IV will require the following:
    a. 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
        ~~i. 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~~
    b. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
16. Requests for 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. Leqembi Iqlik® must be initiated under the guidance and supervision of a health care professional; and
    c. For self or caregiver administration, the prescriber must attest to the following:
        i. Direct guidance for at least 2 consecutive sub-Q doses has been provided by a health care professional; and
        ii. Member or caregiver will be trained by a health care professional on the sub-Q administration, ability to recognize and manage symptoms of hypersensitivity, and proper storage of Leqembi Iqlik®; and

17. For maintenance dosing, the prescriber must verify the member has completed 18 months of an FDA-approved starting dosage regimen; and
18. Initial approvals will be for 6 months. Confirmation that MRIs have been completed per package labeling and were acceptable to the provider ~~prior to the 5th and 7th infusions~~ is required for continuation; and
19. 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
20. Approval quantities will be dependent on the member's weight and/or dosing based on package labeling; and
21. The maximum dose approvable is 10mg/kg per 14 days for the IV formulation and 10mL per 28 days for the sub-Q formulation; and
22. Approvals will not be granted for concurrent use with other amyloid beta-directed monoclonal antibodies.

[1] Biogen. FDA Approves Leqembi Iqlik® (Lecanemab-irmb) Subcutaneous Injection as an Initiation Dose for Early Alzheimer's Disease. Available online at: https://investors.biogen.com/news-releases/news-release-details/fda-approves-leqembi-iqlikr-lecanemab-irmb-subcutaneous. Issued 07/13/2026. Last accessed 08/25/2026.

[2] 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 08/25/2026

Appendix F

Vote to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy) and Update the Approval Criteria for the Anti-Diabetic Medications and Kerendia® (Finerenone)

Oklahoma Health Care Authority
September 2026

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

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.
- **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 type 2 diabetes mellitus (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.

Awiqli® (Insulin Icodec-abae) Product Summary[13,14]

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 Wholesale Acquisition Cost (WAC) of Awiqli® is $66.00 per mL or $99.00 per 1.5mL pen.

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			

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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®)*~~**
	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			

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
		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			
glimepiride (Amaryl®)			glimepiride 3mg tablet*
glipizide (Glucotrol®)			glipizide 2.5mg immediate-release tablet*

Anti-Diabetic Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
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 on a mixed-meal tolerance test (MMTT) or alternative if MMTT is not available (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.

[1] Bayer. U.S. FDA Approves Kerendia® (Finerenone) to Treat Patients with Heart Failure with Left Ventricular Ejection Fraction ≥40% Following Priority Review. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20250713516485/en/U.S.-FDA-Approves-KERENDIA-finerenone-to-Treat-Patients-With-Heart-Failure-With-Left-Ventricular-Ejection-Fraction-40-Following-Priority-Review. Issued 07/14/2025. Last accessed 08/26/2026.

[2] Kirsty™ (Insulin Aspart-xjhz) – New First-Time Interchangeable Biosimilar Approval. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval-kirsty-071525.pdf. Issued 07/15/2025. Last accessed 08/26/2026.

[3] Novo Nordisk. FDA Approves Novo Nordisk's Awiqli®, the First and Only Once-Weekly Basal Insulin Treatment for Adults with Type 2 Diabetes. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/fda-approves-novo-nordisks-awiqli-the-first-and-only-once-weekly-basal-insulin-treatment-for-adults-with-type-2-diabetes-302726839.html. Issued 03/26/2026. Last accessed 08/26/2026.

[4] Lannett Company. Lannett Company, Lanexa Biologics and Sunshine Lake Pharma announce FDA Approval of Langlara™ an Interchangeable Biosimilar of Lantus® (Insulin Glargine). *Business Wire*. Available online at: https://www.businesswire.com/news/home/20260504761789/en/Lannett-Company-Lanexa-Biologics-and-Sunshine-Lake-Pharma-announce-FDA-Approval-of-LANGLARA-an-Interchangeable-Biosimilar-of-Lantus-insulin-glargine. Issued 05/04/2026. Last accessed 08/26/2026.

[5] Sanofi. Sanofi's Tzield® Approved in the US to Delay the Onset of Stage 3 Type 1 Diabetes in Young Children. Available online at: https://www.sanofi.com/en/media-room/press-releases/2026/2026-04-22-05-05-00-3278650. Issued 04/22/2026. Last accessed 08/26/2026.

[6] Tzield® (Teplizumab-mzwv) Prescribing Information. Sanofi. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761183s010lbls014lbl.pdf. Last revised 06/2026. Last accessed 08/26/2026.

[7] Afrezza® (Insulin Human) – Expanded Indication. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/clinical-updates/clinicalupdate-afrezza-052926.pdf. Issued 05/29/2026. Last accessed 08/26/2026.

[8] Sanofi. Sanofi's Tzield® Approved in the US as the First Disease-Modifying Therapy for Patients Recently Diagnosed with Stage 3 Type 1 Diabetes. Available online at: https://www.sanofi.com/en/media-room/press-releases/2026/2026-06-12-22-09-58-3311349. Issued 06/12/2026. Last accessed 08/26/2026.

[9] U.S. FDA. National Drug Code Directory. Available online at: https://dps.fda.gov/ndc. Last accessed 08/26/2026

[10] Farxiga® (Dapagliflozin) – First-Time Generic. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/new-generics/newgenerics-farxiga-041026.pdf. Issued 04/06/2026. Last accessed 08/26/2026.

[11] Januvia® (Sitagliptin) – First-Time Generic. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/new-generics/newgeneric-januvia-052826.pdf. Issued 05/28/2026. Last accessed 08/26/2026.

[12] Janumet® (Sitagliptin/Metformin) – First-Time Generic. *OptumRx®*. Available online at: https://business.optum.com/content/dam/noindex-resources/business/support-documents/new-generics/newgeneric-janumet-052826.pdf. Issued 05/28/2026. Last accessed 08/26/2026.

[13] Awiqli® (Insulin Icodec-abae) Prescribing Information. Novo Nordisk Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761326Orig2s000lbl.pdf. Last revised 03/2026. Last accessed 08/26/2026.

[14] Philis-Tsimikas A, Bajaj H, Begtrup K, et al. Rationale and Design of the Phase 3a Development Programme (ONWARDS 1–6 Trials) Investigating Once-Weekly Insulin Icodec in Diabetes. *Diabetes Obes Metab* 2023; 25(2):331-341. doi: 10.1111/dom14871.

Appendix G

Vote to Prior Authorize Jobevne™ (Bevacizumab-nwgd)

Oklahoma Health Care Authority
September 2026

Market News and Updates[1]

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)	**$82.24**	**$6,579.20**	**$85,529.60**
Avastin® (bevacizumab) (J9035)	$74.82	$5,985.60	$77,812.80
Alymsys® (bevacizumab-maly) (Q5126)	$51.59	$4,127.20	$53,653.60
Zirabev® (bevacizumab-bvzr) (Q5118)	$25.89	$2,071.20	$26,925.60
Mvasi® (bevacizumab-awwb) (Q5107)	$24.53	$1,962.40	$25,511.20
Vegzelma® (bevacizumab-adcd) (Q5129)	$23.65	$1,892.00	$24,596.00

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), 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 and recommends making Vegzelma® (bevacizumab-adcd) a preferred product based on net cost (changes shown in red):

Alymsys® (Bevacizumab-maly), Avzivi® (Bevacizumab-tnjn), and 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), Vegzelma® (bevacizumab-adcd), 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.

[1] 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 08/12/2026.

Appendix H

Vote to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate) and Update the Approval Criteria for the Miscellaneous Cancer Medications

Oklahoma Health Care Authority
September 2026

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

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

- **December 2015:** The FDA approved Vistogard® (uridine triacetate) for the emergency treatment of adult and pediatric patients following a fluorouracil or capecitabine overdose regardless of the presence of symptoms, or who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions within 96 hours following the end of fluorouracil or capecitabine administration. Vistogard® was not covered by SoonerCare until July 2026 when the current manufacturer began participating in the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS).
- **August 2025:** The FDA granted accelerated approval to Modeyso™ (dordaviprone) for the treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy.
- **December 2025:** The FDA approved Omisirge® (omidubicel-onlv) for a new indication for the treatment of adults and pediatric patients 6 years of age and older with severe aplastic anemia (SAA) following reduced intensity conditioning.
- **June 2026:** The FDA approved Tecelra® (afamitresgene autoleucel) for an age expansion down to 12 years of age for the treatment of unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the melanoma-associated antigen A4 (MAGE-A4) antigen as determined by FDA-approved or cleared companion diagnostic devices. Previously, Tecelra® was only FDA approved for adults with this indication.

Modeyso™ (Dordaviprone) Product Summary[5]

Therapeutic Class: Protease activator

Indication(s): Treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy

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

How Supplied: 125mg oral capsules

Dosing and Administration:

- The recommended dosage for adults is 625mg once weekly.
- The recommended dosage in pediatric patients 1 year to younger than 17 years of age who weigh at least 10kg is based on body weight, as follows:

Body Weight (kg)	Recommended Dosage
10kg to <12.5kg	125mg once weekly
12.5kg to <27.5kg	250mg once weekly
27.5kg to <42.5kg	375mg once weekly
42.5kg to <52.5kg	500mg once weekly
≥52.5kg	625mg once weekly

- Dosing should be continued until disease progression or unacceptable toxicity.
- Capsules may be swallowed whole or may be opened and the contents mixed with 15-30mL of liquid (e.g., sports drink, apple juice, lemonade, water) before administration orally as a liquid.

Cost: The Wholesale Acquisition Cost (WAC) of Modeyso™ is $3,200 per capsule. At the maximum recommended dose of 625mg once weekly, this would result in an estimated cost of $64,000 per 28 days or $832,000 per year.

Vistogard® (Uridine Triacetate) Product Summary[6]

Therapeutic Class: Pyrimidine analog

Indication(s): Treatment of adult and pediatric patients:

- Following a fluorouracil or capecitabine overdose regardless of the presence of symptoms, or
- Who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia)

within 96 hours following the end of fluorouracil or capecitabine administration

- Limitation(s) of Use:
  - Vistogard® is not recommended for the non-emergent treatment of adverse reactions associated with fluorouracil or capecitabine because it may diminish the efficacy of these drugs.
  - The safety and efficacy of Vistogard® initiated more than 96 hours following the end of fluorouracil or capecitabine administration has not been established.

How Supplied: Available as orange-flavored oral granules in 10 gram single-dose packets in the following configurations:

- Course of therapy package: 1 carton containing 20 single-dose packets
- 24-hour pack: 1 carton containing 4 single-dose packets

Dosing and Administration:

- Adults: The recommended dose 10 grams (1 packet) orally every 6 hours for 20 doses, without regard to meals.
- Pediatric: The recommended dose is 6.2 grams/m^2 of body surface area (BSA) (not to exceed 10 grams per dose) orally every 6 hours for 20 doses, without regard to meals. See the full *Prescribing Information* for BSA-based dosing.

Cost: The WAC of Vistogard® is $4,646 per single-dose packet. This would result in an estimated cost of $18,584 per day or $92,920 for the recommended 20-dose treatment regimen.

Recommendations

The College of Pharmacy recommends the prior authorization of Modeyso™ (dordaviprone) and Vistogard® (uridine triacetate) with the following criteria (shown in red):

Modeyso™ (Dordaviprone) Approval Criteria [Glioma Diagnosis]:

1. Diagnosis of diffuse midline glioma; and
2. Member must be 1 year of age or older; and
3. Presence of H3 K27M mutation; and
4. Member has progressed on at least 1 prior therapy.

Vistogard® (Uridine Triacetate) Approval Criteria:

1. Member received fluorouracil or capecitabine within the previous 96 hours; and
2. Member meets 1 of the following:
   a. Following fluorouracil or capecitabine overdose regardless of the presence of symptoms; or

    b. Exhibits early-onset, severe or life-threatening toxicity affecting cardiac or central nervous system; or
    c. Exhibits early-onset, unusually severe adverse reactions; and
3. A quantity limit of 20 packets for 5 days will apply; and
    a. Doses administered in an emergency room (ER) or inpatient (IP) setting do not require prior authorization. The number of remaining doses (following any ER or IP doses) must be specified on the request. Only the number of remaining doses for outpatient use will be approved.

Next, the College of Pharmacy recommends updating the Omisirge® (omidubicel-onlv) and Tecelra® (afamitresgene autoleucel) approval criteria based on recent FDA approvals with the following updates (shown in red):

Omisirge® (Omidubicel-onlv) Approval Criteria [Severe Aplastic Anemia Diagnosis]:

1. Diagnosis of severe aplastic anemia; and
2. Member is 6 years of age or older; and
3. Allogeneic stem cell transplant using umbilical cord blood donor source is planned; and
    a. No compatible donor is available; and
    b. Documentation of the donor source must be provided; and
4. Reduced intensity conditioning regimen will be used; and
    a. Documentation of the member's conditioning regimen must be provided; and
5. Will be used to reduce time to neutrophil recovery and incidence of infection.

Tecelra® (Afamitresgene Autoleucel) Approval Criteria [Synovial Sarcoma Diagnosis]:

1. Diagnosis of unresectable or metastatic synovial sarcoma; and
2. Member must be ~~18~~ 12 years of age or older; and
3. Has received previous anthracycline or ifosfamide-containing chemotherapy; and
4. HLA-A*02:01P, -A*02:02P, A*02:03P, or -A*02:06P positive; and
5. Tumor expresses melanoma-associated antigen A4 (MAGE-A4) as detected by an FDA-approved test; and
6. Health care facilities must be able to administer cellular therapies and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and
7. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends updating Voranigo® (vorasidenib) approval criteria to be consistent with the FDA approved age range with the following updates (shown in red):

Voranigo® (Vorasidenib) Approval Criteria [Astrocytoma or Oligodendroglioma Diagnosis]:

1. Diagnosis of grade 2 astrocytoma or oligodendroglioma; and
2. Member must be 12 years of age or older; and
3. Presence of susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection.

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[1] U.S. Food and Drug Administration (FDA). Vistogard® NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/208159Orig1s000ltr.pdf. Issued 12/11/2015. Last accessed 08/25/2026.

[2] U.S. FDA. FDA Grants Accelerated Approval to Dordaviprone for Diffuse Midline Glioma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dordaviprone-diffuse-midline-glioma. Issued 08/06/2025. Last accessed 08/25/2026.

[3] U.S. FDA. FDA Approves First Cellular Therapy to Treat Patients with Severe Aplastic Anemia. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-cellular-therapy-treat-patients-severe-aplastic-anemia. Issued 12/08/2025. Last accessed 08/25/2026.

[4] US WorldMeds. US WorldMeds Receives Full U.S. FDA Approval of Tecelra® (Afamitresgene Autoleucel) with an Expanded Indication, Extending the First Approved Engineered T-Cell Therapy for a Solid Tumor to Children as Young as 12. Available online at: https://www.prnewswire.com/news-releases/us-worldmeds-receives-full-us-fda-approval-of-tecelra-afamitresgene-autoleucel-with-an-expanded-indication-extending-the-first-approved-engineered-t-cell-therapy-for-a-solid-tumor-to-children-as-young-as-12-302806599.html. Issued 06/22/2026. Last accessed 08/25/2026.

[5] Modeyso™ (Dordaviprone) Prescribing Information. Jazz Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219876s000lbl.pdf. Last revised 08/2025. Last accessed 08/25/2026.

[6] Vistogard® (Uridine Triacetate) Prescribing Information. BTG International, Inc. Available online at: https://vistogard.com/Vistogard/media/Main-Media/Professional/PDFs/Vistogard-Prescribing-Information_October-2023.pdf. Last revised 10/2023. Last accessed 08/25/2026.

Appendix I

Vote to Update the Approval Criteria for the Iron Products

Oklahoma Health Care Authority
September 2026

Market News and Updates[1]

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

- **December 2025:** The FDA approved Accrufer® (ferric maltol) for an age expansion for the treatment of iron deficiency in adult and pediatric patients 10 years of age and older. Previously, Accrufer® was only approved for the treatment of iron deficiency in adults.

Recommendations

The College of Pharmacy recommends updating the Accrufer® (ferric maltol) approval criteria based on the recent FDA approved age expansion with the following changes (shown in red):

Accrufer® (Ferric Maltol) Approval Criteria:

1. Diagnosis of iron deficiency anemia (IDA); and
2. Lab results verifying IDA must be submitted; and
3. Member must be ~~18~~ 10 years of age or older; and
4. For members 18 years of age or older, all of the following must be met:
    a. Member must have a documented diagnosis of chronic kidney disease (CKD) or inflammatory bowel disease (IBD) (e.g., Crohn's disease, ulcerative colitis); and
    b. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
    c. A recent, failed trial of Feraheme® (ferumoxytol), Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed® and Venofer® must be provided; and
    d. A patient-specific clinically significant reason why the member cannot utilize all other forms of intravenous (IV) iron must be provided; and
5. For members younger than 18 years of age, all of the following must be met:
    a. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and

   b. A patient-specific clinically significant reason why the member cannot utilize IV iron must be provided; and
6. Initial approvals will be for the duration of 3 months of treatment. Subsequent approvals (for 3 months of treatment) will require updated recent laboratory results documenting continued IDA.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Prescription Oral Medicine for Iron Deficiency in Pediatric Patients Ages 10 and Older. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-prescription-oral-medicine-iron-deficiency-pediatric-patients-ages-10-and-older. Issued 12/22/2025. Last accessed 08/21/2026.

Appendix J

Vote to Update the Approval Criteria for the Iron Chelating Agents

Oklahoma Health Care Authority
September 2026

Recommendations

The College of Pharmacy recommends updating the Jadenu® (deferasirox), Jadenu® Sprinkle (deferasirox), and Ferriprox® (deferiprone) approval criteria with regard to Exjade® (deferasirox) for clarity and to include additional criteria for Ferriprox® tablet (deferiprone twice daily formulation) based on net cost (changes shown in red):

Jadenu® (Deferasirox), Jadenu® Sprinkle (Deferasirox), and Ferriprox® (Deferiprone) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox), which is available without prior authorization, must be provided; and
3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of 6 years of age and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why Jadenu® oral tablets cannot be used even when the tablets are crushed; and
4. For Ferriprox® 1,000mg tablet (deferiprone twice daily formulation), a patient-specific, clinically significant reason other than convenience why the member cannot use and Ferriprox® 1,000mg tablet (deferiprone 3 times daily formulation); and
5. 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.

Appendix K

Vote to Prior Authorize Amcinonide 0.1% Ointment and Update the Approval Criteria for the Topical Corticosteroids

Oklahoma Health Care Authority
September 2026

Market News and Updates[1]

News:

- **July 2026:** Ayurax began marketing amcinonide 0.1% ointment in May 2023; however, it was not covered by SoonerCare until July 2026 when the manufacturer began participating in the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS). The State Maximum Allowable Cost (SMAC) is $27.71 per gram or $1,662.60 per 60-gram tube.

Recommendations

The College of Pharmacy recommends the following changes to the Topical Corticosteroids Product Based Prior Authorization (PBPA) Tier chart based on net costs (changes are shown in red in the following Tier chart):

1. Ultra-High to High Potency:
    a. Prior authorization of amcinonide 0.1% ointment and placement into Tier-3; and
    b. Move augmented betamethasone dipropionate 0.05% (Diprolene®) gel, clobetasol propionate/skin cleanser 0.05% (Clodan®) kit, desoximetasone 0.05% (Topicort®) gel, and halobetasol propionate 0.05% (Ultravate®) lotion from Tier-2 to Tier-3; and
    c. Move desoximetasone 0.25% (Topicort®) spray from Tier-3 to Tier-2; and
    d. Move clobetasol propionate 0.05% (Temovate® Emollient) emollient cream from Tier-1 to Tier-2; and
2. Medium-High to Medium Potency:
    a. Move hydrocortisone butyrate 0.1% solution from Tier-2 to Tier-3; and
    b. Move triamcinolone acetonide 0.1% lotion from Tier-1 to Tier-2; and
3. Low Potency:
    a. Move fluocinolone acetonide/skin cleanser 0.01% (Synalar® TS) kit from Tier-2 to Tier-3.

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®) Diprolene AF®)	C,L,O	~~**augmented betamethasone dipropionate 0.05% (Diprolene®)**~~	~~**G**~~	amcinonide 0.1%	C**,O**
betamethasone dipropionate 0.05% (Diprosone®)	C,O	clobetasol propionate 0.05% (Clobex®, Clodan®)	L,Sh,Spr	**augmented betamethasone dipropionate 0.05% (Diprolene®)**	**G**
clobetasol propionate 0.05% (Olux®)	F	~~**clobetasol propionate/skin cleanser 0.05% kit (Clodan®)**~~	~~**Sh**~~	clobetasol propionate 0.025% (Impoyz®)	C
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	clobetasol propionate emollient 0.05% (Olux-E®, Tovet®)	F
~~**clobetasol propionate emollient 0.05% (Temovate® Emollient**~~	~~**C**~~	**clobetasol propionate emollient 0.05% (Temovate® Emollient**	**C**	**clobetasol propionate/skin cleanser 0.05% kit (Clodan®)**	**Sh**
desoximetasone 0.25% (Topicort®)	C,O	~~**desoximetasone 0.05% (Topicort®)**~~	~~**G**~~	~~**desoximetasone 0.25% (Topicort®)**~~	~~**Spr**~~
fluocinonide 0.05%	C,O,So	**desoximetasone 0.25% (Topicort®)**	**Spr**	**desoximetasone 0.05% (Topicort®)**	**G**
fluocinonide 0.1% (Vanos®)	C	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
halobetasol propionate 0.05% (Ultravate®)	C,O	~~**halobetasol propionate 0.05% (Ultravate®)**~~	~~**L**~~	halcinonide 0.1% (Halog®)	C,So
				halobetasol propionate 0.05%	F
				halobetasol propionate 0.05% (Ultravate®)	**L**

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone valerate 0.12% (Luxiq®)	F	betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)	O,Sus
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.1% (Beta-Val®)	L	clocortolone pivalate 0.1% (Cloderm®)	C
fluticasone propionate 0.005% (Cutivate®)	O	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F	desoximetasone 0.05% (Topicort LP®)	C,O
fluticasone propionate 0.05% (Cutivate®)	C	fluocinolone acetonide 0.025% (Synalar®)	C,O	flurandrenolide 0.05%	L
hydrocortisone valerate 0.2% (Westcort®)	C	fluocinolone acetonide/emollient 0.025% kit (Synalar®)	C,O	fluticasone propionate 0.05% (Cutivate®)	L
mometasone furoate 0.1% (Elocon®)	C,L,O, So	fluocinonide emollient 0.05% (Lidex E®)	C	hydrocortisone butyrate 0.1%	C,L,**So**
triamcinolone acetonide 0.025%	O	hydrocortisone butyrate 0.1%	O,~~**So**~~	triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr
triamcinolone acetonide 0.1%	C,~~**L**~~,O	hydrocortisone probutate 0.1% (Pandel®)	C		
triamcinolone acetonide 0.5%	C,O	hydrocortisone valerate 0.2% (Westcort®)	O		
		triamcinolone acetonide 0.05% (Trianex®)	O		
		triamcinolone acetonide 0.1%	**L**		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C,O	desonide 0.05%	L

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	**fluocinolone acetonide/skin cleanser 0.01% kit (Synalar® TS)**	**C**
hydrocortisone acetate 1%	C,O	fluocinolone acetonide 0.01% (Synalar®)	C	hydrocortisone 2.5% (Texacort®)	So
hydrocortisone acetate 2.5%	C,L,O	~~**fluocinolone acetonide/skin cleanser 0.01% kit (Synalar® TS)**~~	~~**C**~~		
triamcinolone acetonide 0.025%	C,L				

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).
C = cream; F = foam; G = gel; L = lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

[1] U.S. Food and Drug Administration (FDA). National Drug Code Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm. Last revised 07/28/2026. Last accessed 08/26/2026.

Appendix L

Vote to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid) and Update the Approval Criteria for the Various Systemic Antibiotics

Oklahoma Health Care Authority
September 2026

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

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

- **October 2024:** The FDA approved Orlynvah™ (sulopenem etzadroxil/probenecid) for the treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae,* or *Proteus mirabilus* in adult women who have limited or no alternative oral antibacterial treatment options.
- **October 2025:** The FDA approved Contepo™ (fosfomycin for injection) for the treatment of adults with complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible strains of *Escherichia coli* or *Klebsiella pneumoniae*. Despite being available internationally, an intravenous (IV) formulation of fosfomycin has not been available in the United States until this approval.
- **December 2025:** The FDA approved an expanded indication for Blujepa (gepotidacin) as a new oral option for the treatment of uncomplicated urogenital gonorrhea in adult and pediatric patients 12 years of age and older, weighing at least 45kg, and who have limited or no alternative treatment options. The approval of this indication was based on limited clinical and safety data.

News:

- **June 2026:** A doxycycline hyclate 75mg capsule formulation began being marketed. Doxycycline hyclate 75mg is also available in a tablet formulation.

Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Product Summary[5]

Therapeutic Class: Penem antibacterial and renal tubular transport inhibitor combination

Indication(s): Treatment of uUTI caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae,* or *Proteus mirabilus* in adult women who have limited or no alternative oral antibacterial treatment options

- Limitation(s) of Use: Orlynvah™ is not indicated for the treatment of cUTI or complicated intraabdominal infections (cIAI) or as step-down treatment after IV antibacterial treatment.

How Supplied: 500mg/500mg film-coated tablet

Dosing and Administration: 500mg/500mg (1 tablet) orally twice daily for 5 days

- Administration with food is recommended.
- Administration is not recommended in patients with creatinine clearance (CrCl) <15mL/min or patients on hemodialysis.
- Orlynvah™ is contraindicated in patients with known uric acid kidney stones or with concomitant use of ketorolac tromethamine.

Efficacy: The safety and efficacy of Orlynvah™ were evaluated in 2 Phase 3 randomized, double blind clinical trials, designated as Trial 1 and Trial 2 in the *Prescribing Information*.

- Key Inclusion Criteria:
  - Female ≥18 years of age
  - Diagnosis of uUTI
  - Trial 1: Microbiological modified intention-to-treat (micro-MITT) population
    - ≥1 uropathogen isolated at baseline
    - Received ≥1 dose of study drug
    - Micro-MITT susceptible (micro-MITTS) population: baseline pathogen(s) susceptible to amoxicillin/clavulanate
    - Micro-MITT resistant (micro-MITTR) population: baseline pathogen(s) resistant to amoxicillin/clavulanate
  - Trial 2: Micro-MITT population
    - ≥1 uropathogen isolated at baseline
    - Received ≥1 dose of study drug
    - Micro-MITTS population: baseline pathogen(s) susceptible to ciprofloxacin
    - Micro-MITTR population: baseline pathogen(s) resistant to ciprofloxacin
- Key Exclusion Criteria:
  - Signs and symptoms of pyelonephritis
  - Any anatomical abnormality of the urinary tract
  - Receiving hemodialysis

- Intervention(s):
  - Trial 1: Orlynvah™ 500mg/500mg orally twice daily for 5 days vs. amoxicillin/clavulanate 875mg/125mg orally twice daily for 5 days
  - Trial 2: Orlynvah™ 500mg/500mg orally twice daily for 5 days vs. ciprofloxacin 250mg orally twice daily for 3 days
- Primary Endpoint(s):
  - Trial 1 and Trial 2: Composite response (combined microbiological response and clinical cure rates) in the micro-MITTS population 12 days after randomization
- Results:
  - Trial 1:
    - At day 12, for the micro-MITTS population, 61.7% (296/480) of patients in the Orlynvah™ group vs. 55.0% (243/442) of patients in the amoxicillin/clavulanate group met the primary endpoint of composite response; therefore, Orlynvah™ was noninferior to amoxicillin/clavulanate, with a treatment difference of 6.7% [95% confidence interval (CI): 0.3, 13.0].
    - The micro-MITTR population had insufficient power to determine efficacy (N=67).
  - Trial 2:
    - At day 12, in the micro-MITTR population, Orlynvah™ demonstrated superiority to ciprofloxacin with 48.1% (78/162) of patients vs. 32.9% (49/149) meeting the composite response endpoint (treatment difference: 15.3%; 95% CI: 4.3, 25.8; P=0.006).
    - Orlynvah™ did not demonstrate noninferiority to ciprofloxacin in the micro-MITTS population with 60.4% (227/376) vs. 71.8% (300/418) meeting the composite response endpoint (treatment difference: -11.4%; 95% CI: -17.9, -4.8).

Cost: The Wholesale Acquisition Cost (WAC) of Orlynvah™ is $297.50 per tablet, which results in a cost of $2,975.00 per 5-day treatment course based on the FDA-approved dosing of 1 tablet twice daily.

Cost Comparison: IV Products for Treatment of cUTI

Product	Cost Per Unit	Cost Per Dose	Cost Per Day*
Contepo™ (fosfomycin for injection) 6-gram vial	**$182.74**	**$182.74**	**$548.22**
ceftriaxone 2-gram vial (generic)	$2.70	$2.70	$2.70
ciprofloxacin 400mg/40mL vial (generic)	$0.08	$3.20	$6.40

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).
*Costs per dose and per day is based on a typical adult dose of 6 grams every 8 hours for Contepo™, 2 grams once daily for ceftriaxone, and 400mg twice daily for ciprofloxacin.
Unit = mL or vial

Cost Comparison: Doxycycline Products

Product	Cost Per Unit	Cost Per Day*
doxycycline hyclate 75mg capsule (generic)	**$10.00**	**$20.00**
doxycycline hyclate 50mg tablet (generic)	$5.16	$10.32
doxycycline hyclate 75mg tablet (generic)	$0.27	$0.54
doxycycline hyclate 50mg capsule (generic)	$0.14	$0.28
doxycycline hyclate 100mg tablet (generic)	$0.11	$0.22
doxycycline hyclate 100mg capsule (generic)	$0.08	$0.16

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 day is based on a typical adult dose of 1 tablet or capsule twice daily.
Unit = capsule or tablet

Recommendations

The College of Pharmacy recommends the prior authorization of Contepo™ (fosfomycin for injection) and Orlynvah™ (sulopenem etzadroxil/probenecid) with the following criteria (shown in red):

Contepo™ (Fosfomycin for Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI), including acute pyelonephritis, caused by *Escherichia coli* or *Klebsiella pneumoniae* (culture/sensitivity results must be submitted with the request); and
2. A patient-specific, clinically significant reason why the member cannot use an appropriate cephalosporin (e.g., cefuroxime, ceftriaxone, cefepime), penicillin/beta lactamase inhibitor combination (e.g., piperacillin/ tazobactam), a fluoroquinolone (e.g., ciprofloxacin or levofloxacin), or other cost-effective therapeutic equivalent alternative(s); and
3. A quantity limit of 42 vials per 14 days will apply.

Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by designated susceptible microorganisms in members who have limited or no alternative oral treatment options (culture/sensitivity results must be submitted); and
    a. Must not be used for the treatment of complicated urinary tract infections (cUTI) or complicated intraabdominal infections (cIAI) or as step-down treatment after intravenous antibacterial treatment of cUTI or cIAI; and
2. Member must be a female 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g.,

nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
4. A quantity limit of 10 tablets per 5 days will apply.

The College of Pharmacy recommends updating the approval criteria for Blujepa (gepotidacin) based on the new FDA approved indication and for clarity (changes shown in red):

Blujepa (Gepotidacin) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Uncomplicated urinary tract infection (uUTI) caused by ~~the designated microorganisms~~ *Escherichia coli*, *Klebsiella pneumoniae, Citrobacter freundii* complex, *Staphylococcus saprophyticus,* ~~and~~ or *Enterococcus faecalis* (culture/sensitivity results must be submitted); and
      i. Member must be a female 12 years of age or older and weigh ≥40kg; ~~and~~ or
   b. Uncomplicated urogenital gonorrhea in members who have limited or no alternative treatment options; and
      i. Member must be 12 years of age or older and weigh ≥45kg; and
2. Member must have an estimated glomerular filtration rate (eGFR) >30mL/min/1.73m^2) and must not be on dialysis; and
3. Member must not have severe hepatic impairment (Child Pugh C); and
~~4. Prior to and during treatment, the potential for drug interactions should be evaluated, including:~~
   ~~a. Avoid concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole) or inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and~~
   ~~b. Avoid concomitant administration with CYP3A4 substrates with a narrow therapeutic index (e.g., quinidine, cyclosporine); and~~
   ~~c. Monitor digoxin serum concentrations as clinically indicated; and~~
   ~~d. Monitor for adverse effects with concomitant administration with acetylcholinesterase inhibitors, anticholinergic medications, or non-depolarizing neuromuscular blocking agents; and~~
5. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Blujepa and agree to address interactions with concomitant medications according to package labeling; and
6. Prescriber must verify that members with medical conditions that may be exacerbated by acetylcholinesterase inhibition will be monitored for adverse effects; and
7. If administration of Blujepa cannot be avoided in members with a history of QTc interval prolongation, taking antiarrhythmic medications, or taking other medications that may prolong the QTc interval,

prescriber must verify that serum electrolyte abnormalities will be corrected and monitored and an ECG should be collected prior to administration and during treatment, as clinically indicated; and

~~8. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and~~

9. A patient-specific, clinically significant reason why the member cannot use a cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis (e.g., ceftriaxone, nitrofurantoin, fosfomycin, sulfamethoxazole/trimethoprim) must be provided; and

~~10. A quantity limit of 20 tablets per 5 days will apply.~~

11. Approval quantity will be based on package labeling and FDA-approved dosing regimens.

The College of Pharmacy also recommends replacing the Oral Antibiotic Special Formulation approval criteria with individual criteria describing the preferred cost-effective therapeutic equivalent products for clarity and recommends the prior authorization of doxycycline hyclate 75mg capsule within the new approval criteria for the doxycycline special formulations (changes shown in red):

~~**Oral Antibiotic Special Formulation Approval Criteria:**~~

~~1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.~~

~~2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:~~

- ~~Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)~~
- ~~Cephalexin 250mg and 500mg tablets~~
- ~~Cephalexin 750mg capsules~~
- ~~Doxycycline hyclate 75mg and 150mg tablets (Acticlate®)~~
- ~~Doxycycline hyclate 50mg tablet (Targadox®)~~
- ~~Doxycycline hyclate delayed-release (DR) tablets (Doryx®, Doryx® MPC)~~
- ~~Doxycycline monohydrate 75mg capsules~~
- ~~Doxycycline monohydrate 150mg capsules and tablets~~
- ~~Doxycycline monohydrate DR 40mg capsules (Oracea®)~~
- ~~Metronidazole 125mg tablets~~
- ~~Metronidazole 375mg capsules~~
- ~~Minocycline ER tablets (Minolira™)~~
- ~~Minocycline ER tablets (Solodyn®)~~
- ~~Nitrofurantoin 50mg/5mL suspension~~

Amoxicillin/Clavulanate Potassium Extended Release (ER) Tablets (Augmentin XR®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the generic immediate release (IR) tablet formulations, which are available without prior authorization, must be provided.

Cephalexin 750mg Capsule and Cephalexin 250mg and 500mg Tablets Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the 250mg or 500mg capsule formulations, which are available without prior authorization, must be provided.

Doxycycline Hyclate 75mg and 150mg Tablets (Acticlate®), Doxycycline Hyclate 75mg Capsule, Doxycycline Hyclate 50mg Tablet (Targadox®), Doxycycline Hyclate Delayed Release (DR) Tablets (Doryx®, Doryx® MPC), Doxycycline Monohydrate 75mg Capsule, Doxycycline Monohydrate 150mg Capsules and Tablets, and Doxycycline Monohydrate DR 40mg Capsules (Oracea®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic immediate release (IR) doxycycline hyclate 20mg tablet, 50mg capsule, or 100mg capsule or tablet or doxycycline monohydrate 50mg capsule or tablet, 75mg tablet, or 100mg capsule or tablet, which are available without prior authorization, must be provided; and
2. For doxycycline hyclate 75mg capsule, a patient specific, clinically significant reason why the member cannot use the doxycycline hyclate 75mg tablet formulation must be provided.

Metronidazole 125mg Tablet and 375 mg Capsule Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use a dosing regimen with the 250mg or 500mg generic metronidazole tablets, which are available without prior authorization, must be provided.

Minocycline (50mg, 75mg, and 100mg) Immediate-Release (IR) Tablet, Minocycline ER Tablet (Minolira™), and Minocycline ER Tablet (Solodyn®) Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member ~~requires the IR tablet formulation and~~ cannot use the IR capsule formulation and/or other cost effective therapeutic equivalent medication(s).

Nitrofurantoin 50mg/5mL Suspension Approval Criteria:

1. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral capsule formulations cannot be used; and

2. A patient-specific, clinically significant reason why the member cannot use the generic nitrofurantoin 25mg/5mL suspension, which is available without prior authorization for members 10 years of age or younger, must be provided.

The College of Pharmacy also recommends updating the approval criteria for Avycaz® (ceftazidime/avibactam), Baxdela® (delafloxacin), ciprofloxacin 250mg/mL and 500mg/mL oral suspension and levofloxacin 25mg/mL oral solution, Likmez® (metronidazole 500mg/5mL suspension), and Zerbaxa® (ceftolozane/avibactam) based on clinical practice and for clarity (changes shown in red):

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); ~~and~~ or
   d. Other diagnosis in which treatment with Avycaz® is supported by compendia or clinical literature (documentation must be submitted with the request); and
2. Member must be at least 31 weeks gestational age or older; and
3. For the diagnosis of cIAI, Avycaz® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use a ~~an appropriate~~ penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or other cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria ~~[Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]~~:

1. An FDA approved diagnosis of 1 of the following caused by designated susceptible bacteria (culture/sensitivities must be provided):
   a. Acute Bacterial Skin and Skin Structure Infection (ABSSSI) ~~caused by designated susceptible bacteria; and~~ or
   b. Community Acquired Bacteria Pneumonia (CABP); and

2. A patient-specific, clinically significant reason why the member cannot use a cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis (e.g., other fluroquinolone, beta-lactam, doxycycline, linezolid, trimethoprim/sulfamethoxazole, vancomycin) must be provided; and
3. ~~A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and~~
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

~~Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:~~

1. ~~An FDA approved diagnosis of CABP caused by designated susceptible bacteria; and~~
2. ~~A patient-specific, clinically significant reason why the member cannot use an appropriate beta lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem, ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, monotherapy with a respiratory fluoroquinolone (e.g., levofloxacin, moxifloxacin, gemifloxacin), or other cost-effective therapeutic equivalent alternative(s) must be provided; and~~
3. ~~Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and~~

Ciprofloxacin 250mg/mL and 500mg/mL Oral Suspension and Levofloxacin 25mg/mL Oral Solution Approval Criteria:

1. ~~Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations cannot be used.~~
2. Products will be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations, which are available without prior authorization, cannot be used, including but not limited to:
    a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
    b. Clinically indicated dose cannot be achieved with available tablet formulations; or
    c. Treatment course was initiated inpatient; and

3. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request.

Likmez® (Metronidazole 500mg/5mL Suspension) Approval Criteria:

1. Products will be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age require a ~~A~~ patient-specific clinically significant reason (beyond convenience) must be provided regarding why the member cannot use the 250mg and 500mg tablets, which are available without prior authorization, including but not limited to:
   a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
   b. Clinically indicated dose cannot be achieved with available tablet formulations; or
   c. Treatment course was initiated inpatient; and
2. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request; and
3. A quantity limit of 200mL per 10 days will apply

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); ~~and~~ or
   d. Other diagnosis in which treatment with Zerbaxa® is supported by compendia or clinical literature (documentation must be submitted with the request); and
2. For the diagnosis of HABP/VABP, member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Zerbaxa® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use a ~~an appropriate~~ penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole when indicated, or

other cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Lastly, the College of Pharmacy recommends adding age restriction criteria for the nitrofurantoin 25mg/5mL suspension, which is available without prior authorization, for clarity (shown in red):

Nitrofurantoin 25mg/5mL Suspension Approval Criteria:

1. Nitrofurantoin 25mg/5mL suspension will not require prior authorization for members 10 years of age or younger. For members 11 years of age or older, a patient-specific, clinically significant reason why the member cannot use nitrofurantoin oral capsules must be provided.

[1] U.S. Food and Drug Administration (FDA). FDA Approves New Treatment for Uncomplicated Urinary Tract Infections in Adult Women Who Have Limited or No Alternative Oral Antibiotic Treatment Options. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-new-treatment-uncomplicated-urinary-tract-infections-adult-women-who-have-limited-or-no. Issued 10/24/2024. Last accessed 08/25/2026.
[2] Contepo™ (Fosfomycin for Injection) Prescribing Information. Meitheal. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/212271s000lbl.pdf. Last revised 10/22/2025. Last accessed 08/25/2026.
[3] GSK. Blujepa (Gepotidacin) Approved by US FDA as Oral Option for Treatment of Uncomplicated Urogenital Gonorrhea (uGC). Available online at: https://us.gsk.com/en-us/media/press-releases/blujepa-gepotidacin-approved-by-us-fda-as-oral-option-for-treatment-of-uncomplicated-urogenital-gonorrhea-ugc/. Issued 12/11/2025. Last accessed 08/25/2026.
[4] Doxycycline Hyclate 75mg Capsule Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fad03768-f1d2-459f-965e-0ec29f189f1f. Last revised 06/30/2026. Last accessed 08/25/2026.
[5] Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Prescribing Information. Interim Therapeutics. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/213972s000lbl.pdf. Last revised 12/23/2025. Last accessed 08/25/2026.

Appendix M

Vote to Prior Authorize Zycubo® (Copper Histidinate)

Oklahoma Health Care Authority
September 2026

Market News and Updates[1]

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

- **January 2026:** The FDA approved Zycubo® (copper histidinate) for the treatment of Menkes disease in pediatric patients, making it the first FDA-approved therapy for this rare, inherited copper transport disorder.

Zycubo® (Copper Histidinate) Product Summary[2]

Therapeutic Class: Copper replacement product

Indication(s): Treatment of Menkes disease in pediatric patients

- Limitation(s) of Use: Zycubo® is not indicated for the treatment of occipital horn syndrome.

How Supplied: 2.9mg of copper histidinate (equivalent to 0.5mg elemental copper) as a lyophilized powder or cake in a single-dose vial (SDV) for reconstitution

Dosing and Administration:

- Before initiating Zycubo®, baseline serum copper and ceruloplasmin levels, serum electrolytes, kidney and liver function, and complete blood count (CBC) should be obtained.
- After initiating Zycubo®, laboratory values should be monitored every 6 weeks for the first 6 months, then every 3 months for 18 months, and then every 6 months thereafter during Zycubo® treatment.
- Zycubo® should be administered subcutaneously (sub-Q) with the dosing frequency based on age:
  - <1 year of age: 1.45mg twice daily (8-12 hours between injections)
  - 1 year to <17 years of age: 1.45mg once daily

Efficacy: The efficacy of Zycubo® for the treatment of Menkes disease was evaluated by assessing overall survival in 2 open-label, single-arm clinical trials (Trial 1 and Trial 2). Data from both trials were pooled and compared with an untreated contemporaneous external control cohort. Patients in the pooled efficacy population were stratified based on whether treatment was initiated within 4 weeks of birth (early treatment) or after 4 weeks of birth (late treatment).

- Pooled Efficacy Population:
  - Patients with confirmed Menkes disease carrying severe *ATP7A* pathogenic variants
  - Born after 1999
  - Patients pooled from 2 open-label trials
  - Stratified into early (≤4 weeks of age) and late (>4 weeks of age) treatment cohorts
  - Compared with untreated external controls
- Intervention: Patients received sub-Q Zycubo® for up to 3 years dosed as 1.45mg twice daily if younger than 1 year of age or 1.45mg once daily if 1 year of age older.
- Outcome(s):
  - Primary Outcome: The primary efficacy analysis compared the overall survival in patients in the Zycubo®-ET (Early Treatment) and EC-ET (External Control Early Treatment) cohorts.
  - Secondary Outcome: The secondary efficacy analysis compared overall survival between the Zycubo®-LT (Late Treatment) cohort and the EC-LT (External Control Late Treatment) cohort.
- Pooled Efficacy Results:
  - Early Treatment Cohort: The percentage of patients alive was 52% (16/31) in the Zycubo®-ET cohort compared with 12% (2/17) in the EC-ET cohort. Median overall survival was 177.1 months [95% confidence interval (CI): 33, not estimable)] with Zycubo® versus 17.6 months (95% CI: 11.5, 28.6) in the EC-ET cohort, corresponding to a 78% reduction in the risk of death [hazard ratio (HR): 0.22; 95% CI: 0.10, 0.49].
  - Late Treatment Cohort: The percentage of patients alive was 34% (12/35) in the Zycubo®-LT cohort compared with 12% (2/16) in the EC-LT cohort. Median overall survival was 62.4 months (95% CI: 29.6, 80.7) with Zycubo® versus 20.7 months (95% CI: 12.6, 28.6) in the EC-LT cohort, corresponding to a 73% reduction in the risk of death (HR: 0.27; 95% CI: 0.12, 0.57).

Cost: The Wholesale Acquisition Cost (WAC) of Zycubo® is $1,867 per SDV. This would result in an estimated monthly cost of $56,010 or $672,120 annually for children 1 year of age or older. For infants younger than 1 year of age, the estimated monthly cost is $112,020 or $1,344,240 per year.

Recommendations

The College of Pharmacy recommends the prior authorization Zycubo® (copper histidinate) with the following criteria (shown in red):

Zycubo® (Copper Histidinate) Approval Criteria:

1. An FDA approved diagnosis of Menkes disease; and

2. Diagnosis must be confirmed by 1 of the following (results of the selected test must be submitted):
    a. Plasma catecholamine analysis indicating elevated ratios of dihydroxyphenylacetic acid to dihydroxyphenylglycol and dopamine to norepinephrine; or
    b. Genetic testing identifying pathogenic or likely pathogenic variants in the *ATP7A* gene; or
    c. If plasma catecholamine analysis or genetic testing is pending:
        i. Documentation of clinical signs and symptoms consistent with Menkes disease; and
3. Member must be younger than 18 years of age; and
4. Member must not have occipital horn syndrome; and
5. Zycubo® must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of Menkes disease (or an advanced care practitioner with a supervising physician who is a geneticist, neurologist, or other specialist with expertise in the treatment of Menkes disease); and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Zycubo®; and
7. For member or caregiver administration, the prescriber must verify the member or caregiver will be trained by a health care provider on proper preparation, administration, and storage of Zycubo®; and
8. Initial approval and subsequent approvals will be for the duration of 1 year. Subsequent approvals will be granted if the prescriber documents the member is responding well to therapy; or
    a. If the diagnosis of Menkes disease was based on clinical signs and symptoms, initial approvals will be for 3 months. Subsequent approvals for the duration of 1 year will require submitted documentation of a plasma catecholamine analysis or genetic testing confirming the diagnosis; and
9. A quantity limit of 1 vial (2.9mg) per day will apply; or
    a. For members younger than 1 year of age, a quantity limit override will be granted based on FDA approved dosing.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Children With Menkes Disease. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-children-menkes-disease. Last revised 01/2026. Last accessed 08/27/2026.
[2] Zycubo® (Copper Histidinate). Prescribing Information. Sentynl Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/211241s000lbl.pdf. Last revised 01/2026. Last accessed 08/27/2026.

Appendix N

Vote to Prior Authorize Morphine Oral Solution Syringes and Tapentadol Tablet, Extended-Release (ER) Tablet, and Oral Solution and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications

Oklahoma Health Care Authority
September 2026

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

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

- **September 2025:** The FDA approved a new 0.25mL syringe of morphine sulfate oral solution 100mg per 5mL (20mg/mL). It was previously available in a 0.5mL and 1mL oral syringe in the same concentration.
- **January 2026:** The FDA approved a new generic formulation of Nucynta® (tapentadol) immediate-release (IR) tablets to Epic Pharma through an Abbreviated New Drug Application (ANDA) in 50mg, 75mg, and 100mg IR tablets. Currently, brand name Nucynta® and Nucynta® ER are not covered by SoonerCare due to the manufacturer no longer participating in the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS).
- **July 2026:** The FDA approved a new generic tapentadol 20mg/mL oral solution in January 2026 through an ANDA. The National Drug Code Directory indicates a start marketing date of July 13, 2026.

News:

- **February 2026:** Hikma Pharmaceuticals launched an authorized generic of IR Nucynta® (tapentadol) for patients in the United States.
- **March 2026:** Hikma Pharmaceuticals launched an authorized generic of Nucynta® ER (tapentadol ER) for patients in the United States.

Cost Comparison: Morphine Oral Solution

Product	Cost Per Unit	Cost Per 30 Days
morphine sulfate 20mg/mL syringe (generic)	**$3.94**	**$472.80***
morphine sulfate 5mg/0.25mL syringe (generic)	**$3.10**	**$372.00***
morphine sulfate 10mg/0.5mL syringe (generic)	**$2.96**	**$355.20***
morphine sulfate 100mg/5mL solution (generic)	$0.31	$37.20¥
morphine sulfate 20mg/5mL solution (generic)	$0.07	$42.00¥
morphine sulfate 10mg/5mL solution (generic)	$0.04	$24.00α

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 syringe
*Cost per 30 days is based on the use of 1 syringe four times daily.
¥Cost per 30 days is based on the use of 80mg of morphine sulfate daily.
αCost per 30 day is based on the use of 40mg of morphine sulfate daily.

Cost Comparison: Tapentadol[7,8]

Product	Cost Per Unit	Cost Per 30 Days
tapentadol 250mg ER tablet (generic)	**$48.39**	**$2,903.40***
tapentadol 20mg/mL oral solution (generic)	**$3.75**	**$2,250.00¥**
tapentadol 100mg tablet (generic)	**$14.10**	**$1,692.00¥**

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).
ER = extended-release, Unit = mL or tablet
*Cost per 30 days based on the FDA approved dose of 250mg twice daily.
¥Cost per 30 days based on the FDA approved dose of 100mg every 6 hours.

Recommendations

The College of Pharmacy recommends the following changes to the Opioid Analgesics Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red in the following Tier chart and approval criteria):

1. Prior authorization of tapentadol tablet, tapentadol oral solution, and tapentadol ER tablet with placement into the Special PA Tier with the following additional criteria; and
2. Prior authorization of morphine oral solution syringes with placement into the Special PA Tier with the following additional criteria; and
3. Making buprenorphine ER buccal film (Belbuca®) brand preferred; and
4. Moving hydrocodone/ibuprofen (IBU) 5/200mg and 7.5/200mg tablets (Vicoprofen®, Ibudone®, Reprexain™) from Tier-1 to Tier-2.

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®) – **Brand Preferred**	methadone soln (Dolophine®)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tramadol ER tab (Ultram® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER) – **Brand Preferred**	**tapentadol ER tab**
	tramadol ER tab (Ryzolt®)	hydromorphone ER tab (Exalgo®)	tramadol ER cap (ConZip®)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
		methadone tab (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
Short-Acting			
APAP/butalbital/ caff/codeine cap 50/325/40/30mg (Fioricet® with Codeine)	hydrocodone/IBU tab ~~**10/200mg**~~ (Ibudone®, Reprexain™**, Vicoprofen®**)		APAP/butalbital/ caff/codeine cap 50/300/40/30mg (Fioricet® with Codeine)
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)		APAP/codeine elixir & soln
codeine tab			hydrocodone/ APAP soln
codeine/APAP tab (Tylenol® with Codeine)			hydrocodone/ APAP tab (Xodol®)
hydrocodone/ APAP tab (Norco®)			levorphanol tab
~~**hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®; Ibudone®, Reprexain™)**~~			**morphine oral soln syringes**
hydromorphone tab & soln (Dilaudid®)			oxycodone tab (RoxyBond™)
meperidine tab & soln (Demerol®)			oxycodone/APAP tab (Nalocet®)
morphine IR tab & soln (MSIR®)			oxycodone/APAP tab & soln (Prolate®)
oxycodone/APAP tab & soln (Percocet®)			**tapentadol tab & soln**

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
oxycodone IR cap (Oxy IR®)			tramadol 25mg, 75mg, & 100mg tab
oxycodone IR tab & soln (Roxicodone®)			tramadol soln (Qdolo™)
tramadol 50mg tab (Ultram®)			***Oncology Only:***
tramadol/APAP (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

*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).
APAP = acetaminophen; ASA = aspirin; caff = caffeine; cap = capsule; ER = extended-release; IBU = ibuprofen; IR = immediate-release; PA = prior authorization; SL = sublingual; soln = solution; tab = tablet

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Actiq® is approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:
    a. Authorization consideration for members younger than 12 years of age requires a patient-specific, clinically significant reason for use of these products despite the medication being contraindicated for the member's age; or
    b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.
4. Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/ caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.
5. Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:
    a. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; or

   b. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior authorization is required, unless the prescription is written by an otolaryngologist or a dentist; and
   c. For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.
6. Levorphanol Tablet Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
7. Methadone Oral Solution Approval Criteria:
   a. For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or
   b. For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.
8. Morphine Oral Solution Syringes (5mg/0.25mL Syringe, 10mg/0.5mL Syringe, and 20mg/mL Syringe) Approval Criteria:
   a. For morphine oral solution syringes, a patient-specific, clinically significant reason why the member cannot use morphine oral solution in bulk solution must be provided.
9. Oxycodone (RoxyBond™) Approval Criteria:
   a. A patient specific, clinically significant reason why the member cannot use any other available short-acting opioid analgesic must be provided.
10. Oxycodone/APAP Unique Formulations and Strengths Approval Criteria:
   a. For Nalocet® (oxycodone/APAP 2.5mg/300mg) tablet and Prolate® (oxycodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg) tablets, a patient specific, clinically significant reason why the member cannot use generic Percocet® (oxycodone/APAP 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, or 10mg/325mg) tablets must be provided; and
   b. For Prolate® (10mg-300mg/5mL) oral solution, a patient specific, clinically significant reason why the member cannot use generic oxycodone/APAP tablets and generic oxycodone/APAP (5mg-325mg/5mL) oral solution must be provided.
11. Oxymorphone ER Tablet Approval Criteria:

    a. A patient specific, clinically significant reason why the member cannot use any other available ER opioid analgesic must be provided.
12. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    c. A quantity limit of 2,400mL per 30 days will apply.
13. Tapentadol ER Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other lower-tiered ER opioid analgesic must be provided.
14. Tapentadol Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other lower-tiered short-acting opioid analgesic must be provided.
15. Tapentadol Oral Solution Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use lower-tiered opioid analgesic oral solutions must be provided; and
    b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation must be provided.
16. Tramadol 25mg, 75mg, and 100mg Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose or split a tramadol 50mg tablet to achieve a 25mg or 75mg dose must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

The College of Pharmacy also recommends the following changes to the MAT medications based on clinical practice (changes shown in red):

Suboxone® [Buprenorphine/Naloxone Sublingual (SL) Film] and Zubsolv® (Buprenorphine/ Naloxone SL Tablet) Approval Criteria:

1. Generic buprenorphine/naloxone SL tablet and buprenorphine SL tablet are the preferred products. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why the preferred SL tablets are not appropriate; and
2. Member must have an FDA approved diagnosis of opioid abuse/ dependence [i.e., opioid use disorder (OUD)]; and
3. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
4. Approvals will be for the duration of ~~90 days~~ 6 months to allow for concurrent medication monitoring; and
5. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 60 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg: A quantity limit of 60 SL tablets per 30 days will apply.

Sublocade® [Buprenorphine Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder (OUD); and
2. Member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
3. Concomitant treatment with opioids (including tramadol) will be denied; and
4. Medication should only be prepared and administered by a health care provider; and
5. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone

sublingual (SL) tablets or buprenorphine SL tablets) must be provided; and

6. For new starts, a patient-specific, clinically reason why the member cannot use Brixadi® (buprenorphine ER injection), which is available without a prior authorization, must be provided. Members currently stable on Sublocade® may be approved for continuation of therapy; and
7. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
8. Approvals will be for the duration of ~~90 days~~ 6 months to allow for concurrent medication monitoring; and
9. The following quantity limits will apply:
    a. Sublocade® 100mg/0.5mL and 300mg/1.5mL: 1 monthly dose per 28 days
        i. A quantity limit override will be approved for initial dosing for members who need the second injection 1 week after the first injection when requested.

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[1] U.S. Food and Drug Administration (FDA). National Drug Code (NDC) Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm. Last accessed 08/25/2026.
[2] Morphine Sulfate Solution Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=67f0ee8d-696e-4c08-9007-3df0e3988bad. Last revised 06/09/2026. Last accessed 08/25/2026.
[3] U.S. FDA. Drugs@FDA: FDA-Approved Drugs Abbreviated New Drug Application (ANDA): 214378. Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=214378. Last revised 01/2026. Last accessed 08/25/2026.
[4] U.S. FDA. Drugs@FDA: FDA-Approved Drugs Abbreviated New Drug Application (ANDA): 219119. Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=219119. Last revised 01/2026. Last accessed 08/25/2026.
[5] Hikma Pharmaceuticals. Hikma Launches Authorized Generic of Nucynta (Tapentadol) in the U.S. Available online at: https://www.hikma.com/news/hikma-launches-authorised-generic-of-nucynta-tapentadol-in-the-us/. Issued 02/25/2026. Last accessed 08/25/2026.
[6] Hikma Pharmaceuticals. Hikma Launches Authorized Generic of Nucynta ER (Tapentadol) Extended-Release in the U.S. Available online at: https://www.hikma.com/news/hikma-launches-authorised-generic-of-nucynta-er-tapentadol-extended-release-in-the-us/. Issued 03/11/2026. Last accessed 08/25/2026.
[7] Tapentadol Extended-Release Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=38de863e-56ff-4c43-9ab8-9b3e1ba82858. Last revised 02/26/2026. Last accessed 08/25/2026.
[8] Tapentadol Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fecd2104-5bf3-47ed-a6f0-5c6ebb0a17b4. Last revised 01/28/2026. Last accessed 08/25/2026.

Appendix O

Fiscal Year 2026 Annual Review of Cystic Fibrosis (CF) Medications

Oklahoma Health Care Authority
September 2026

Current Prior Authorization Criteria

Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 *F508del* mutation in the CF transmembrane conductance regulator (*CFTR*) gene or a mutation in the *CFTR* gene that is responsive based on clinical and/or *in vitro* data; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 6 years of age or older; and
3. Members using Alyftrek® must be supervised by a pulmonary specialist; and
4. If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), or Trikafta® (elexacaftor/ tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi®, Symdeko®, or Trikafta® use, the prescriber must indicate that information on the prior authorization request; and
5. Prescriber must verify that member has been counseled on proper administration of Alyftrek® including taking with a fat-containing food; and
6. Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Alyftrek®, every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and
7. Prescriber must verify that the member does not have severe hepatic impairment; and
8. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
9. Member must not be taking strong or moderate CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Alyftrek®; and

10. The following quantity limits will apply:
    a. Alyftrek® 4/20/50mg tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
    b. Alyftrek® 10/50/125mg tablets: A quantity limit of 2 tablets per day or 56 tablets per 28 days; and
11. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
12. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), or Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor); and
13. Subsequent approvals will be for the duration of 1 year.

Cayston® (Aztreonam), Pulmozyme® (Dornase Alfa), and Inhaled Tobramycin Products (Bethkis®, Kitabis® Pak, Tobi®, and Tobi® Podhaler®) Approval Criteria:

1. Use of inhaled tobramycin products, Pulmozyme® (dornase alfa), and Cayston® (aztreonam) is reserved for members who have a diagnosis of cystic fibrosis (CF).
    a. Generic Tobi® (tobramycin 300mg/5mL) nebulized solution is the preferred inhaled tobramycin product. Authorization of Bethkis®, Kitabis® Pak, or Tobi® Podhaler® requires a patient-specific, clinically significant reason why the preferred inhaled tobramycin product (generic Tobi® 300mg/5mL nebulized solution) is not appropriate for the member.
    b. Preferred inhaled tobramycin products (generic Tobi® 300mg/5mL nebulized solution), dornase alfa, and aztreonam inhalation will not require a prior authorization and claims will pay at the point of sale if member has a reported diagnosis of CF within the past 12 months of claims history.
    c. If the member does not have a reported diagnosis, a manual prior authorization will be required for coverage consideration.
2. Use of inhaled tobramycin products and Cayston® (aztreonam) is restricted to 28 days of therapy per every 56 days to ensure cycles of 28 days on therapy followed by 28 days off therapy.
    a. Use outside of this recommended regimen may be considered for coverage via a manual prior authorization submission with a

patient-specific, clinically significant reason why the member would need treatment outside of the FDA approved dosing.
   b. Pharmacies should process the prescription claim with a 56-day supply.

Kalydeco® (Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) with a mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing that is responsive to ivacaftor based on clinical and/or *in vitro* assay data; and
   a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
   b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 1 month of age or older; and
3. Members using Kalydeco® must be supervised by a pulmonary disease specialist; and
4. Prescriber must verify the member has been counseled on proper administration of Kalydeco® including taking with a fat-containing food; and
5. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Kalydeco®, every 3 months during the first year of treatment, and annually thereafter; and
6. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
7. Member must not be taking any of the following medications concomitantly with Kalydeco®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
8. For members 1 month to younger than 6 months of age:
   a. Member must not have any level of hepatic impairment; and
   b. Member must not be taking concomitant moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
9. The following quantity limits will apply:
   a. Oral tablets: A quantity limit of 2 tablets per day or 56 tablets per 28 days; or
   b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
10. An age restriction of 1 month to 5 years of age will apply to Kalydeco® oral granule packets. Members 6 years of age or older will require a

patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and

11. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
12. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
13. Subsequent approvals will be for 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
3. Member must be 12 months of age or older; and
4. Members using Orkambi® must be supervised by a pulmonary specialist; and
5. Prescriber must verify the member has been counseled on proper administration of Orkambi® including taking with a fat-containing food; and
6. The prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and
7. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
8. Members must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply; or
    b. Oral granules: A quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and

10. An age restriction of 12 months to 5 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
11. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
12. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
13. Subsequent approvals will be for the duration of 1 year.

Symdeko® (Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 6 years of age or older; and
3. Members using Symdeko® must be supervised by a pulmonary specialist; and
4. If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and
5. Prescriber must verify that member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
6. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and
7. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and

8. Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
10. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
11. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®; and
12. Subsequent approvals will be for the duration of 1 year.

Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 *F508del* mutation in the CF transmembrane conductance regulator (*CFTR*) gene or a mutation in the *CFTR* gene that is responsive based on clinical and/or *in vitro* data; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 2 years of age or older; and
3. Members using Trikafta® must be supervised by a pulmonary specialist; and
4. If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi® or Symdeko® use, the prescriber must indicate that information on the prior authorization request; and
5. Prescriber must verify that member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and
6. Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Trikafta®,

every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and
7. Prescriber must verify that the member does not have severe hepatic impairment; and
8. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
9. Member must not be taking any of the following medications concomitantly with Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and
10. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
    b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
11. For Trikafta® oral granules, an age restriction of 2 years to 5 years of age will apply. Members 6 years of age or older will require a patient-specific, clinically significant reason why the Trikafta® tablets cannot be used; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
13. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor); and
14. Subsequent approvals will be for the duration of 1 year.

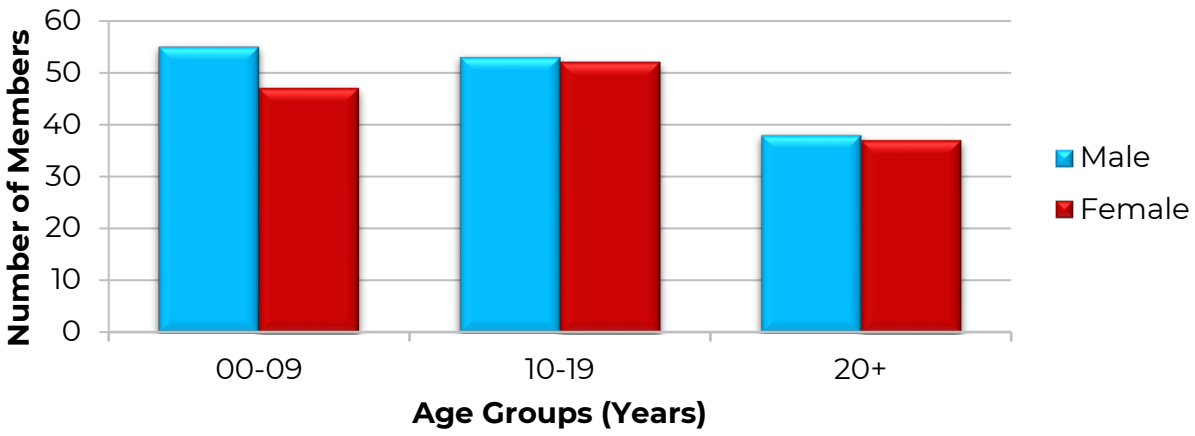
Utilization of CF Medications: Fiscal Year 2026

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

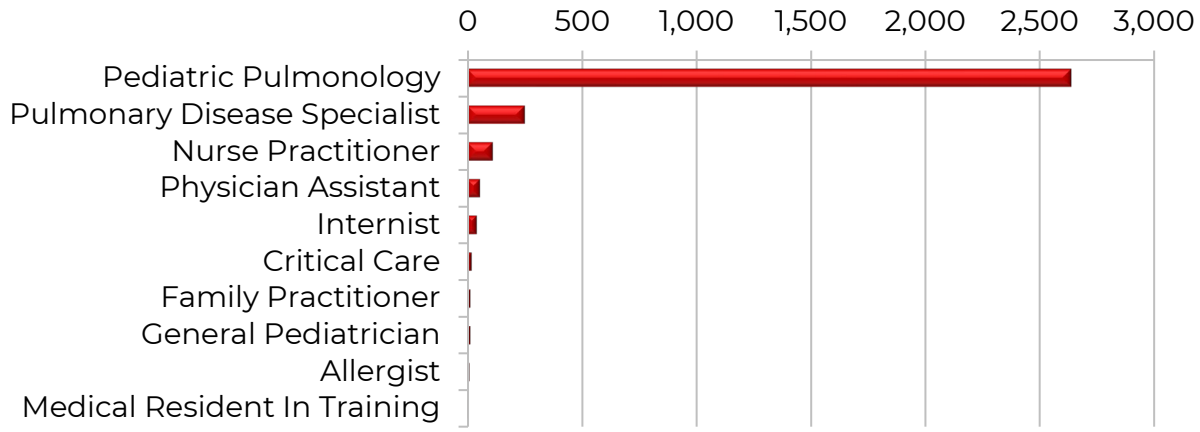
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	191	1,711	$24,420,274.81	$14,272.52	$429.01	185,895	56,922
Aetna	30	322	$5,297,729.08	$16,452.57	$559.19	28,052	9,474
Humana	51	699	$10,697,796.04	$15,304.43	$507.44	62,205	21,082
OCH	45	498	$7,581,916.35	$15,224.73	$507.25	47,605	14,947
2025 Total	**277**	**3,230**	**$47,997,716.28**	**$14,859.97**	**$468.61**	**323,757**	**102,425**
Fiscal Year 2026							
FFS	201	1,699	$25,090,566.41	$14,767.84	$446.90	179,067	56,143
Aetna	27	276	$4,970,546.94	$18,009.23	$610.11	22,041	8,147
Humana	53	712	$12,325,439.53	$17,311.01	$588.94	60,995	20,928
OCH	49	480	$8,156,200.84	$16,992.09	$563.04	43,775	14,486
2026 Total	**282**	**3,167**	**$50,542,753.72**	**$15,959.19**	**$506.93**	**305,878**	**99,704**
% Change	**1.80%**	**-2.00%**	**5.30%**	**7.40%**	**8.20%**	**-5.50%**	**-2.70%**
Change	**5**	**-63**	**$2,545,037.44**	**$1,099.22**	**$38.32**	**-17,879**	**-2,721**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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



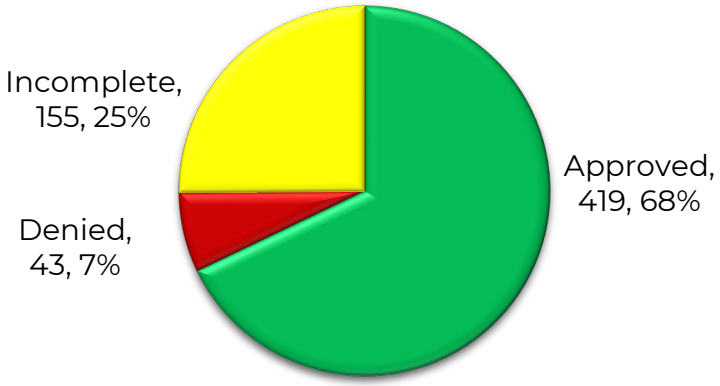
Top Prescriber Specialties of CF Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of CF Medications

There were 617 prior authorization requests submitted for CF medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	281	67%	124	30%	15	4%	**420**
Aetna	21	68%	4	13%	6	19%	**31**
Humana	57	81%	11	16%	2	3%	**70**
OCH	60	63%	16	17%	20	21%	**96**
Total	**419**	**68%**	**155**	**25%**	**43**	**7%**	**617**

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

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

Anticipated Patent Expiration(ss):

- Kalydeco® (ivacaftor tablets): February 2030
- Tobi® Podhaler® (tobramycin inhalation powder): November 2030
- Orkambi® (lumacaftor/ivacaftor tablets and granules): June 2031
- Kalydeco® (ivacaftor granules): August 2033
- Symdeko® (tezacaftor/ivacaftor and ivacaftor tablets): April 2035
- Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor granules): December 2037
- Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor tablets): July 2038
- Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor tablets): August 2040

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

- **September 2025:** The FDA updated the labeling for all CF transmembrane conductance regulator (CFTR) modulators, including Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor), Kalydeco® (ivacaftor), Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), and Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor), to include information on the risks of increased intracranial pressure disorders. The new labeling included updates to the *Warnings and Precautions* sections of the package labeling for each product and are based on reported cases of intracranial hypertension in the post marketing setting.
- **March 2026:** The FDA updated the labeling for all CFTR modulators, including Alyftrek®, Kalydeco®, Orkambi®, Symdeko®, and Trikafta®, to include information on the risks of neuropsychiatric events. The new labeling included updates to the *Warnings and Precautions* sections of the package labeling for each product and are based on reported cases of serious neuropsychiatric events, including symptoms of anxiety, depression, suicidal ideation and behavior, and sleep disturbances in the post marketing setting. The events were reported in adult and pediatric patients with and without a previous history of neuropsychiatric symptoms and symptoms may occur within the first 3 months of treatment initiation.
- **March 2026:** The FDA approved a label expansion for Alyftrek® and Trikafta® for the treatment of CF with a variant in the *CFTR* gene that is either responsive based on clinical and/or *in vitro* data or results in production of CFTR protein. The label expansions were supported by clinical and/or *in vitro* data from 564 variants demonstrating response to Alyftrek® and 521 variants demonstrating response to Trikafta®. As such, approximately 800 more people with a clinical diagnosis of CF in the United States are now eligible for a CFTR modulator for the first time.

Pipeline:

- **Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor):** Alyftrek® is being studied for the treatment of CF in patients 2 to 5 years of age. Currently, Alyftrek® is only FDA approved for patients 6 years of age or older. A Phase 3 open-label trial showed that Alyftrek® was generally safe and well tolerated in patients 2 to 5 years of age and treatment with Alyftrek® resulted in a rapid, clinically meaningful improvement in CFTR function with a mean reduction in sweat chloride (SwCl) from a baseline on Trikafta® of -9.6mmol/L through week 24, with 92% of children achieving SwCl concentrations of <60mmol/L (the diagnostic threshold for CF), and 65% of children reaching SwCl values of <30mmol/L. These improvements in CFTR function surpass those seen in trials with any other CFTR modulator in this age group. Vertex announced they plan to submit for regulatory approval of Alyftrek® in children 2 to 5 years of age in the first half of 2026.
  Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor): Trikafta® is being studied for the treatment of CF in patients 1 to <2 years of age. Currently, Trikafta® is only FDA approved for patients 2 years of age or older. A Phase 3 open-label trial showed that Trikafta® was generally safe and well tolerated in patients 1 to <2 years of age. Treatment with Trikafta® in this age group resulted in rapid, statistically significant, and clinically meaningful decreases in SwCl, with a mean reduction of -71.8mmol/L from a baseline without CFTR modulator treatment through week 24, with 98% of children achieving concentrations <60mmol/L and 68.6% reaching <30mmol/L. In June 2026, Vertex announced they have initiated regulatory submission of Trikafta® in children 1 to <2 years of age.

Recommendations

The College of Pharmacy recommends updating the Alyftrek® (vanzacaftor/ tezacaftor/deutivacaftor) and Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) approval criteria based on the new FDA approved label expansions and to be consistent with clinical practice (changes shown in red):

Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 variant ~~*F508del* mutation~~ in the CF transmembrane conductance regulator (*CFTR*) gene ~~or a mutation in the *CFTR* gene~~ that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein; and
   a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of at least 1 variant in the *CFTR* gene that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein ~~a *CFTR*~~

~~mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use~~; and

b. Documentation must be submitted with results of *CFTR* genetic testing; and

2. Member must be 6 years of age or older; and
3. Members using Alyftrek® must be supervised by a pulmonary specialist; and
4. ~~If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), or Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi®, Symdeko®, or Trikafta® use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Alyftrek® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Alyftrek®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Alyftrek®; and
8. ~~Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Alyftrek®, every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and~~
9. ~~Prescriber must verify that the member does not have severe hepatic impairment; and~~
10. ~~Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
11. ~~Member must not be taking strong or moderate CYP3A inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone) concomitantly with Alyftrek®; and~~
12. The following quantity limits will apply:
    a. Alyftrek® 4/20/50mg tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
    b. Alyftrek® 10/50/125mg tablets: A quantity limit of 2 tablets per day or 56 tablets per 28 days; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as

improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor), Symdeko® (tezacaftor/ivacaftor and ivacaftor), or Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor)~~; and

15. Subsequent approvals will be for the duration of 1 year.

Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who have at least 1 variant ~~*F508del* mutation~~ in the CF transmembrane conductance regulator (*CFTR*) gene ~~or a mutation in the *CFTR* gene~~ that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of at least 1 variant in the *CFTR* gene that is responsive based on clinical and/or *in vitro* data or results in production of CFTR protein ~~a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use~~; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 2 years of age or older; and
3. Members using Trikafta® must be supervised by a pulmonary specialist; and
4. ~~If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor) and experiencing adverse effects associated with Orkambi® or Symdeko® use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Trikafta®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Trikafta®; and
8. ~~Prescriber must verify that liver functions tests (ALT, AST, alkaline phosphate, and bilirubin) will be assessed prior to initiating Trikafta®, every month for the first 6 months, every 3 months for the next 12 months, and annually thereafter; and~~

~~9. Prescriber must verify that the member does not have severe hepatic impairment; and~~
~~10. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
~~11. Member must not be taking any of the following medications concomitantly with Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and~~
12. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 3 tablets per day or 84 tablets per 28 days; or
    b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
13. For Trikafta® oral granules, an age restriction of 2 years to 5 years of age will apply. Members 6 years of age or older will require a patient-specific, clinically significant reason why the Trikafta® tablets cannot be used; and
14. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
15. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events than with a previous CFTR therapy must be provided for members who switched from Orkambi® (lumacaftor/ivacaftor) or Symdeko® (tezacaftor/ivacaftor and ivacaftor)~~; and
16. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends updating the Kalydeco® (ivacaftor), Orkambi® (lumacaftor/ivacaftor), and Symdeko® (tezacaftor/ivacaftor) approval criteria to be consistent with the other CFTR modulators (changes shown in red):

Kalydeco® (Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) with a mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing that is responsive to ivacaftor based on clinical and/or *in vitro* assay data; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR*

mutation followed by verification with bi-directional sequencing when recommended by the mutation test's instructions for use; and

b. Documentation must be submitted with results of *CFTR* genetic testing; and

2. Member must be 1 month of age or older; and
3. Members using Kalydeco® must be supervised by a pulmonary disease specialist; and
4. Prescriber must verify the member has been counseled on proper administration of Kalydeco® including taking with a fat-containing food; and
5. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Kalydeco®; and
6. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Kalydeco®; and
7. ~~Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Kalydeco®, every 3 months during the first year of treatment, and annually thereafter; and~~
8. ~~Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
9. ~~Member must not be taking any of the following medications concomitantly with Kalydeco®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
10. For members 1 month to younger than 6 months of age:
    a. Member must not have any level of hepatic impairment; and
    b. Member must not be taking concomitant moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
11. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 2 tablets per day or 56 tablets per 28 days; or
    b. Oral granules: A quantity limit of 2 packets per day or 56 packets per 28 days; and
12. An age restriction of 1 month to 5 years of age will apply to Kalydeco® oral granule packets. Members 6 years of age or older will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and

14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
15. Subsequent approvals will be for 1 year.

Orkambi® (Lumacaftor/Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator (*CFTR*) gene detected by genetic testing; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
3. Member must be 12 months of age or older; and
4. Members using Orkambi® must be supervised by a pulmonary specialist; and
5. Prescriber must verify the member has been counseled on proper administration of Orkambi® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Orkambi®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Orkambi®; and
8. ~~The prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Orkambi®, every 3 months during the first year of treatment, and annually thereafter; and~~
9. ~~Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
10. ~~Members must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
11. The following quantity limits will apply:
    a. Oral tablets: A quantity limit of 4 tablets per day or 112 tablets per 28 days will apply; or
    b. Oral granules: A quantity limit of 2 granule packets per day or 56 packets per 28 days will apply; and
12. An age restriction of 12 months to 5 years of age will apply to Orkambi® oral granule packets. Members 6 years of age or older will require a

patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and

13. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
14. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval; and
15. Subsequent approvals will be for the duration of 1 year.

Symdeko® (Tezacaftor/Ivacaftor and Ivacaftor) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members who are homozygous for the *F508del* mutation or who have at least 1 mutation in the CF transmembrane conductance regulator *(CFTR)* gene detected by genetic testing that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence; and
    a. If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a *CFTR* mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use; and
    b. Documentation must be submitted with results of *CFTR* genetic testing; and
2. Member must be 6 years of age or older; and
3. Members using Symdeko® must be supervised by a pulmonary specialist; and
~~4. If member is currently stabilized on Orkambi® (lumacaftor/ivacaftor) and experiencing adverse effects associated with Orkambi® use, the prescriber must indicate that information on the prior authorization request; and~~
5. Prescriber must verify that member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Symdeko®; and
7. Prescriber must evaluate the potential for drug interactions according to package labeling, prior to and during treatment with Symdeko®; and
~~8. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Symdeko®, every 3 months during the first year of treatment, and annually thereafter; and~~

9. ~~Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and~~
10. ~~Member must not be taking any of the following medications concomitantly with Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and~~
11. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; and
12. Approvals will be based on the recommended dosing per package labeling based on the member's age and recent weight, if applicable. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
13. Initial approval will be for the duration of 6 months. After 6 months of utilization, compliance and information regarding efficacy, such as improvement in forced expiratory volume in 1 second (FEV_1), will be required for continued approval. ~~Additionally, after 6 months of utilization, information regarding efficacy as previously mentioned or fewer adverse events must be provided for members who switched from Orkambi® to Symdeko®~~; and
14. Subsequent approvals will be for the duration of 1 year.

Utilization Details of CF Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ELEXACAFTOR/TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS						
TRIKAFTA TAB 100-50-75/150MG	843	108	$23,687,428.97	$28,098.97	7.81	46.87%
TRIKAFTA GRA 100-50-75/75MG	245	27	$6,956,254.69	$28,392.88	9.07	13.76%
TRIKAFTA TAB 50-25-37.5/75MG	194	24	$5,512,632.22	$28,415.63	8.08	10.91%
TRIKAFTA GRA 80-40-60/59.5MG	48	10	$1,360,233.80	$28,338.20	4.8	2.69%
SUBTOTAL	**1,330**	**169**	**$37,516,549.68**	**$28,207.93**	**7.87**	**74.23%**
DORNASE ALFA PRODUCTS						
PULMOZYME SOL 1MG/ML	1,238	173	$5,355,456.22	$4,325.89	7.16	10.60%
SUBTOTAL	**1,238**	**173**	**$5,355,456.22**	**$4,325.89**	**7.16**	**10.60%**
TOBRAMYCIN NEBULIZED PRODUCTS						
TOBRAMYCIN NEB 300MG/5ML	284	104	$101,880.89	$358.74	2.73	0.20%
KITABIS PAK NEB 300MG/5ML	4	1	$18,045.64	$4,511.41	4	0.04%
SUBTOTAL	**288**	**105**	**$119,926.53**	**$416.41**	**2.74**	**0.24%**
VANZACAFTOR/TEZACAFTOR/DEUTIVACAFTOR COMBINATION PRODUCTS						
ALYFTREK TAB 10-50-125MG	129	28	$3,435,539.32	$26,632.09	4.61	6.80%
ALYFTREK TAB 4-20-50MG	34	6	$966,131.42	$28,415.63	5.67	1.91%
SUBTOTAL	**163**	**34**	**$4,401,670.74**	**$27,004.11**	**4.79**	**8.71%**
LUMACAFTOR/IVACAFTOR COMBINATION PRODUCTS						
ORKAMBI GRA 100-125MG	71	11	$1,650,777.69	$23,250.39	6.45	3.27%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORKAMBI GRA 75-94MG	6	2	$139,502.34	$23,250.39	3	0.28%
SUBTOTAL	**77**	**13**	**$1,790,280.03**	**$23,250.39**	**5.92**	**3.54%**
AZTREONAM PRODUCTS						
CAYSTON INH 75MG	31	13	$403,431.37	$13,013.92	2.38	0.80%
SUBTOTAL	**31**	**13**	**$403,431.37**	**$13,013.92**	**2.38**	**0.80%**
TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS						
SYMDEKO TAB 100-150/150MG	18	2	$448,116.66	$24,895.37	9	0.89%
SUBTOTAL	**18**	**2**	**$448,116.66**	**$24,895.37**	**9**	**0.89%**
IVACAFTOR PRODUCTS						
KALYDECO GRA 50MG	8	3	$227,325.04	$28,415.63	2.67	0.45%
KALYDECO GRA 13.4MG	3	2	$85,246.89	$28,415.63	1.5	0.17%
KALYDECO GRA 25MG	3	2	$85,246.89	$28,415.63	1.5	0.17%
KALYDECO GRA 5.8MG	1	1	$28,415.63	$28,415.63	1	0.06%
SUBTOTAL	**15**	**8**	**$426,234.45**	**$28,415.63**	**1.88**	**0.84%**
TOBRAMYCIN POWDER PRODUCTS						
TOBI PODHALER CAP 28MG	7	1	$81,088.04	$11,584.01	7	0.16%
SUBTOTAL	**7**	**1**	**$81,088.04**	**$11,584.01**	**7**	**0.16%**
TOTAL	**3,167**	**282***	**$50,542,753.72**	**$15,959.19**	**11.23**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; GRA = granule; INH = inhalation; NEB = nebulized; SOL = solution; TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

[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 08/2026. Last accessed 08/10/2026.
[2] U.S. FDA. Trikafta® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/212273Orig1s015,217660Orig1s009ltr.pdf . Issued 09/25/2025. Last accessed 08/10/2026.
[3] U.S. FDA. Trikafta® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2026/212273Orig1s017;217660Orig1s010ltr.pdf . Issued 03/17/2026. Last accessed 08/10/2026.
[4] Vertex Pharmaceuticals. Vertex Announces US FDA Approval for Label Extensions of Alyftrek® and Trikafta®, Expanding Availability of These Medicines to ~95% of All People with CF in the United States. Available online at: https://news.vrtx.com/news-releases/news-release-details/vertex-announces-us-fda-approval-label-extensions-alyftrekr-and. Issued 04/01/2026. Last accessed 08/10/2026.
[5] Vertex Pharmaceuticals. Vertex Presents New Data on Alyftrek® at European Cystic Fibrosis Conference. Available online at: https://news.vrtx.com/news-releases/news-release-details/vertex-presents-new-data-alyftrekr-european-cystic-fibrosis. Issued 06/05/2026. Last accessed 08/10/2026.

Appendix P

Fiscal Year 2026 Annual Review of Amyloidosis Medications

Oklahoma Health Care Authority
September 2026

Current Prior Authorization Criteria

Amvuttra® (Vutrisiran) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. The treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis; or
    b. The treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular (CV) mortality, CV hospitalizations, and urgent heart failure visits; and
2. For the diagnosis of hATTR-PN:
    a. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
    b. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; or
3. For the diagnosis of ATTR-CM:
    a. Diagnosis confirmed by:
        i. Genetic confirmation of transthyretin (*TTR*) gene mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
        ii. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
    b. Presence of amyloid deposits confirmed by:
        i. Nuclear scintigraphy; or
        ii. Endomyocardial biopsy; and
    c. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
    d. Member must have medical history of heart failure (NYHA Class I to III); and
4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and

6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Amvuttra® will not be approved for concomitant use with Attruby® (acoramidis), Onpattro® (patisiran), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
9. Authorization for Amvuttra® for the diagnosis of hATTR-PN will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and
10. A quantity limit of 0.5mL per 90 days will apply; and
11. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Attruby® (Acoramidis) Approval Criteria:

1. An FDA approved indication for the treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
    a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
    b. Cardiac imaging (including ultrasound or MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
    a. Nuclear scintigraphy; or
    b. Endomyocardial biopsy; and
4. Member must be 18 years of age or older; and
5. Member must have medical history of heart failure (NYHA Class I to III); and
6. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
7. Attruby™ must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Attruby™ will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
9. 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 approval will be for 1 year; and
10. A quantity limit of 112 tablets per 28 days will apply.

Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
9. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
10. 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
11. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Vyndamax® (Tafamidis) Approval Criteria:

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
    a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
    b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:

   a. Nuclear scintigraphy; or
   b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and
5. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
6. Prescriber must confirm the member has not undergone a liver transplant; and
7. Vyndamax® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Vyndamax® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Onpattro® (patisiran), or Wainua® (eplontersen); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
10. A quantity limit of 1 Vyndamax® capsule per day will apply.

Wainua® (Eplontersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Wainua®; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Wainua® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Onpattro® (patisiran), or Vyndamax® (tafamidis); 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 and member has not undergone a liver transplant; and

10. A quantity limit of 0.8mL per 28 days will apply.

Utilization of Amyloidosis Medications: Fiscal Year 2026

Fiscal Year 2026 Utilization: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	2	2	$238,724.82	$119,362.41	$1,326.25	1	180
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
2025 Total	**2**	**2**	**$238,724.82**	**$119,362.41**	**$1,326.25**	**1**	**180**
Fiscal Year 2026							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	1	5	$214,211.20	$42,842.24	$1,530.08	4	140
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2026 Total	**1**	**5**	**$214,211.20**	**$42,842.24**	**$1,530.08**	**4**	**140**
% Change	**-50.00%**	**150.00%**	**-10.30%**	**-64.10%**	**15.40%**	**300.00%**	**-22.20%**
Change	**-1**	**3**	**-$24,513.62**	**-$76,520.17**	**$203.83**	**3**	**-40**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Fiscal Year 2026 Utilization: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	1	3	$362,327.75	$120,775.92	3
Aetna	1	2	$2,980.50	$1,409.25	2
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2025 Total	**2**	**5**	**$365,308.25**	**$73,061.65**	**2.5**
Fiscal Year 2026					
FFS	1	3	$375,317.25	$125,105.75	3
Aetna	1	3	$374,237.75	$124,745.92	3
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2026 Total	**2**	**6**	**$749,555.00**	**$124,925.83**	**3**
% Change	**0.00%**	**20.00%**	**105.18%**	**70.99%**	**20.00%**
Change	**0**	**1**	**$384,246.75**	**$51,864.18**	**0.5**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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

- Due to the limited number of members utilizing amyloidosis medications during fiscal year 2026, detailed demographic information could not be provided.

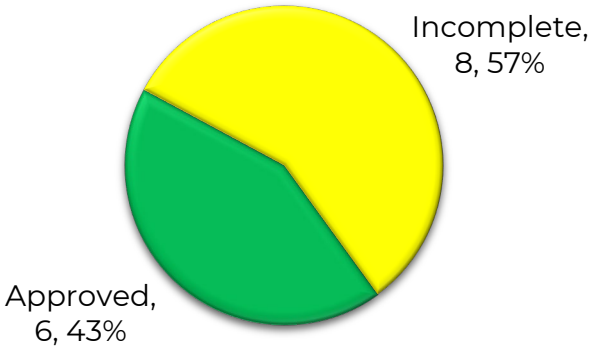
Top Prescriber Specialties of Amyloidosis Medications by Number of Claims: Pharmacy Claims (All Plans)

- The only prescriber specialty listed on paid pharmacy claims for amyloidosis medications during fiscal year 2026 was cardiologist.

Prior Authorization of Amyloidosis Medications

There were 14 prior authorization requests submitted for the amyloidosis medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	4	33%	8	67%	0	0%	**12**
Aetna	1	100%	0	0%	0	0%	**1**
Humana	1	100%	0	0%	0	0%	**1**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**6**	**43%**	**8**	**57%**	**0**	**0%**	**14**

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):

- Tegsedi® (inotersen): April 2031
- Wainua® (eplontersen): August 2034

- Onpattro® (patisiran): August 2035
- Vyndamax® (tafamidis): August 2035
- Amvuttra® (vutrisiran): July 2036
- Attruby® (acoramidis): August 2039

News:

- **April 2026:** The FDA approved a single-dose prefilled syringe formulation of Wainua® (eplontersen) intended for administration by a health care provider.

Pipeline:

- **Anselamimab:** Anselamimab is an investigational monoclonal antibody that demonstrated statistically significant benefits in a subgroup analysis of adults with advanced kappa light chain (AL) amyloidosis when added to standard of care plasma dyscrasia (PCD) treatments when compared to placebo. The primary endpoint was combined time to all-cause mortality and frequency of cardiovascular hospitalizations (CVH). In the kappa light chain AL subgroup, survival was improved by 62% [hazard ratio: 0.38; 95% confidence interval (CI): 0.17, 0.86; nominal P=0.012] and CVH were reduced by 71% (incidence risk ratio: 0.29; 95% CI: 0.10, 0.87; nominal P=0.028). In contrast, anselamimab did not meet the primary endpoint in the overall AL amyloidosis population, which also included adults with the lambda AL isotype.
- **Cliramitug (ALXN2220):** Cliramitug is an investigational monoclonal antibody currently being studied in the ongoing Phase 3 DepleTTR-CM trial for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM). The mechanism of action is intended to deplete cardiac amyloid deposits with the potential to restore cardiac function. The primary completion date of the trial is currently estimated to be in late 2027.

Recommendations

The College of Pharmacy recommends updating the Amvuttra® (vutrisiran) approval criteria based on net costs and for consistency with the approval criteria for the other amyloidosis medications (changes shown in red):

Amvuttra® (Vutrisiran) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. The treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis; or
   b. The treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular (CV) mortality, CV hospitalizations, and urgent heart failure visits; and
2. For the diagnosis of hATTR-PN:

a. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
b. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; or

3. For the diagnosis of ATTR-CM:
   a. Diagnosis confirmed by:
      i. Genetic confirmation of transthyretin (*TTR*) gene mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
      ii. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
   b. Presence of amyloid deposits confirmed by:
      i. Nuclear scintigraphy; or
      ii. Endomyocardial biopsy; and
   c. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
   d. Member must have medical history of heart failure (NYHA Class I to III); and
4. Member must be 18 years of age or older; and
5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
8. Prescriber must confirm the member has not undergone a liver transplant; and
9. Amvuttra® will not be approved for concomitant use with Attruby® (acoramidis), Onpattro® (patisiran), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
10. ~~Authorization for Amvuttra® for the diagnosis of hATTR-PN will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and~~
11. A quantity limit of 0.5mL per 90 days will apply; and
12. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

The College of Pharmacy also recommends updating the Attruby® (acoramidis), Onpattro® (patisiran) and Vyndamax® (tafamidis) approval criteria for consistency with the approval criteria for the other amyloidosis medications (changes shown in red):

Attruby® (Acoramidis) Approval Criteria:

1. An FDA approved indication for the treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) ~~in adults~~ to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
    a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
    b. Cardiac imaging (including ultrasound or MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
    a. Nuclear scintigraphy; or
    b. Endomyocardial biopsy; and
4. Member must be 18 years of age or older; and
5. Member must have medical history of heart failure (NYHA Class I to III); and
6. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
7. Attruby™ must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Attruby™ will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
9. 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 approval will be for 1 year; and
10. A quantity limit of 112 tablets per 28 days will apply.

Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Member must be 18 years of age or older; and

5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
8. Prescriber must confirm the member has not undergone a liver transplant; and
9. Prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
10. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Vyndamax® (tafamidis), or Wainua® (eplontersen); and
11. 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
12. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Vyndamax® (Tafamidis) Approval Criteria:

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) ~~in adults~~ to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
    a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
    b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
    a. Nuclear scintigraphy; or
    b. Endomyocardial biopsy; and
4. Member must be 18 years of age or older; and
5. Member must have medical history of heart failure (NYHA Class I to III); and
6. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
7. Prescriber must confirm the member has not undergone a liver transplant; and

8. Vyndamax® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
9. Vyndamax® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Onpattro® (patisiran), or Wainua® (eplontersen); and
10. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
11. A quantity limit of 1 Vyndamax® capsule per day will apply.

Lastly, the College of Pharmacy recommends updating the Wainua® (eplontersen) criteria based on the approval of the single-dose prefilled syringe and for consistency with the approval criteria for the other amyloidosis medications (changes shown in red).

Wainua® (Eplontersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Member must be 18 years of age or older; and
4. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
5. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
6. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
7. For authorization of the single-dose autoinjector, the prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Wainua®; and
8. For authorization of the single-dose prefilled syringe, the prescriber must verify the injection will be administered by a health care professional; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Wainua® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby® (acoramidis), Onpattro® (patisiran), or Vyndamax® (tafamidis); and

11. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
12. A quantity limit of 0.8mL per 28 days will apply.

Utilization Details of Amyloidosis Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
WAINUA INJ 45MG/0.8ML	5	1	$214,211.20	$42,842.24	5	100%
TOTAL	**5**	**1***	**$214,211.20**	**$42,842.24**	**5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VUTRISIRAN INJ (J0225)	6	2	$749,555.00	$124,925.83	3
TOTAL	**6†**	**2***	**$749,555.00**	**$124,925.83**	**3**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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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 08/2025. Last accessed 08/25/2026.
[2] Wainua® (Eplontersen) Prescribing Information. AstraZeneca Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/217388s005lbl.pdf. Last updated 04/16/2026. Last accessed 08/25/2026.
[3] AstraZeneca. CARES Phase III Clinical Programme Did Not Meet Primary Endpoint in Overall Light Chain Amyloidosis Population, However, Demonstrated Anselamimab as Potential First Anti-Fibril Therapy in Kappa Light Chain Amyloidosis. Available online at: https://www.astrazeneca.com/media-centre/press-releases/2026/cares-phase-iii-clinical-programme-did-not-meet-primary-endpoint-in-overall-light-chain-amyloidosis-population.html. Issued 05/29/2026. Last accessed 08/25/2026.
[4] Neurimmune. Pipeline: Cliramitug (ATTR Cardiomyopathy). Available online at: https://neurimmune.com/pipeline/cliramitug. Last accessed 08/25/2026.
[5] Study of ALXN2220 Versus Placebo in Adults With ATTR-CM (DepleTTR-CM). *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT06183931. Last revised 08/10/2026. Last accessed 08/25/2026.

Appendix Q

Fiscal Year 2026 Annual Review of Bladder Control Medications

Oklahoma Health Care Authority
September 2026

Current Prior Authorization Criteria

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
fesoterodine (Toviaz®)	tolterodine (Detrol®)	darifenacin (Enablex®)	oxybutynin 2.5mg tablets+
mirabegron (Myrbetriq®) tablets – **Brand Preferred**	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®) granulesß	oxybutynin patch (Oxytrol®)+
oxybutynin tablets and syrup (Ditropan®)		trospium ER (Sanctura XR®)	vibegron (Gemtesa®)+
oxybutynin ER (Ditropan XL®)			
solifenacin (VESIcare®)			
trospium (Sanctura®)			

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 specific to Gemtesa® (vibegron), oxybutynin 2.5mg tablets, and Oxytrol® (oxybutynin patch) applies.
ßThe Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.
ER = extended-release; PA = prior authorization; susp = suspension

Bladder Control Medications Tier-2 Approval Criteria:

1. A trial of all Tier-1 medications that yielded an inadequate clinical response or adverse effects; or
2. A unique indication which the Tier-1 medications lack.

Bladder Control Medications Tier-3 Approval Criteria:

1. A trial of all Tier-2 medications that yielded inadequate clinical response or adverse effects; or
2. A unique indication which the Tier-2 medications lack.

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; 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.

Oxybutynin 2.5mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including splitting an oxybutynin 5mg tablet to achieve a 2.5mg dose, must be provided.

Oxytrol® (Oxybutynin 3.9mg/Day Patch) Approval Criteria:

1. An FDA approved diagnosis of overactive bladder; and
2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
3. A quantity limit of 8 patches per 30 days will apply.

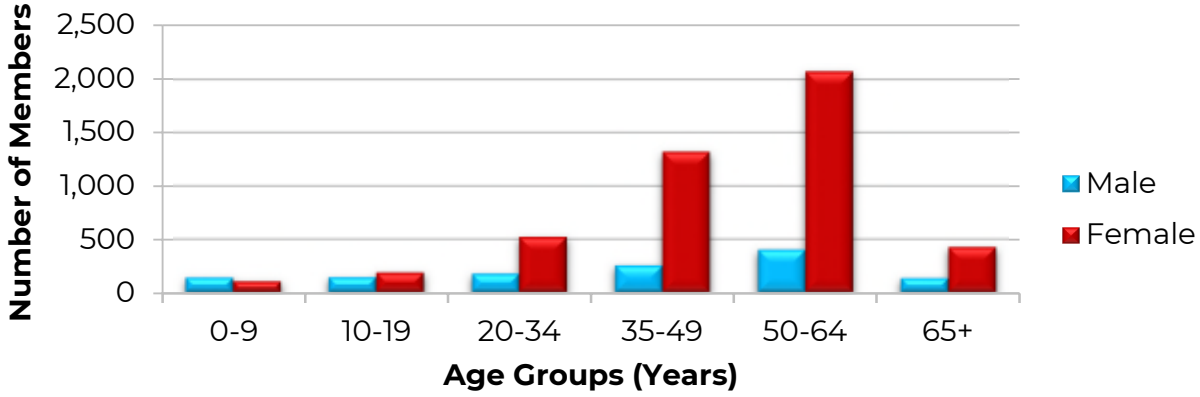
Utilization of Bladder Control Medications: Fiscal Year 2026

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

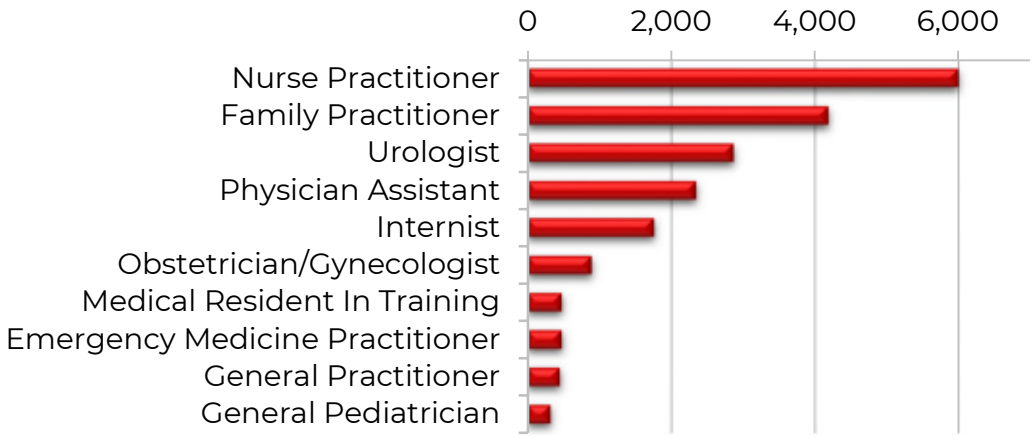
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	2,772	10,258	$674,540.76	$65.76	$1.60	667,777	422,169
Aetna	877	2,232	$152,757.49	$68.44	$1.46	139,355	104,533
Humana	1,140	3,383	$255,757.00	$75.60	$1.62	213,887	158,209
OCH	969	2,273	$165,671.40	$72.89	$1.35	165,612	123,076
2025 Total	**5,412**	**18,146**	**$1,248,726.65**	**$68.82**	**$1.55**	**1,186,631**	**807,987**
Fiscal Year 2026							
FFS	3,047	11,638	$1,089,191.72	$93.59	$2.35	707,928	463,945
Aetna	976	2,630	$283,691.04	$107.87	$2.35	166,884	120,758
Humana	1,255	3,774	$424,831.11	$112.57	$2.43	226,320	174,913
OCH	996	2,559	$286,040.73	$111.78	$2.23	166,352	128,325
2026 Total	**5,838**	**20,601**	**$2,083,754.60**	**$101.15**	**$2.35**	**1,267,485**	**887,941**
% Change	**7.90%**	**13.50%**	**66.90%**	**47.00%**	**51.60%**	**6.80%**	**9.90%**
Change	**426**	**2,455**	**$835,027.95**	**$32.33**	**$0.80**	**80,854**	**79,954**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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



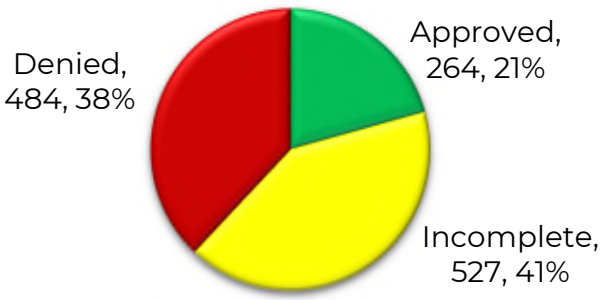
Top Prescriber Specialties of Bladder Control Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Bladder Control Medications

There were 1,275 prior authorization requests submitted for bladder control medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	108	8%	416	33%	128	10%	**652**
Aetna	40	3%	36	3%	115	9%	**191**
Humana	21	2%	23	2%	124	10%	**168**
OCH	95	7%	52	4%	117	9%	**264**
Total	**264**	**21%**	**527**	**41%**	**484**	**38%**	**1,275**

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

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Toviaz® (fesoterodine tablet): December 2027
- Myrbetriq® (mirabegron tablet): March 2030
- Nocdurna® (desmopressin acetate sublingual tablet): April 2030
- Gemtesa® (vibegron tablet): December 2030
- Gelnique® (oxybutynin gel): March 2031
- Vesicare LS® (solifenacin oral suspension): May 2031
- Myrbetriq® (mirabegron granule): September 2036

Pipeline

- **Iltamiocel:** Iltamiocel is an investigational transurethral injection of autologous muscle-derived cell therapy for urinary sphincter repair (AMDC-USR) currently being studied in women with post-surgical persistent or recurrent stress urinary incontinence. The ongoing Phase 3, randomized, double-blind, placebo-controlled trial, CELLEBRATE, has an estimated primary completion date of September 2026.

Recommendations

The College of Pharmacy recommends the following changes to the Bladder Control Medications Product Based Prior Authorization (PBPA) category based on net costs (changes shown in red):

1. Moving oxybutynin patch (Oxytrol®) from the Special PA Tier to Tier-1 and removing the unique criteria; and
2. Moving tolterodine ER (Detrol LA®) from Tier-2 to Tier-1; and
3. Moving fesoterodine (Toviaz®) from Tier-1 to Tier-2; and
4. Moving darifenacin (Enablex®) from Tier-3 to Tier-2; and
5. Moving tolterodine (Detrol®) to the Special PA Tier; and
6. Updating the approval criteria for Gemtesa® (vibegron) based on net costs and clinical practice.

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
~~**fesoterodine (Toviaz®)**~~	tolterodine (Detrol®)	~~**darifenacin (Enablex®)**~~	oxybutynin 2.5mg tablets+
mirabegron (Myrbetriq®) tablets – **Brand Preferred**	~~**tolterodine ER (Detrol LA®)**~~	mirabegron (Myrbetriq®) granulesß	~~**oxybutynin patch (Oxytrol®)+**~~
oxybutynin (Ditropan®) tablets and syrup	**fesoterodine (Toviaz®)**	trospium ER (Sanctura XR®)	vibegron (Gemtesa®)+
oxybutynin ER (Ditropan XL®)	**darifenacin (Enablex®)**		
oxybutynin patch (Oxytrol®)			
solifenacin (VESIcare®)			
tolterodine ER (Detrol LA®)			
trospium (Sanctura®)			

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 specific to Gemtesa® (vibegron)~~,~~ and oxybutynin 2.5mg tablets~~, and Oxytrol® (oxybutynin patch)~~ applies.
ßThe Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.
ER = extended-release; PA = prior authorization; susp = suspension

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; 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
    a. For members with a contraindication to anticholinergics, documentation of the contraindication and a patient-specific, clinically significant reason why the member cannot use Myrbetriq® (mirabegron) must be provided; and
    b. For members unable to take Myrbetriq® (mirabegron) due to hypertension, the prescriber must attest that the member has severe, uncontrolled hypertension as defined in the Myrbetriq® package labeling (i.e., systolic blood pressure ≥180mmHg and/or

diastolic blood pressure ≥110mmHg) and documentation of member's blood pressure readings must be provided; and

4. A quantity limit of 30 tablets per 30 days will apply.

~~**Oxytrol® (Oxybutynin 3.9mg/Day Patch) Approval Criteria:**~~

~~1. An FDA approved diagnosis of overactive bladder; and~~

~~2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and~~

~~3. A quantity limit of 8 patches per 30 days will apply.~~

Utilization Details of Bladder Control Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
OXYBUTYNIN PRODUCTS						
OXYBUTYNIN TAB 5MG	4,236	1,528	$65,960.98	$15.57	2.77	3.17%
OXYBUTYNIN TAB 10MG ER	2,800	1,060	$45,465.04	$16.24	2.64	2.18%
OXYBUTYNIN TAB 5MG ER	2,111	870	$32,964.40	$15.62	2.43	1.58%
OXYBUTYNIN TAB 15MG ER	1,253	368	$21,487.74	$17.15	3.4	1.03%
OXYBUTYNIN SOL 5MG/5ML	673	204	$11,661.79	$17.33	3.3	0.56%
SUBTOTAL	**11,073**	**4,030**	**$177,539.95**	**$16.03**	**2.75**	**8.52%**
MIRABEGRON PRODUCTS						
MYRBETRIQ TAB 50MG	1,802	421	$755,419.05	$419.21	4.28	36.25%
MYRBETRIQ TAB 25MG	1,631	484	$679,173.72	$416.42	3.37	32.59%
MIRABEGRON TAB 50MG ER	115	45	$31,358.48	$272.68	2.56	1.5%
MIRABEGRON TAB 25MG ER	73	39	$20,268.10	$277.65	1.87	0.97%
SUBTOTAL	**3,621**	**989**	**$1,486,219.35**	**$410.44**	**3.66**	**71.32%**
SOLIFENACIN PRODUCTS						
SOLIFENACIN TAB 5MG	1,847	681	$34,886.75	$18.89	2.71	1.67%
SOLIFENACIN TAB 10MG	1,550	549	$30,583.68	$19.73	2.82	1.47%
VESICARE LS SUS 5MG/5ML	5	2	$2,021.64	$404.33	2.5	0.1%
VESICARE TAB 10MG	1	1	$376.21	$376.21	1	0.02%
SUBTOTAL	**3,403**	**1,233**	**$67,868.28**	**$19.94**	**2.76**	**3.26%**
TROSPIUM PRODUCTS						
TROSPIUM CL TAB 20MG	956	233	$24,782.81	$25.92	4.1	1.19%
SUBTOTAL	**956**	**233**	**$24,782.81**	**$25.92**	**4.1**	**1.19%**
FESOTERODINE PRODUCTS						
FESOTERODINE TAB 8MG ER	263	78	$15,204.30	$57.81	3.37	0.73%
FESOTERODINE TAB 4MG ER	208	75	$10,294.01	$49.49	2.77	0.49%
TOVIAZ TAB 4MG	1	1	$846.92	$846.92	1	0.04%
SUBTOTAL	**472**	**154**	**$26,345.23**	**$55.82**	**3.06**	**1.26%**
TIER-1 SUBTOTAL	**19,525**	**6,639**	**$1,782,755.62**	**$91.31**	**2.94**	**85.55%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 UTILIZATION						
TOLTERODINE PRODUCTS						
TOLTERODINE CAP 4MG ER	160	47	$2,998.05	$18.74	3.4	0.14%
TOLTERODINE TAB 2MG	124	24	$2,660.49	$21.46	5.17	0.13%
TOLTERODINE CAP 2MG ER	63	24	$1,219.83	$19.36	2.63	0.06%
TOLTERODINE TAB 1MG	38	8	$878.22	$23.11	4.75	0.04%
TIER-2 SUBTOTAL	**385**	**103**	**$7,756.59**	**$20.15**	**3.74**	**0.37%**
TIER-3 UTILIZATION						
TROSPIUM PRODUCTS						
TROSPIUM CL CAP 60MG ER	63	15	$5,750.58	$91.28	4.2	0.28%
SUBTOTAL	**63**	**15**	**$5,750.58**	**$91.28**	**4.2**	**0.28%**
DARIFENACIN PRODUCTS						
DARIFENACIN TAB 15MG ER	13	2	$289.32	$22.26	6.5	0.01%
DARIFENACIN TAB 7.5MG ER	1	1	$27.24	$27.24	1	0%
SUBTOTAL	**14**	**3**	**$316.56**	**$22.61**	**4.67**	**0.02%**
MIRABEGRON PRODUCTS						
MYRBETRIQ SUS 8MG/ML	12	1	$690.27	$57.52	12	0.03%
SUBTOTAL	**12**	**1**	**$690.27**	**$57.52**	**12**	**0.03%**
TIER-3 SUBTOTAL	**89**	**19**	**$6,757.41**	**$75.93**	**4.68**	**0.32%**
SPECIAL PA UTILIZATION						
VIBEGRON PRODUCTS						
GEMTESA TAB 75MG	590	141	$284,552.52	$482.29	4.18	13.66%
SUBTOTAL	**590**	**141**	**$284,552.52**	**$482.29**	**4.18**	**13.66%**
OXYBUTYNIN PRODUCTS						
OXYBUTYNIN TAB 2.5MG	11	9	$1,270.26	$115.48	1.22	0.06%
OXYTROL PATCH 3.9MG/24HR	1	1	$662.20	$662.20	1	0.03%
SUBTOTAL	**12**	**10**	**$1,932.46**	**$161.04**	**1.2**	**0.09%**
SPECIAL PA SUBTOTAL	**602**	**151**	**$286,484.98**	**$475.89**	**3.99**	**13.75%**
TOTAL	**20,601**	**5,838***	**$2,083,754.60**	**$101.15**	**3.53**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CL = chloride; ER = extended-release; HR = hour; PA = prior authorization; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

[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 08/2026. Last accessed 08/03/2026.

[2] Kaufman M, Canestrari E, Nisha P, et al. CELLEBRATE: A Double-Blind, Randomized, Controlled Study Assessing the Efficacy and Safety of the Iltamiocel Cell Therapy in the Treatment of Women with Persistent or Recurrent Stress Urinary Incontinence Following Surgical Treatment. *The Journal of Urology* 2025; 213:5S2. doi: 10.1097/01.JU.0001110436.86964.27.

Appendix R

Fiscal Year 2026 Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Beizray™ (Docetaxel), Beizray™ Kit (Docetaxel/ Albumin), Docivyx™ (Docetaxel), Inluriyo™ (Imlunestrant), and Veppanu™ (Vepdegestrant)

Oklahoma Health Care Authority
September 2026

Current Prior Authorization Criteria

Utilization data for Keytruda® (pembrolizumab) and Keytruda Qlex™ (pembrolizumab/berahyaluronidase alfa-pmph) and approval criteria for indications other than breast cancer can be found in the December 2025 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Afinitor® (everolimus) and Lynparza® (olaparib) and approval criteria for indications other than breast cancer can be found in the June 2026 DUR Board packet. These medications and criteria are reviewed annually with the genitourinary and gynecologic cancer medications.

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

1. Diagnosis of advanced breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Hormone receptor (HR)-positive; and
4. Used in combination with exemestane, fulvestrant, or tamoxifen; and
5. Member must have failed treatment with, have a contraindication to, or be intolerant to letrozole or anastrozole.

Datroway® (Datopotamab Deruxtecan-dlnk) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of unresectable or metastatic breast cancer; and
2. Disease is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative; and
3. Member has received prior endocrine-based therapy and chemotherapy; and
4. Used as a single agent.

Datroway® (Datopotamab Deruxtecan-dlnk) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic NSCLC; and
2. Disease is epidermal growth factor receptor (EGFR)-mutated; and

3. Member has received prior EGFR-directed therapy and platinum-based chemotherapy; and
4. Used as a single agent.

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

1. Adult members with unresectable or metastatic disease; and
    a. For human epidermal growth factor receptor 2 (HER2)-positive disease, must meet the following:
        i. Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and
        ii. Member has received ≥1 prior anti-HER2-based regimens; or
    b. For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet 1 of the following:
        i. Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; or
        ii. Disease is hormone receptor (HR)-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy; or
    c. For HER-2 ultralow (IHC 0 with membrane staining) disease, must meet the following:
        i. Disease is HR-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy.

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

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

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.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic gastric or GEJ adenocarcinoma; and
2. Human epidermal growth factor receptor 2 (HER2)-positive disease; and
3. Member has received at least 1 prior trastuzumab-based regimen.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of unresectable or metastatic NSCLC; and
2. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
3. Member must have received a prior systemic therapy.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of an unresectable or metastatic human epidermal receptor type 2 (HER2)-positive immunohistochemistry (IHC) 3+ solid tumor; and
2. Has received prior systemic treatment with no satisfactory alternative treatment options.

Halaven® (Eribulin) Approval Criteria [Recurrent or Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Used in 1 of the following settings:
    a. Previously received ≥2 chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting; or
    b. In combination with margetuximab-cmkb or trastuzumab for human epidermal growth factor receptor 2 (HER2)-positive disease that is:
        i. Hormone receptor (HR)-negative; or
        ii. HR-positive with or without endocrine therapy; or
    c. As a single-agent for HER2-negative disease that is:
        i. HR-negative; or
        ii. HR-positive with visceral crisis or endocrine therapy refractory.

Halaven® (Eribulin) Approval Criteria [Liposarcoma Diagnosis]:

1. Diagnosis of unresectable or metastatic liposarcoma; and
2. Previously received an anthracycline-containing chemotherapy regimen.

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. Preferred trastuzumab products include Kanjinti®, Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Herceptin Hylecta™, 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.

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.

Herceptin® (Trastuzumab), Hercessi™ (Trastuzumab-strf), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. 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.

Ibrance® (Palbociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced, metastatic, hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
2. Used in combination with:
    a. An aromatase inhibitor in female members; or
    b. Fulvestrant in women with disease progression following endocrine therapy; or
    c. An aromatase inhibitor or fulvestrant in male patients; or
    d. Inavolisib and fulvestrant in patients with disease progression following endocrine therapy.

Itovebi™ (Inavolisib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
2. PIK3CA-mutated; and
3. Used in combination with palbociclib and fulvestrant; and
4. Following recurrence on or after completing adjuvant endocrine therapy.

Ixempra® (Ixabepilone) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of metastatic or locally advanced breast cancer; and
2. Used in combination with capecitabine; and
    a. After failure of an anthracycline and a taxane unless anthracycline contraindicated; or
3. Used as a single agent; and
    a. Used in 1 of the following settings:

        i. After failure of capecitabine, an anthracycline, and a taxane; or
        ii. In members with no response to preoperative systemic therapy; or
        iii. After at least 1 line of therapy for recurrent unresectable (local or regional) disease; or
        iv. Disease is human epidermal growth factor receptor 2 (HER2)-negative; or
4. Used in combination with trastuzumab; and
    a. Disease is HER2-positive; and
    b. Fourth-line or subsequent therapy.

Kadcyla® (Ado-Trastuzumab Emtansine) Approval Criteria [Early Stage or Locally Advanced Breast Cancer Diagnosis]:

1. Diagnosis of early stage or locally advanced breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Used as adjuvant treatment in members with residual invasive disease after neoadjuvant therapy with taxane and trastuzumab-based treatment; and
4. Maximum duration of a total of 14 cycles.

Kadcyla® (Ado-Trastuzumab Emtansine) Approval Criteria [Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Previously received trastuzumab and a taxane, separately or in combination; and
4. Members should also have either:
    a. Received prior therapy for metastatic disease; or
    b. Developed disease recurrence during or within 6 months of completing adjuvant therapy; and
5. Used as a single agent; or
    a. If brain metastases are present, may be used in combination with neratinib.

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

1. Diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer; and
    a. Tumors express programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥10; and
    b. Used in combination with chemotherapy; or
2. Diagnosis of early stage triple-negative breast cancer; and
    a. Disease is considered high-risk; and

b. Used in combination with chemotherapy as neoadjuvant therapy and may be continued as a single agent as adjuvant treatment after surgery.

Kisqali® (Ribociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Hormone receptor (HR)-positive; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Used in 1 of the following settings:
    a. Diagnosis of stage II or III early breast cancer at high risk for recurrence as adjuvant therapy; and
        i. In combination with an aromatase inhibitor; or
    b. Diagnosis of advanced or metastatic breast cancer, as initial therapy; and
        i. In combination with an aromatase inhibitor; or
    c. Diagnosis of advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy; and
        i. In combination with fulvestrant.

Kisqali® Femara® Co-Pack (Ribociclib/Letrozole) Approval Criteria [Breast Cancer Diagnosis]:

1. Hormone receptor (HR)-positive; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Used in 1 of the following settings:
    a. Diagnosis of stage II or III early breast cancer at high risk of recurrence, as adjuvant therapy; or
    b. Diagnosis of advanced or metastatic breast cancer, as initial therapy.

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-negative, high-risk early breast cancer previously treated with neoadjuvant or adjuvant chemotherapy; and
    a. Used in the adjuvant setting; and
    b. Positive test for a germline BRCA-mutation (gBRCAm); and
    c. Maximum treatment duration of 1 year; or
2. Diagnosis of metastatic breast cancer; and
    a. Member must have shown progression on previous chemotherapy; and
    b. Members with hormone receptor positive disease must have failed prior endocrine therapy or are considered to not be a candidate for endocrine therapy.

Nerlynx® (Neratinib) Approval Criteria [Non-Metastatic Breast Cancer Diagnosis]:

1. For adjuvant treatment in early-stage breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
3. Neratinib must be used to follow adjuvant trastuzumab-based therapy.

Nerlynx® (Neratinib) Approval Criteria [Recurrent or Metastatic Breast Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic breast cancer; and
2. Member must have human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
3. Used in combination with capecitabine; or
4. Used in combination with ado-trastuzumab emtansine, capecitabine, or paclitaxel if brain metastases are present.

Orserdu® (Elacestrant) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
2. Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; and
3. Tumor is positive for ESR1-mutation; and
4. Female members must be postmenopausal or, if pre-menopausal, member must be treated with ovarian ablation/suppression; and
5. Has progressed after at least 1 prior endocrine therapy.

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

1. Human epidermal growth factor receptor 2 (HER2)-positive; and
2. Used in 1 of the following settings:
    a. Metastatic breast cancer in members who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease:
        i. Used in combination with trastuzumab and chemotherapy; or
    b. Neoadjuvant treatment of members with locally advanced, inflammatory, or early stage breast cancer (either >2cm in diameter or node positive):
        i. Used in combination with trastuzumab and chemotherapy; or
    c. Adjuvant systemic therapy for members with node positive, HER2-positive tumors or members with high-risk node negative tumors [tumor >1cm; tumor 0.5 to 1cm with histologic or nuclear grade 3; estrogen receptor (ER)/progesterone receptor (PR) negative; or younger than 35 years of age]:
        i. Used in combination with trastuzumab and chemotherapy; or

ii. Used in combination with trastuzumab and docetaxel following doxorubicin/cyclophosphamide (AC); or
iii. Used in combination with docetaxel/carboplatin/trastuzumab (TCH); or
iv. Used in combination with trastuzumab following neoadjuvant therapy with paclitaxel/docetaxel/carboplatin/ trastuzumab/pertuzumab (pTCHP).

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, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression.

Phesgo® (Pertuzumab/Trastuzumab/Hyaluronidase-zzxf) Approval Criteria [Breast Cancer Diagnosis]:

1. Human epidermal growth factor receptor 2 (HER2)-positive disease; and
2. Used in 1 of the following settings:
    a. Neoadjuvant treatment of members with locally advanced, inflammatory, or early stage breast cancer; or
    b. Adjuvant treatment of members with early breast cancer; or
    c. In combination with docetaxel for members with metastatic disease.

Piqray® (Alpelisib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer that has progressed on or after an endocrine-based regimen; and
2. Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative; and
3. PIK3CA-mutated disease; and
4. In combination with fulvestrant.

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

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

or segmental mastectomy, axillary dissection, and breast irradiation; or
   c. To reduce the risk of invasive breast cancer in women with ductal carcinoma in situ (DCIS), following breast surgery and radiation; or
   d. To reduce the incidence of breast cancer in women at high risk for breast cancer; and
2. A patient-specific, clinically significant reason why the member cannot use tamoxifen oral tablets must be provided.

Talzenna® (Talazoparib) Approval Criteria [Breast Cancer Diagnosis]:
1. Diagnosis of recurrent or metastatic breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-negative; and
3. Presence of BRCA1/BRCA2-germline mutated disease; and
4. Disease is hormone receptor (HR)-negative or is HR-positive and endocrine therapy refractory; and
5. Patient has symptomatic visceral disease; and
6. Must be used as a single-agent.

Talzenna® (Talazoparib) Approval Criteria [Prostate Cancer Diagnosis]:
1. Diagnosis of metastatic, castration-resistant prostate cancer; and
2. Disease is homologous recombination repair (HRR) gene-mutated; and
3. Used in combination with enzalutamide.

Trodelvy® (Sacituzumab Govitecan-hziy) Approval Criteria [Breast Cancer Diagnosis]:
1. Diagnosis of triple-negative breast cancer; and
   a. Unresectable locally advanced or metastatic disease; and
   b. Member must have received ≥2 prior therapies, at least 1 of which was for metastatic disease; or
2. Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
   a. Unresectable locally advanced or metastatic disease; and
   b. Member has previously received endocrine-based therapy and ≥2 additional systemic therapies in the metastatic setting.

Truqap® (Capivasertib) Approval Criteria [Breast Cancer Diagnosis]:
1. Diagnosis of locally advanced or metastatic breast cancer; and
2. Hormone receptor (HR)-positive; and
3. Human epidermal growth factor receptor 2 (HER2)-negative; and
4. Used in combination with fulvestrant; and
5. Contains 1 or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test; and
6. Member meets 1 of the following:
   a. Progressed following at least 1 endocrine-based regimen in the metastatic setting; or

b. Progressed within 12 months of completing adjuvant therapy.

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

1. Diagnosis of advanced unresectable or metastatic breast cancer; and
2. Used in combination with trastuzumab and capecitabine; and
3. Disease is human epidermal growth factor receptor 2 (HER2)-positive; and
4. Following progression of ≥1 prior anti-HER2 regimen(s) in the metastatic setting.

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

1. Diagnosis of RAS wild-type, human epidermal growth factor receptor 2 (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 [Breast Cancer Diagnosis]:

1. Diagnosis of metastatic or recurrent breast cancer; and
2. Human epidermal growth factor receptor 2 (HER2)-positive; and
3. Lapatinib must be used in combination with 1 of the following:
    a. Trastuzumab; or
    b. Capecitabine; or
    c. An aromatase inhibitor (e.g., exemestane, letrozole, anastrozole) if also estrogen receptor (ER) positive.

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.

Verzenio® (Abemaciclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
    a. Hormone receptor positive disease; and
    b. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in 1 of the following settings:
            1. In combination with an aromatase inhibitor as initial endocrine-based therapy; or

        2. In combination with fulvestrant with disease progression following endocrine therapy; or
        3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy; or
2. Diagnosis of early-stage breast cancer; and
    a. Hormone receptor positive disease; and
    b. HER2-negative disease; and
    c. Node-positive disease high risk for recurrence; and
    d. Used as adjuvant treatment in combination with endocrine therapy.

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 Breast Cancer Medications: Fiscal Year 2026

The following utilization data includes medications indicated for breast cancer; however, the data does not differentiate between breast cancer and other diagnoses, for which use may be appropriate.

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	144	615	$6,952,073.60	$11,304.18	$331.34	29,656	20,982
Aetna	65	307	$2,636,387.39	$8,587.58	$253.13	14,238	10,415
Humana	73	317	$2,013,581.26	$6,351.99	$185.46	14,558	10,857
OCH	62	311	$2,422,623.65	$7,789.79	$264.88	14,969	9,146
2025 Total	**293**	**1,550**	**$14,024,665.90**	**$9,048.17**	**$272.85**	**73,421**	**51,400**
Fiscal Year 2026							
FFS	137	543	$6,216,914.03	$11,449.20	$327.10	26,548	19,006
Aetna	80	361	$3,359,602.03	$9,306.38	$249.97	17,884	13,440
Humana	78	320	$3,653,998.17	$11,418.74	$295.06	17,331	12,384
OCH	70	348	$2,476,982.36	$7,117.77	$212.09	15,722	11,679
2026 Total	**321**	**1,572**	**$15,707,496.59**	**$9,992.05**	**$277.96**	**77,485**	**56,509**
% Change	**9.60%**	**1.40%**	**12.00%**	**10.40%**	**1.90%**	**5.50%**	**9.90%**
Change	**28**	**22**	**$1,682,830.69**	**$943.88**	**$5.11**	**4,064**	**5,109**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

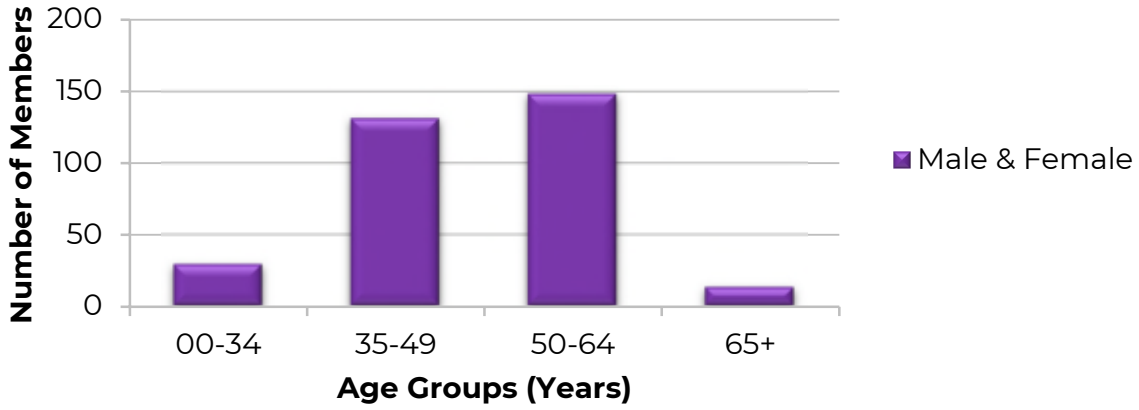
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	87	775	$3,644,904.53	$4,703.10	8.91
Aetna	23	157	$707,716.66	$4,507.75	6.83
Humana	23	196	$945,323.91	$4,823.08	8.52
OCH	24	248	$1,019,684.60	$4,111.63	10.33
2025 Total	**136**	**1,375**	**$6,317,629.70**	**$4,594.64**	**10.11**
Fiscal Year 2026					
FFS	136	963	$4,076,903.16	$4,233.54	7.08
Aetna	39	319	$1,417,851.93	$4,444.68	8.18
Humana	40	353	$1,250,552.78	$3,542.64	8.83
OCH	37	331	$1,501,007.05	$4,534.76	8.95
2026 Total	**221**	**1,966**	**$8,246,314.92**	**$4,194.46**	**8.9**
% Change	**62.50%**	**42.98%**	**30.53%**	**-8.71%**	**-11.97%**
Change	**85**	**591**	**$1,928,685.22**	**-$400.18**	**-1.21**

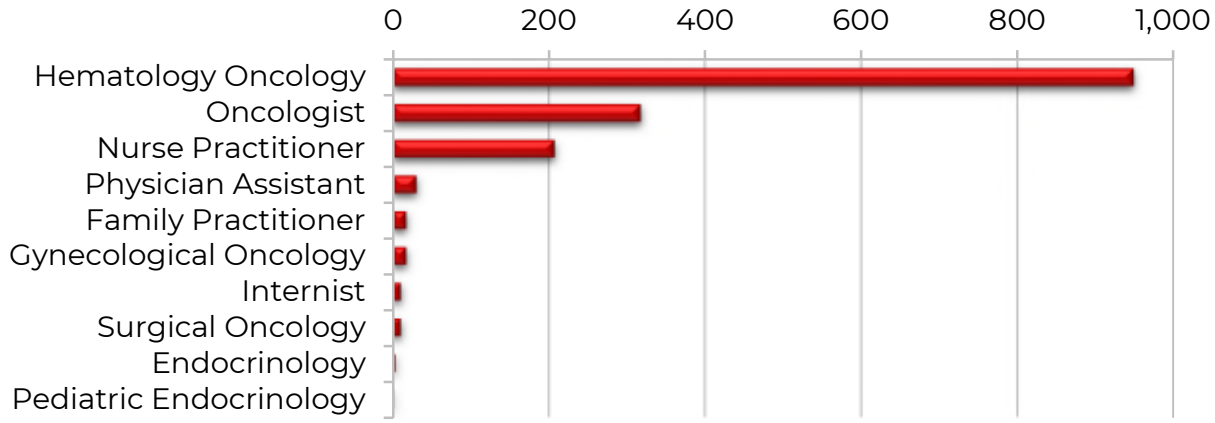
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

- Aggregate drug rebates collected during fiscal year 2025 for breast cancer medications totaled $8,453,316.17.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2025 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2026 are still being collected at this time. The costs included in this report do not reflect net costs.

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



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

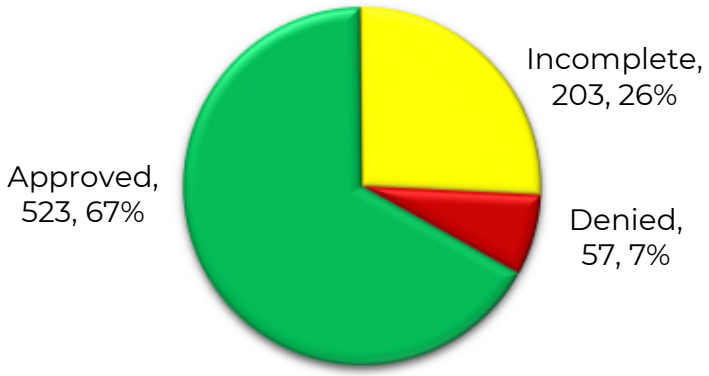


Prior Authorization of Breast Cancer Medications

There were 783 prior authorization requests submitted for breast cancer medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

[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	318	69%	127	28%	16	3%	**461**
Aetna	26	36%	28	39%	18	25%	**72**
Humana	103	87%	11	9%	5	4%	**119**
OCH	76	58%	37	28%	18	14%	**131**
Total	**523**	**67%**	**203**	**26%**	**57**	**7%**	**783**

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]

Anticipated Patent Expiration(s):

- Halaven® (eribulin): July 2027
- Nerlynx® (neratinib): July 2031
- Verzenio® (abemaciclib): September 2031
- Talzenna® (talazoparib): October 2031
- Piqray® (alpelisib): April 2033
- Truqap® (capivasertib): April 2033
- Ibrance® (palbociclib capsule): August 2034
- Docivyx™ (docetaxel): March 2036
- Beizray™ (docetaxel): May 2036
- Ibrance® (palbociclib tablet): August 2036
- Kisqali® (ribociclib): October 2036
- Kisqali® Femara® Co-Pack (ribociclib/letrozole): October 2036
- Orserdu® (elacestrant): January 2038
- Veppanu™ (vepdegestrant): January 2038
- Tukysa® (tucatinib): April 2038
- Itovebi™ (inavolisib): June 2038
- Inluriyo™ (imlunestrant): July 2039

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

- **November 2022:** The FDA approved Docivyx™ (docetaxel) as a new formulation of docetaxel. It is indicated for all of the same indications as Taxotere® (docetaxel), including for use in the treatment of breast cancer, non-small cell lung cancer (NSCLC), castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck.
- **October 2024:** The FDA approved Beizray™ (docetaxel) as a new formulation of docetaxel. It is indicated for all of the same indications as Taxotere® (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck. Beizray™ was not covered by SoonerCare until October 2025, when the current manufacturer began marketing the product.
- **September 2025:** The FDA approved Inluriyo™ (imlunestrant) for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy.
- **December 2025:** The FDA approved Enhertu® (fam-trastuzumab deruxtecan-nxki) for a new indication, in combination with pertuzumab, as first-line treatment of adult patients with unresectable or metastatic HER2-positive immunohistochemistry (IHC) 3+ or in situ hybridization (ISH)-positive breast cancer, as determined by an FDA-authorized test.
- **May 2026:** The FDA approved Veppanu™ (vepdegestrant) for the treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least 1 line of endocrine therapy.
- **May 2026:** The FDA approved Enhertu® (fam-trastuzumab deruxtecan-nxki) for 2 new indications for early breast cancer. The first new indication is as neoadjuvant treatment of adult patients with HER2-positive IHC 3+ or ISH-positive Stage II or III breast cancer, as determined by an FDA-authorized test, followed by a taxane, trastuzumab, and pertuzumab (THP). The second new indication is as adjuvant treatment of adult patients with HER2-positive IHC 3+ or ISH-positive breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment.
- **May 2026:** The FDA approved Datroway® (datopotamab deruxtecan-dlnk) for a new indication for the treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who

are not candidates for programmed death 1 (PD-1)/programmed death ligand 1 (PD-L1) inhibitor therapy.
- **June 2026:** The FDA approved Truqap® (capivasertib) for a new indication, in combination with abiraterone and prednisone, for the treatment of adult patients with metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test.
- **June 2026:** The FDA approved Ibrance® (palbociclib) for a new indication, in combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with hormone receptor (HR)-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment.
- **June 2026:** The FDA approved Trodelvy® (sacituzumab govitecan-hziy) for 2 new indications for the first-line treatment of TNBC. The first new indication is as a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC who are not candidates for PD-1 or PD-L1 inhibitor-based therapy. The second new indication is for use in combination with pembrolizumab or pembrolizumab/berahyaluronidase alfa-pmph for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 combined positive score (CPS) ≥10 as determined by an FDA-authorized test.

Guideline Update(s):
- The National Comprehensive Cancer Network (NCCN) guidelines for colon and rectal cancer no longer recommend the use of lapatinib in combination with trastuzumab for a diagnosis of unresectable, advanced, or metastatic HER2-amplified colorectal cancer.

Beizray™ (Docetaxel) and Beizray™ Kit (Docetaxel/Albumin) Product Summary[14]

Therapeutic Class: Microtubule inhibitor

Indication(s): Indicated for all of the same indications as Taxotere® (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck

How Supplied:
- Single-dose vials (SDVs):
  - 20mg/mL SDV
  - 80mg/4mL SDV
- Kits containing the following:

- 80mg Kit: 1 SDV of Beizray™ 80mg/4mL plus 1 SDV of intravenous (IV) solution stabilizer (50mL, 25% albumin human USP solution)
- 160mg Kit: 2 SDVs of Beizray™ 80mg/4mL plus 1 SDV of IV solution stabilizer (50mL, 25% albumin human USP solution)

Dosing and Administration: The recommended dosage depends on the specific indication. Please refer to the full *Prescribing Information* for dosage and administration details.

Docivyx™ (Docetaxel) Product Summary[15]

Therapeutic Class: Microtubule inhibitor

Indication(s): Indicated for all of the same indications as Taxotere® (docetaxel), including for use in the treatment of breast cancer, NSCLC, castration-resistant prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck

How Supplied:
- 20mg/2mL SDV
- 80mg/8mL SDV
- 160mg/16mL SDV

Dosing and Administration: The recommended dosage depends on the specific indication. Please refer to the full *Prescribing Information* for dosage and administration details.

Cost Comparison: Docetaxel Products

Product	Cost Per mg	Cost Per 21 Days*	Cost Per 6 Doses
Beizray™ (docetaxel) vial or kit J9174	**$46.81**	**$7,489.60**	**$44,937.60**
Docivyx™ (docetaxel) vial J9172	**$46.29**	**$7,406.40**	**$44,438.40**
docetaxel vial (generic) J9171	$0.46	$73.60	$441.60

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 based on use of up to 160mg per dose every 3 weeks and continued for 6 doses.

Inluriyo™ (Imlunestrant) Product Summary[16]

Therapeutic Class: Estrogen receptor antagonist

Indication(s): Treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least 1 line of endocrine therapy

How Supplied: 200mg oral tablet

Dosing and Administration: The recommended dosage is 400mg orally once daily, on an empty stomach, until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) is $401.79 per 200mg tablet. This would result in an estimated cost of $22,500.24 per 28 days or $292,503.12 per year based on recommended dosing.

Veppanu™ (Inavolisib) Product Summary[17]

Therapeutic Class: Heterobifunctional protein degrader

Indication(s): Treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least 1 line of endocrine therapy

How Supplied: 100mg and 200mg oral tablets

Dosing and Administration: The recommended dose is 200mg orally once daily with food continued until disease progression or unacceptable toxicity.

Cost: The WAC is $980.00 per 200mg tablet. This would result in an estimated cost of $29,400.00 per 30 days or $352,800.00 per year based on recommended dosing.

Cost Comparison: Trastuzumab Products

Product	Cost Per 10mg	Cost Per 21 Days*	Cost Per Year
Herceptin® (trastuzumab) J9355	$70.24	$3,160.80	$53,733.60
Kanjinti® (trastuzumab-anns) Q5117	$60.52	$2,723.40	$46,297.80
Herzuma® (trastuzumab-pkrb) Q5113	$54.94	$2,472.30	$29,667.60
Hercessi™ (trastuzumab-strf) Q5146	$32.46	$1,460.70	$24,831.90
Ogivri® (trastuzumab-dkst) Q5114	$31.95	$1,437.75	$24,441.75
Ontruzant® (trastuzumab-dttb) Q5112	$20.99	$944.55	$16,057.35
Trazimera® (trastuzumab-qyyp) Q5116	$13.03	$586.35	$9,967.95

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 21 days based on use of (3) 150mg vials per dose (6mg/kg every 3 weeks for a 75kg member)

Recommendations

The College of Pharmacy recommends the prior authorization of Beizray™ (docetaxel), Beizray™ Kit (docetaxel/albumin), Docivyx™ (docetaxel), Inluriyo™ (imlunestrant), and Veppanu™ (vepdegestrant) with the following criteria (shown in red):

Beizray™ (Docetaxel), Beizray™ Kit (Docetaxel/Albumin), and Docivyx™ (Docetaxel) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use generic docetaxel formulations, which are available without a prior authorization, must be provided.

Inluriyo™ (Imlunestrant) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
2. Estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease; and
3. Tumor is positive for estrogen receptor-1 (ESR-1) mutation; and
4. Disease has progressed following at least 1 line of endocrine therapy; and
5. Member must be 18 years of age or older.

Veppanu™ (Vepdegestrant) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of advanced or metastatic breast cancer; and
2. Disease is recurrent unresectable (local or regional), or metastatic; and
3. Estrogen receptor (ER)-positive, human epidermal growth factor 2 (HER2)-negative disease; and
4. Tumor is positive for estrogen receptor-1 (ESR1) mutation; and
5. Has progressed after at least 1 line of endocrine therapy; and
6. Member is 18 years of age or older.

The College of Pharmacy also recommends updating the approval criteria for Datroway® (datopotamab deruxtecan-dlnk), Enhertu® (fam-trastuzumab deruxtecan-nxki), Ibrance® (palbociclib), Trodelvy® (sacituzumab govitecan-hziy), and Truqap® (capivasertib) based on recent FDA approvals with the following changes (shown in red):

Datroway® (Datopotamab Deruxtecan-dlnk) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of unresectable or metastatic breast cancer; and
2. Used in 1 of the following settings:
    a. Disease is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative; and
        i. Member has received prior endocrine-based therapy and chemotherapy; ~~and~~ or

b. Disease is triple-negative breast cancer (TNBC); and
    i. Member has received no prior systemic therapy; and
    ii. Member is not a candidate for programmed death 1 (PD-1)/programmed death ligand 1 (PD-L1) inhibitor therapy; and
    iii. No germline BRCA 1/2 pathogenic variant; and
3. Used as a single agent.

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

1. Adult members with unresectable or metastatic disease; and
    a. For human epidermal growth factor receptor 2 (HER2)-positive [immunohistochemistry (IHC) 3+ or in situ hybridization (ISH)-positive] disease, must meet the following:
        i. Used as first-line treatment, in combination with pertuzumab; or
        ii. Used as monotherapy; and
            1. Member received prior therapy in the metastatic, neoadjuvant, or adjuvant setting and developed disease recurrence during or within 6 months of completing therapy; and
            2. Member has received ≥1 prior anti-HER2-based regimens; or
        iii. Stage II or III disease, used as neoadjuvant treatment, and followed by a taxane, trastuzumab, and pertuzumab (THP); or
        iv. Residual invasive disease following neoadjuvant treatment with trastuzumab (with or without pertuzumab) and taxane-based treatment; or
    b. For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet 1 of the following:
        i. Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; or
        ii. Disease is hormone receptor (HR)-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy; or
    c. For HER-2 ultralow (IHC 0 with membrane staining) disease, must meet the following:
        i. Disease is HR-positive, and member has received 1 or more prior endocrine therapies in the metastatic setting and has progressed on that endocrine therapy.

Ibrance® (Palbociclib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic, hormone receptor positive~~, human epidermal growth factor receptor 2 (HER2) negative~~ breast cancer; and
2. For human epidermal growth factor receptor 2 (HER2)-negative disease:
    a. Used in combination with:
        i. An aromatase inhibitor in female members; or
        ii. Fulvestrant in women with disease progression following endocrine therapy; or
        iii. An aromatase inhibitor or fulvestrant in male patients; or
        iv. Inavolisib and fulvestrant in patients with disease progression following endocrine therapy; or
3. For HER2-positive disease:
    a. Used in combination with trastuzumab, with or without pertuzumab, and endocrine therapy; and
    b. Used as maintenance treatment following induction treatment.

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

1. Diagnosis of triple-negative breast cancer; and
    a. Used as first line therapy:
        i. Used as monotherapy if member is not a candidate for PD-1 or PD-L1 inhibitor therapy; or
        ii. Used in combination with pembrolizumab for tumors expressing PD-L1 (CPS ≥10) as determined by an FDA-authorized test; or
    b. Used as second line or later therapy:
        i. Unresectable locally advanced or metastatic disease; and
        ii. Member must have received ≥2 prior therapies, at least 1 of which was for metastatic disease; or
2. Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer; and
    a. Unresectable locally advanced or metastatic disease; and
    b. Member has previously received endocrine-based therapy and ≥2 additional systemic therapies in the metastatic setting.

Truqap® (Capivasertib) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer; and
2. Used in combination with abiraterone and prednisone; and
3. Disease is PTEN-deficient as detected by FDA-authorized test; and
4. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and

5. Member is 18 years of age or older.

Additionally, the College of Pharmacy recommends updating the Tykerb® (lapatinib) approval criteria based on NCCN recommendations (changes shown in red):

~~**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.~~

Lastly, the College of Pharmacy recommends updating the approval criteria for the trastuzumab products based on NCCN recommendations and net costs (changes and additions shown in red):

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. Preferred trastuzumab products include Hercessi™, ~~Kanjinti®,~~ Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Herceptin Hylecta™, ~~Hercessi™,~~ Herzuma®, Kanjinti®, or Ogivri®) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Hercessi™, ~~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.

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

Herceptin® (Trastuzumab), Hercessi™ (Trastuzumab-strf), Herzuma® (Trastuzumab-pkrb), Kanjinti® (Trastuzumab-anns), Ogivri® (Trastuzumab-dkst), Ontruzant® (Trastuzumab-dttb), and Trazimera® (Trastuzumab-qyyp) Approval Criteria [Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Diagnosis]:

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. Preferred trastuzumab products include Hercessi™, ~~Kanjinti®,~~ Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Herceptin Hylecta™, ~~Hercessi™,~~ Herzuma®, Kanjinti®, or Ogivri®) will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products (Hercessi™, ~~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.

Utilization Details of Breast Cancer Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TAMOXIFEN PRODUCTS						
TAMOXIFEN TAB 20MG	586	150	$14,695.37	$25.08	3.91	0.09%
TAMOXIFEN TAB 10MG	50	24	$848.31	$16.97	2.08	0.01%
SUBTOTAL	**636**	**174**	**$15,543.68**	**$24.44**	**3.66**	**0.10%**
RIBOCICLIB PRODUCTS						
KISQALI TAB 600MG DOSE	209	30	$3,837,736.69	$18,362.38	6.97	24.43%
KISQALI TAB 400MG DOSE	137	32	$2,042,550.04	$14,909.12	4.28	13.00%
KISQALI TAB 200MG DOSE	14	5	$107,105.94	$7,650.42	2.8	0.68%
SUBTOTAL	**360**	**67**	**$5,987,392.67**	**$16,631.65**	**5.37**	**38.12%**
ABEMACICLIB PRODUCTS						
VERZENIO TAB 150MG	161	35	$2,344,489.97	$14,562.05	4.6	14.93%
VERZENIO TAB 100MG	138	30	$2,202,083.88	$15,957.13	4.6	14.02%
VERZENIO TAB 50MG	29	7	$445,436.77	$15,359.89	4.14	2.84%
SUBTOTAL	**328**	**72**	**$4,992,010.62**	**$15,219.54**	**4.56**	**31.78%**
PALBOCICLIB PRODUCTS						
IBRANCE TAB 125MG	50	11	$837,467.23	$16,749.34	4.55	5.33%
IBRANCE TAB 100MG	27	7	$450,668.39	$16,691.42	3.86	2.87%
IBRANCE CAP 75MG	24	4	$304,898.03	$12,704.08	6	1.94%
IBRANCE TAB 75MG	20	4	$333,383.08	$16,669.15	5	2.12%
IBRANCE CAP 125MG	8	3	$131,787.28	$16,473.41	2.67	0.84%
IBRANCE CAP 100MG	5	1	$79,420.35	$15,884.07	5	0.51%
SUBTOTAL	**134**	**30**	**$2,137,624.36**	**$15,952.42**	**4.47**	**13.61%**
CAPIVASERTIB PRODUCTS						
TRUQAP PAK 200MG	22	4	$528,137.02	$24,006.23	5.5	3.36%
TRUQAP TAB 200MG	6	3	$145,263.87	$24,210.65	2	0.92%
TRUQAP PAK 160MG	1	1	$23,617.07	$23,617.07	1	0.15%
SUBTOTAL	**29**	**8**	**$697,017.96**	**$24,035.10**	**3.63**	**4.44%**
TUCATINIB PRODUCTS						
TUKYSA TAB 150MG	27	5	$725,665.11	$26,876.49	5.4	4.62%
SUBTOTAL	**27**	**5**	**$725,665.11**	**$26,876.49**	**5.4**	**4.62%**
ELACESTRANT PRODUCTS						
ORSERDU TAB 345MG	17	8	$441,096.66	$25,946.86	2.13	2.81%
SUBTOTAL	**17**	**8**	**$441,096.66**	**$25,946.86**	**2.13**	**2.81%**
TALAZOPARIB PRODUCTS						
TALZENNA CAP 0.25MG	11	1	$213,018.35	$19,365.30	11	1.36%
TALZENNA CAP 1MG	1	1	$19,706.05	$19,706.05	1	0.13%
SUBTOTAL	**12**	**2**	**$232,724.40**	**$19,393.70**	**6**	**1.48%**
NERATINIB PRODUCTS						
NERLYNX TAB 40MG	10	4	$190,357.10	$19,035.71	2.5	1.21%
SUBTOTAL	**10**	**4**	**$190,357.10**	**$19,035.71**	**2.5**	**1.21%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALPELISIB PRODUCTS						
PIQRAY 300MG TAB DOSE	6	1	$142,860.54	$23,810.09	6	0.91%
PIQRAY 250MG TAB DOSE	1	1	$25,714.30	$25,714.30	1	0.16%
SUBTOTAL	**7**	**2**	**$168,574.84**	**$24,082.12**	**3.5**	**1.07%**
TRASTUZUMAB-DTTB PRODUCTS						
ONTRUZANT INJ 150MG	7	1	$37,142.35	$5,306.05	7	0.24%
SUBTOTAL	**7**	**1**	**$37,142.35**	**$5,306.05**	**7**	**0.24%**
INAVOLISIB PRODUCTS						
ITOVEBI TAB 9MG	3	1	$37,324.02	$12,441.34	3	0.24%
SUBTOTAL	**3**	**1**	**$37,324.02**	**$12,441.34**	**3**	**0.24%**
IMLUNESTRANT PRODUCTS						
INLURIYO TAB 200MG	2	1	$45,022.82	$22,511.41	2	0.29%
SUBTOTAL	**2**	**1**	**$45,022.82**	**$22,511.41**	**2**	**0.29%**
TOTAL	**1,572**	**321***	**$15,707,496.59**	**$9,992.05**	**4.9**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection; PAK = Pack; TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DOCETAXEL J9171 (TAXOTERE)	376	102	$18,761.00	$49.90	3.69
PERTUZUMAB J9306 (PERJETA)	354	58	$2,572,487.95	$7,266.92	6.1
FAM-TRAST DER-NXKI J9358 (ENHERTU)	304	41	$2,351,902.96	$7,736.52	7.41
TRAST-QYYP Q5116 (TRAZIMERA)	232	39	$258,750.33	$1,115.30	5.95
TRAST-ANNS Q5117 (KANJINTI)	215	32	$485,018.15	$2,255.90	6.72
ADO-TRAST EMT J9354 (KADCYLA)	136	12	$687,763.07	$5,057.08	11.33
SACITUZ GOV-HZIY J9317 (TRODELVY)	131	14	$915,422.36	$6,987.96	9.36
DOCETAXEL J9172 (DOCIVYX)	69	11	$342,880.81	$4,969.29	6.27
PERTUZ/TRAST/HYAL-ZZXF J9316 (PHESGO)	47	14	$328,811.40	$6,995.99	3.36
TRAST-DTTB Q5112 (ONTRUZANT)	36	9	$38,643.35	$1,073.43	4
ERIBULIN MESYLATE J9179 (HALAVEN)	26	2	$31,819.90	$1,223.84	13
TRASTUZUMAB J9355 (HERCEPTIN)	17	2	$67,140.75	$3,949.46	8.5
DATOPOT DER-DLNK J9011 (DATROWAY)	9	2	$88,316.88	$9,812.99	4.5
IXABEPILONE J9207 (IXEMPRA)	6	2	$37,656.00	$6,276.00	3
TRAST-DKST Q5114 (OGIVRI)	6	1	$14,536.83	$2,422.81	6
TRAST/HYAL-OYSK J9356 (HERCEPTIN HYL)	1	1	$3,594.60	$3,594.60	1
TRAST-PKRB Q5113 (HERZUMA)	1	1	$2,808.58	$2,808.58	1
TOTAL	**1,966**	**221**	**$8,246,314.92**	**$4,194.46**	**8.9**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
DATOPOT = datopotamab; DER = deruxtecan; EMT = emtansine; GOV = govitecan; HYAL = hyaluronidase; HYL = Hylecta; PERTUZ = pertuzumab; SACITUZ = sacituzumab; TRAST = trastuzumab
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

[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 08/2026. Last accessed 08/12/2026.
[2] U.S. FDA. Docivyx™ NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/215813Orig1s000ltr.pdf. Issued 11/22/2022. Last accessed 08/12/2026.
[3] U.S. FDA. Beizray™ NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/218711Orig1s000ltr.pdf. Issued 10/23/2024. Last accessed 08/11/2026.
[4] U.S. FDA. FDA Approves Imlunestrant for ER-Positive, HER2-Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-imlunestrant-er-positive-her2-negative-esr1-mutated-advanced-or-metastatic-breast. Issued 09/25/2025. Last accessed 08/11/2026.
[5] U.S. FDA. FDA Approves Fam-Trastuzumab Deruxtecan-nxki with Pertuzumab for Unresectable or Metastatic HER2-Positive Breast Cancer. Available online at: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-approves-fam-trastuzumab-deruxtecan-nxki-pertuzumab-unresectable-or-metastatic-her2-positive. Issued 12/15/2025. Last accessed 08/11/2026.
[6] U.S. FDA. FDA Approves Vepdegestrant for ER-Positive, HER2-Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-vepdegestrant-er-positive-her2-negative-esr1-mutated-advanced-or-metastatic-breast. Issued 05/01/2026. Last accessed 08/11/2026.
[7] U.S. FDA. FDA Approves Two Separate Indications for Fam-Trastuzumab Deruxtecan-nxki In HER2-Positive Early-Stage Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-two-separate-indications-fam-trastuzumab-deruxtecan-nxki-her2-positive-early-stage. Issued 05/15/2026. Last accessed 08/11/2026.
[8] U.S. FDA. FDA Approves Datopotamab Deruxtecan-dlnk for Unresectable or Metastatic Triple-Negative Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-datopotamab-deruxtecan-dlnk-unresectable-or-metastatic-triple-negative-breast-cancer. Issued 05/22/2026. Last accessed 08/11/2026.
[9] U.S. FDA. FDA Approves Capivasertib with Abiraterone and Prednisone for PTEN-Deficient Androgen Pathway Modulation-Naïve or -Sensitive Prostate Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-capivasertib-abiraterone-and-prednisone-pten-deficient-androgen-pathway-modulation. Issued 06/12/2026. Last accessed 08/11/2026.
[10] U.S. FDA. FDA Approves Palbociclib with Trastuzumab, with or without Pertuzumab, and Endocrine Therapy for the Maintenance Treatment of HR-Positive, HER2-Positive Metastatic Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-palbociclib-trastuzumab-or-without-pertuzumab-and-endocrine-therapy-maintenance. Issued 06/24/2026. Last accessed 08/11/2026.
[11] U.S. FDA. FDA Approves Sacituzumab Govitecan-hziy as Monotherapy and in Combination with Pembrolizumab for First-Line Treatment of Triple-Negative Breast Cancer. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-sacituzumab-govitecan-hziy-monotherapy-and-combination-pembrolizumab-first-line. Issued 06/24/2026. Last accessed 08/11/2026.
[12] National Comprehensive Cancer Network (NCCN). Colon Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Last revised 04/07/2026. Last accessed 08/25/2026.
[13] NCCN. Rectal Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Last revised 04/07/2026. Last accessed 08/25/2026.
[14] Beizray™ (Docetaxel) and Beizray™ Kit (Docetaxel/Albumin) Prescribing Information. Zydus Pharmaceuticals (USA), Inc. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8fb7d980-d6c7-468b-a9f0-adff16101a4b. Last revised 12/2025. Last accessed 08/11/2026.
[15] Docivyx™ (Docetaxel) Prescribing Information. Ingenus Pharmaceuticals, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/215813s001s002lbl.pdf. Last revised 04/2024. Last accessed 08/12/2026.

[16] Inluriyo™ (Imlunestrant) Prescribing Information. Eli Lilly and Company. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218881s000lbl.pdf. Last revised 09/2025. Last accessed 08/11/2026.
[17] Veppanu™ (Vepdegestrant) Prescribing Information. Pfizer, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/219835Orig1s000lbl.pdf. Last revised 05/2026. Last accessed 08/11/2026.

Appendix S

Fiscal Year 2026 Annual Review of Various Ophthalmic Medications and the 30-Day Notice to Prior Authorize Epioxa® HD/Epioxa® (Riboflavin 5'-Phosphate Ophthalmic Solution) and Lumvoa® (Veligrotug-vvze)

Oklahoma Health Care Authority
September 2026

Current Prior Authorization Criteria

Encelto™ (Revakinagene Taroretcel-lwey) Approval Criteria:

1. An FDA approved diagnosis of idiopathic macular telangiectasia (MacTel) type 2; and
2. The diagnosis must be supported by evidence of fluorescein leakage and at least 1 of the following other features typical of MacTel Type 2:
   a. Hyperpigmentation that is outside of a 500-micron radius from the center of the fovea; or
   b. Retinal opacification; or
   c. Crystalline deposits; or
   d. Right-angle vessels; or
   e. Inner/outer lamellar cavities; and
3. Member must be 18 years of age or older; and
4. Encelto™ must be prescribed and administered by a qualified ophthalmologist under aseptic conditions; and
5. Member must have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00mm^2 measured by spectral domain-optical coherence tomography (SD-OCT); and
6. Member must have a best corrected visual acuity (BCVA) of 20/80 or better; and
7. Member must not have neovascular MacTel type 2: and
8. Member must not have ocular or periocular infections; and
9. Member must not have known hypersensitivity to Endothelial Serum Free Media (Endo-SFM); and
10. If the member is taking an antithrombotic medication (i.e., oral anticoagulants, aspirin, and nonsteroidal anti-inflammatory drugs) they have been counseled to temporarily discontinue therapy with their antithrombotic medication prior to Encelto™ implantation due to the risk of vitreous hemorrhage; and
11. Prescriber must verify the member will be monitored for vision loss, infectious endophthalmitis, retinal tear and/or detachment, vitreous hemorrhage, implant extrusion, cataract formation, suture related

complications, and delayed dark adaptation after Encelto™ implantation and treated, if appropriate; and
12. A quantity limit of 1 implant per eye per lifetime will apply.

Luxturna® (Voretigene Neparvovec-rzyl) Approval Criteria:

1. An FDA approved diagnosis of biallelic *RPE65* mutation-associated retinal dystrophy; and
    a. Diagnosis must be confirmed by genetic testing; and
2. Member must have sufficient viable retinal cells in both eyes as determined by the treating physician(s); and
3. Member must have best corrected visual acuity of 20/60 or worse in both eyes and/or visual field <20 degrees in any meridian in both eyes; and
4. Member must be 4 years of age or older; and
5. Member must not have participated in a previous *RPE65* gene therapy study or have previously received treatment with Luxturna®; and
6. Member must not have had intraocular surgery in the past 6 months; and
7. Female members of childbearing age must not be pregnant and must have a negative pregnancy test immediately prior to administration of Luxturna®; and
8. Male and female members of childbearing age must be willing to use effective contraception during treatment with Luxturna® and for at least 4 months after administration of Luxturna®; and
9. Member must take the recommended systemic oral corticosteroid regimen, starting 3 days prior to administration of Luxturna® to each eye, and continuing after administration of Luxturna®, as per package labeling; and
10. Luxturna® must be prescribed and administered by a retinal surgeon with expertise in the treatment of biallelic *RPE65* mutation-associated retinal dystrophy and in the administration of Luxturna® at an Ocular Gene Therapy Treatment Center; and
    a. Luxturna® must be shipped via cold chain supply shipping and delivery to the Ocular Gene Therapy Treatment Center where the member is scheduled to receive treatment; and
    b. Luxturna® must be stored frozen prior to preparation for administration (Luxturna® should be administered within 4 hours of preparation); and
    c. The receiving facility must have a mechanism in place to track patient-specific Luxturna® from receipt to storage to administration; and
11. Luxturna® must be administered subretinally to each eye on separate days within a close interval, but no fewer than 6 days apart; and
    a. The scheduled procedure date for each eye must be provided; and

12. Only 1 single-dose vial per eye will be approved per member per lifetime; and
    a. Each single-dose vial of Luxturna® is to be dispensed immediately prior to the scheduled procedure for the specific eye; or
13. A prior authorization request with patient-specific information may be submitted for consideration of Luxturna® for members not meeting all of the current prior authorization criteria requirements.

Oxervate® (Cenegermin-bkbj) Approval Criteria:

1. An FDA approved diagnosis of neurotrophic keratitis; and
2. Oxervate® must be prescribed by an optometrist or ophthalmologist; and
3. Prescriber must verify that the member has persistent epithelial defect (PED) (stage 2 disease) or corneal ulceration (stage 3 disease) of at least 2 weeks duration that is refractory to 1 or more conventional non-surgical treatments for neurotrophic keratitis; and
    a. Specific non-surgical treatments and dates of trials must be listed on the prior authorization request; and
4. Prescriber must verify that the member has evidence of decreased corneal sensitivity within the area of the PED or corneal ulcer and outside of the area of the defect in at least 1 corneal quadrant; and
5. Prescriber must verify the member has been counseled on the proper administration and storage of Oxervate®; and
6. Approvals will be for a maximum duration of 8 weeks of total therapy per eye; and
7. A quantity limit of 2 weekly kits per 14 days will apply. A quantity limit override will be approved for 4 weekly kits per 14 days with prescriber documentation of treatment in both eyes.

Photrexa®/Photrexa® Viscous (Riboflavin 5'-Phosphate) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Progressive keratoconus; or
    b. Corneal ectasia following refractive surgery; and
2. Must be prescribed by and administered by an optometrist or ophthalmologist trained in the corneal cross-linking procedure; and
3. Must be used in combination with the KXL® System in the corneal cross-linking procedure; and
4. Must be administered using the epithelial-off procedure as specified in the package labeling; and
5. A quantity limit of 1 kit (6mL) per eye will apply.

Tepezza® (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease (TED) in adult members 18 years of age and older; and

    a. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza®, and for at least 6 months after the last dose of Tepezza®; and
4. Member must not have had prior surgical treatment for TED; or
    a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza® for members who have had prior surgical treatment for TED, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza®; and
5. Medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of TED; and
    a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza® must be provided on the prior authorization request; and
6. Tepezza® must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Tepezza® must be administered by a health care professional. Prior authorization requests must indicate how Tepezza® will be administered; and
    a. Tepezza® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tepezza® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza®; and
8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Approvals will be for a maximum of 8 total infusions.

Vuity® (Pilocarpine Hydrochloride 1.25% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication of the treatment of presbyopia in adults; and
2. Must be prescribed by an ophthalmologist or optometrist; and
3. Prescriber must verify the member does not have iritis; and

4. Prescriber must verify the member has been counseled on the risk of retinal detachment with use of Vuity® and when to seek immediate medical care; and
5. Prescriber must verify the member has been advised to use caution with night driving and hazardous occupations in poor illumination as vision may not be clear in these conditions while using Vuity®; and
6. A patient-specific, clinically significant reason why the member cannot use corrective lenses must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use generic pilocarpine ophthalmic solution (Isopto® Carpine) must be provided.

Utilization of Various Ophthalmic Medications: Fiscal Year 2026

Fiscal Year 2026 Utilization: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	1	4	$115,433.40	$28,858.35	$2,061.31	56	56
Humana	5	16	$442,102.20	$27,631.39	$1,973.67	224	224
OCH	3	9	$346,414.28	$38,490.48	$2,439.54	173	142
2025 Total	**9**	**29**	**$903,949.88**	**$31,170.69**	**$2,142.06**	**453**	**422**
Fiscal Year 2026							
FFS	8	23	$1,241,269.87	$53,968.26	$3,283.78	340	378
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	3	8	$175,743.70	$21,967.96	$1,033.79	99	170
OCH	1	2	$93,631.27	$46,815.64	$2,229.32	5	42
2026 Total	**12**	**33**	**$1,510,644.84**	**$45,777.12**	**$2,560.41**	**444**	**590**
% Change	**33.30%**	**13.80%**	**67.10%**	**46.90%**	**19.50%**	**-2.00%**	**39.80%**
Change	**3**	**4**	**$606,694.96**	**$14,606.43**	**$418.35**	**-9**	**168**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2025					
FFS	6	28	$1,398,019.91	$49,929.28	4.67
Aetna	6	45	$1,459,311.00	$32,429.13	7.5
Humana	1	8	$190,584.00	$23,823.00	8
OCH	0	0	$0.00	$0.00	0
2025 Total	**13**	**81**	**$3,047,914.91**	**$37,628.58**	**6.23**
Fiscal Year 2026					

FFS	3	13	$619,795.90	$47,676.61	4.33
Aetna	2	5	$96,677.50	$19,335.50	2.5
Humana	3	5	$41,351.00	$8,270.20	1.67
OCH	2	2	$9,116.00	$4,558.00	1
2026 Total	**10**	**25**	**$766,944.40**	**$30,677.78**	**2.5**
% Change	**-23.08%**	**-69.14%**	**-74.84%**	**-18.47%**	**-59.87%**
Change	**-3**	**-56**	**-$2,280,970.51**	**-$6,950.80**	**-3.73**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Demographics of Members Utilizing Various Ophthalmic Medications (Pharmacy Claims)

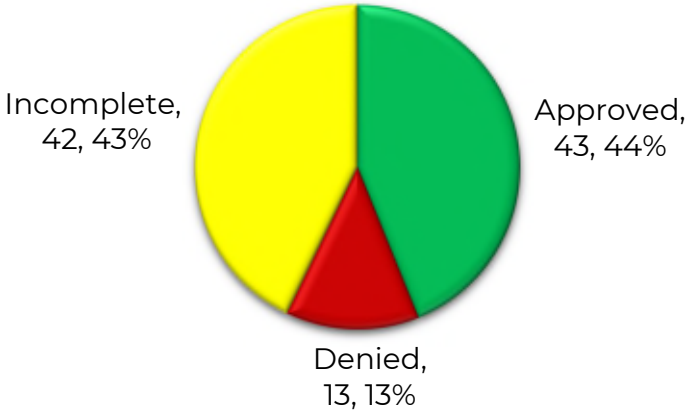
- Due to the limited number of members utilizing various ophthalmic medications during fiscal year 2026, detailed demographic information could not be provided.

Top Prescriber Specialties of Various Ophthalmic Medications by Number of Claims (Pharmacy Claims)

Prior Authorization of Various Ophthalmic Medications

There were 98 prior authorization requests submitted for the various ophthalmic medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	25	37%	35	51%	8	12%	**68**
Aetna	14	88%	0	0%	2	13%	**16**
Humana	3	33%	6	67%	0	0%	**9**
OCH	1	20%	1	20%	3	60%	**5**
Total	**43**	**44%**	**42**	**43%**	**13**	**13%**	**98**

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

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

Anticipated Patent Expiration(s):

- Vuity® (pilocarpine 1.25% ophthalmic solution): April 2039

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

- **October 2025:** The FDA approved Epioxa® HD/Epioxa® (riboflavin 5'-phosphate) to treat keratoconus in adults and pediatric patients 13 years of age and older, in conjunction with the O_2n System and the Boost Goggles. Epioxa® HD/Epioxa® does not require the removal of the epithelium like the previously approved Photrexa®/Photrexa® Viscous (riboflavin 5'-phosphate). The efficacy of Epioxa® HD/Epioxa® with epithelium-on corneal collagen cross-linking (CXL) with UV-A irradiation and supplemental oxygen in patients with keratoconus was evaluated in 2 prospective, randomized, parallel-group, sham procedure/vehicle-controlled trials. The primary endpoint was a change from baseline in the maximum corneal curvature (K_{max}) in the CXL treatment group and in the sham procedure/vehicle control group. In both studies, the CXL treatment group showed an improvement in K_{max} (decrease in corneal curvature) whereas the sham procedure/vehicle control group showed deterioration (increase in corneal curvature). The treatment difference between groups was about -1.0 diopter in both trials, which was determined to be statistically significant. The Wholesale Acquisition Cost (WAC) of Epioxa® HD/Epioxa® is $78,500 per kit; therefore, to treat both eyes, the cost would be $157,000.
- **June 2026:** The FDA approved Lumvoa® (veligrotug-vvze) for the treatment of thyroid eye disease (TED).

News:

- **January 2026:** Glaukos announced the discontinuation of Photrexa®/Photrexa® Viscous (riboflavin 5'-phosphate) cross-linking kit.

Pipeline:

- **Elegrobart:** Elegrobart is an extended half-life monoclonal antibody targeting the insulin-like growth factor-1 receptor (IGF-1R) that is being

evaluated for the treatment of TED. The results from the Phase 3 REVEAL-2 clinical trial showed higher proptosis and diplopia responder rates in the elegrobart treated group versus the placebo group with both dosing regimens, either every 4 weeks or every 8 weeks. Viridian, the manufacturer of elegrobart, stated they plan to submit a Biologics License Application (BLA) to the FDA in quarter 1 of 2027. If approved by the FDA, elegrobart will be supplied in an autoinjector.

Lumvoa® (Veligrotug-vvze) Product Summary[7,8,9,10,11]

Therapeutic Class: IGF-1R inhibitor

Indication(s): For the treatment of TED regardless of thyroid eye disease activity or duration

How Supplied: 500mg/10mL(50mg/1mL) solution in a single-dose vial

Dosing and Administration:

- The recommended dose of Lumvoa® is 10mg/kg every 3 weeks for a total of 5 infusions.
- Lumvoa® should be administered by intravenous (IV) infusion over 30 to 45 minutes.

Efficacy: The efficacy of Lumvoa® was evaluated in 2 randomized, double masked, placebo-controlled trials, THRIVE (active TED) and THRIVE-2 (chronic TED).

- Key Inclusion Criteria:
  - ≥18 years of age
  - Must agree to use highly effective contraception as specified in the protocol
  - Female TED participants must have a negative serum pregnancy test at screening
  - THRIVE:
    - Moderate to severe active TED with documented evidence of ocular symptoms or signs that began within 15 months prior to screening.
    - Clinical Activity Score (CAS) of ≥3 on the 7-item scale of the study eye
  - THRIVE-2:
    - Moderate to severe chronic TED with documented evidence of ocular symptoms or signs that began greater than 15 months prior to screening
    - A clinical diagnosis of TED, with any CAS (0-7)
- Key Exclusion Criteria:
  - Prior treatment with another anti-IGF-1R therapy

    - Previous orbital irradiation or surgery for TED in the study eye; however, prior orbital decompression surgery was permitted in either study if surgery was limited to the bone
- Intervention:
    - Randomized to receive Lumvoa® or placebo in a 2:1 ratio
    - The study eye was the most proptotic eye by exophthalmometry, with the other designated as the non-study eye.
- Primary Outcome: Proptosis responder rate (PRR) in study eye at week 15 which was defined as the percent of patients with ≥2mm reduction in proptosis in the study eye from baseline without ≥2mm increase in the non-study eye measured by exophthalmometer.
- Results:
    - THRIVE:
        - The percent PRR at week 15 was 70% in the Lumvoa® treated group and 5% in the placebo treated group with a treatment difference of 65% [95% confidence interval (CI): 52, 78; P<0.01].
        - The proptosis average change from baseline at week 15 was -2.9mm in the Lumvoa® treated group versus -0.5mm in the placebo treated group with a treatment difference of -2.4mm (95% CI: -3, -1.8; P<0.01).
    - THRIVE-2:
        - The percent PRR at week 15 was 57% in the Lumvoa® treated group and 8% in the placebo treated group with a treatment difference of 49% (95% CI: 38, 60, P<0.01).
        - The proptosis average change from baseline at week 15 was -2.4mm in the Lumvoa® treated group versus -0.5mm in the placebo treated group with a treatment difference of -1.9mm (95% CI: -2.4, -1.4; P<0.01).

Cost Comparison:

Product	Cost Per Unit	Cost Per Treatment Course
Lumvoa (veligrotug-vvze) 500mg/10mL sol	**$4,480**	**$448,000¥**
Tepezza® (teprotumumab-trbw) 500mg vial	$19,451.83	$447,392.09*

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 = mL or vial
¥Cost per treatment course is based on a 75kg patient receiving the FDA approved dose of 10mg/kg every 3 weeks for a total of 5 infusions.
*Cost per treatment course is based on a 75kg patient receiving the FDA approved dose of 10mg/kg for the initial dose followed by 20mg/kg every 3 weeks for 7 additional infusions.

Recommendations

The College of Pharmacy recommends the prior authorization of Epioxa® HD/Epioxa® (riboflavin 5'-phosphate) with the following criteria (shown in red):

Epioxa® HD/Epioxa® (Riboflavin 5'-Phosphate) Approval Criteria:

1. A diagnosis of 1 of the following:
    a. Keratoconus; or
    b. Corneal ectasia following refractive surgery; and
2. Member must be 13 years of age or older; and
3. Must be administered by an optometrist or ophthalmologist trained in the corneal cross-linking procedure; and
4. Must be used in combination with the O_2n System and Boost Goggles in the corneal cross-linking (CXL) procedure; and
5. Must be administered using the epithelial-on procedure as specified in the package labeling; and
6. Member must not have any contraindications to Epioxa® HD/Epioxa® or to the CXL procedure or have any current or previous ocular conditions in the eye to be treated that may predispose the eye for future complications after the procedure; or
    a. The prescriber has assessed the member and determined the risks outweigh the benefits of the procedure and has counseled the member on the potential risks; and
7. Member must not have previous use of Photrexa®/Photrexa® Viscous (riboflavin 5'-phosphate) with the CXL procedure in the eye to be treated; and
8. A quantity limit of 1 kit (4mL) per eye per lifetime will apply.

The College of Pharmacy recommends the prior authorization of Lumvoa® (veligrotug-vvze) with the following criteria (shown in red):

Lumvoa® (Veligrotug-vvze) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease (TED) in adult members 18 years of age and older; and
    a. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Lumvoa®, and for at least 6 months after the last dose of Lumvoa®; and
4. Member must not have had prior surgical treatment for TED unless eye surgery was limited to the bone; or

    a. A prior authorization request with patient-specific information may be submitted for consideration of Lumvoa® for members who have had prior surgical treatment for TED, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Lumvoa®; and
5. Medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of TED; and
    a. The name of the ophthalmologist and endocrinologist recommending treatment with Lumvoa® must be provided on the prior authorization request; and
6. Lumvoa® must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Lumvoa® must be administered by a health care professional. Prior authorization requests must indicate how Lumvoa® will be administered; and
    a. Lumvoa® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Lumvoa® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Lumvoa®; and
8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Member must not have received previous treatment with Tepezza® (teprotumumab-trbw); and
10. Approvals will be for a maximum of 5 total infusions.

The College of Pharmacy also recommends updating the approval criteria for Tepezza® (teprotumumab-trbw) based on the FDA approval of Lumvoa® (veligrotug-vvze) (changes shown in red):

Tepezza® (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease (TED) in adult members 18 years of age and older; and
    a. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza®, and for at least 6 months after the last dose of Tepezza®; and

4. Member must not have had prior surgical treatment for TED; or
    a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza® for members who have had prior surgical treatment for TED, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza®; and
5. Medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of TED; and
    a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza® must be provided on the prior authorization request; and
6. Tepezza® must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Tepezza® must be administered by a health care professional. Prior authorization requests must indicate how Tepezza® will be administered; and
    a. Tepezza® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or
    b. Tepezza® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza®; and
8. The member's current weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Member must not have received previous treatment with Lumvoa® (veligrotug-vvze); and
10. Approvals will be for a maximum of 8 total infusions.

Utilization Details of Various Ophthalmic Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OXERVATE SOL 20MCG/ML	19	8	$825,898.25	$43,468.33	2.38	54.67%
TEPEZZA INJ 500MG	11	3	$684,391.66	$62,217.42	3.67	45.30%
PILOCARPINE SOL 1.25%	3	1	$354.93	$118.31	3	0.02%
TOTAL	**33**	**12***	**$1,510,644.84**	**$45,777.12**	**2.75**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Medical Claims (All Plans)

PRODUCT UTILIZED	+TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J3241 TEPROTUMUMAB-TRBW INJ 500MG	21	6	$748,704.40	$35,652.59	3.5
J2787 RIBOFLAVIN 5'-PHOSPHATE (PHOTREXA)	4	4	$18,236.00	$4,559.00	1
TOTAL	**25**	**10**	**$766,944.40**	**$30,667.78**	**2.5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
INJ = injection
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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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 08/2026. Last accessed 08/24/2026.
[2] Glaukos. Glaukos Announces FDA Approval of Epioxa®. Available online at: https://investors.glaukos.com/news/news-details/2025/Glaukos-Announces-FDA-Approval-of-Epioxa/default.aspx. Issued 10/20/25. Last accessed 08/24/2026.
[3] Epioxa® HD and Epioxa® Prescribing Information. Glaukos. Available online at: https://www.epioxa.com/wp-content/uploads/2025/10/epioxa-prescribing-information-final.pdf. Last revised 10/2025. Last accessed 07/24/2026.
[4] Viridian Therapeutics, Inc. Viridian Therapeutics Announces U.S. FDA Approval and Launch of Lumvoa® (Veligrotug-vvze) for the Treatment of Thyroid Eye Disease. Available online at: https://www.businesswire.com/news/home/20260625016249/en/Viridian-Therapeutics-Announces-U.S.-FDA-Approval-and-Launch-of-Lumvoa-veligrotug-vvze-for-the-Treatment-of-Thyroid-Eye-Disease. Issued 06/26/2026. Last accessed 08/24/2026.
[5] Glaukos Corporation – Discontinuation of Photrexa® (Riboflavin 5-Phosphate) Cross-Linking Kit. *OptumRx®*. Available online: https://business.optum.com/content/dam/noindex-resources/business/support-documents/drug-recalls-availability/drugwithdrawal-photrexa-012726.pdf. Issued 01/20/2026. Last accessed 08/24/2026.
[6] Viridian Therapeutics, Inc. Viridian Therapeutics Announces Positive Topline Results from Elegrobart Phase 3 REVEAL-2 Clinical Trial in Chronic Thyroid Eye Disease. Available online at: https://investors.viridiantherapeutics.com/news/news-details/2026/Viridian-Therapeutics-Announces-Positive-Topline-Results-from-Elegrobart-Phase-3-REVEAL2-Clinical-Trial-in-Chronic-Thyroid-Eye-Disease/default.aspx. Issued 05/05/2026. Last accessed 08/24/2026.
[7] Lumvoa® (Veligrotug-vvze) Prescribing Information. Viridian Therapeutics, Inc. Available online at: https://www.lumvoahcp.com/content/lumvoa-prescribing-information.pdf. Last revised 06/2026. Last accessed 08/24/2026.
[8] A Safety, Tolerability and Efficacy Study of Veligrotug (VRDN 001) in Health Volunteers and Participants With Thyroid Eye Disease (TED) (THRIVE). *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT05176639. Last revised 07/18/2025. Last accessed 08/24/2026.
[9] An Efficacy, Safety, and Tolerability Study of Veligrotug (VRDN-001), in Participants with Chronic Thyroid Eye Disease (TED) (THRIVE-2). *ClinicalTrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT06021054. Last revised 10/23/2025. Last accessed 08/24/2026.
[10] Yen M, Cockerham K, Saeed P, et al. THRIVE: A Phase 3, Randomized, Double-Masked, Placebo-Controlled Study of Veligrotug for Active Thyroid Eye Disease. Ophthalmology 2026; 133(9): 1085-1096. doi: 10.1016/j.ophtha.2026.04.022.
[11] Tepezza® (Teprotumumab-trbw) Prescribing Information. Horizon Therapeutics. Available online at: https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/tepezza/tepezza_fpi_english.pdf. Last revised 11/2025. Last accessed 08/24/2026.

Appendix T

Fiscal Year 2026 Annual Review of Antihistamine Medications (Systemic) and 30-Day Notice to Prior Authorize Cetirizine Oral Solution Unit-Dose Cups (UDCs)

Oklahoma Health Care Authority
September 2026

Current Prior Authorization Criteria

Oral Antihistamine Medications		
Tier-1[+]	**Tier-2**	**Tier-3**
OTC cetirizine (Zyrtec®)	OTC levocetirizine (Xyzal®)*	clemastine
OTC loratadine (Claritin®)		desloratadine (Clarinex®)[¥]

[+]Tier-1 products are covered for pediatric members with no authorization necessary. OTC products are only covered for pediatric members.
*Xyzal® is only covered for members 0 to 20 years of age. Xyzal® solution is available for children 6 months to 6 years of age.
[¥]An age restriction of 6 years to 11 years of age applies for Clarinex® RediTabs®.
OTC = over-the-counter

Oral Antihistamine Medications Tier-2 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of all Tier-1 products within the last 30 days; and
3. Approvals will be for the duration of 1 year.

Oral Antihistamine Medications Tier-3 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of all Tier-1 and Tier-2 products within the last 60 days (unless no age-appropriate Tier-2 product exists); and
3. Approvals will be for the duration of 1 year.

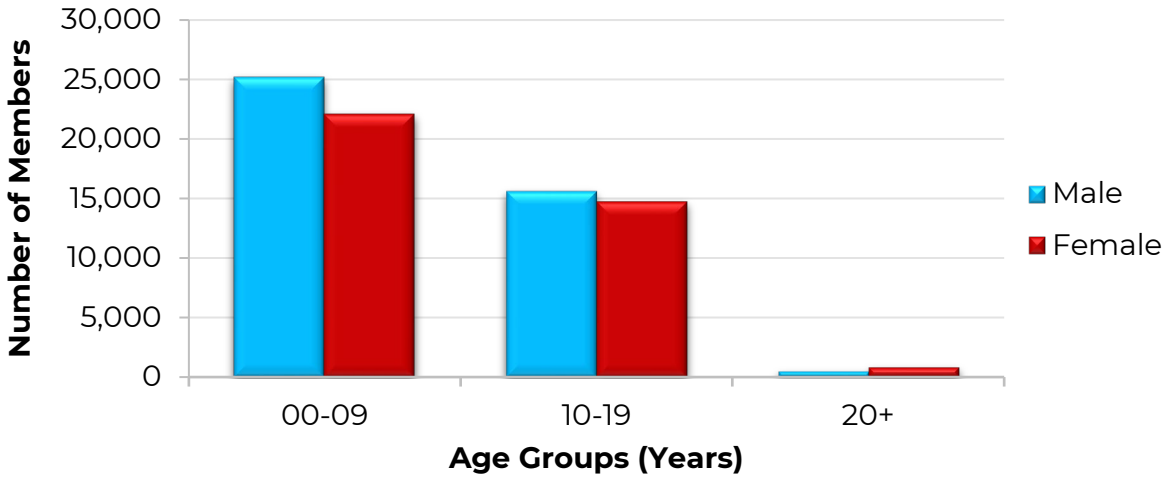
Utilization of Systemic Antihistamine Medications: Fiscal Year 2026

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

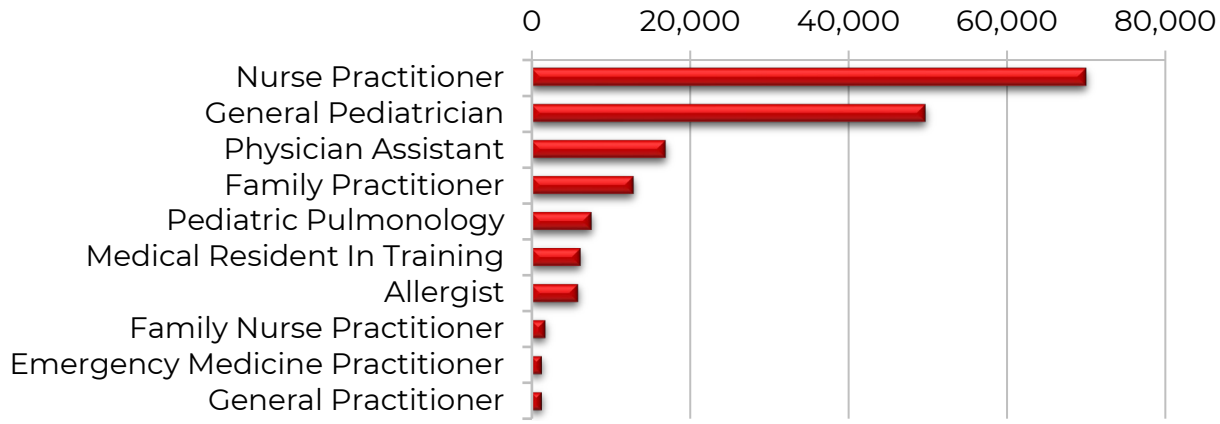
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	26,094	57,974	$735,824.09	$12.69	$0.37	5,749,170	1,975,741
Aetna	19,694	41,511	$461,931.82	$11.13	$0.33	4,299,642	1,414,175
Humana	19,871	42,623	$504,061.24	$11.83	$0.34	4,419,622	1,484,185
OCH	24,200	55,937	$661,018.93	$11.82	$0.35	5,529,037	1,870,807
2025 Total	**85,324**	**198,045**	**$2,362,836.08**	**$11.93**	**$0.35**	**19,997,471**	**6,744,908**
Fiscal Year 2026							
FFS	22,674	50,571	$922,148.15	$18.23	$0.53	5,957,137	1,744,591
Aetna	18,568	39,250	$453,416.06	$11.55	$0.34	4,095,832	1,332,721
Humana	18,622	39,848	$489,281.21	$12.28	$0.35	4,160,836	1,388,471
OCH	22,819	48,972	$617,964.15	$12.62	$0.34	5,313,756	1,808,447
2026 Total	**78,940**	**178,641**	**$2,482,809.57**	**$13.90**	**$0.40**	**19,527,562**	**6,274,230**
% Change	**-7.50%**	**-9.80%**	**5.10%**	**16.50%**	**14.30%**	**-2.30%**	**-7.00%**
Change	**-6,384**	**-19,404**	**$119,973.49**	**$1.97**	**$0.05**	**-469,909**	**-470,678**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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



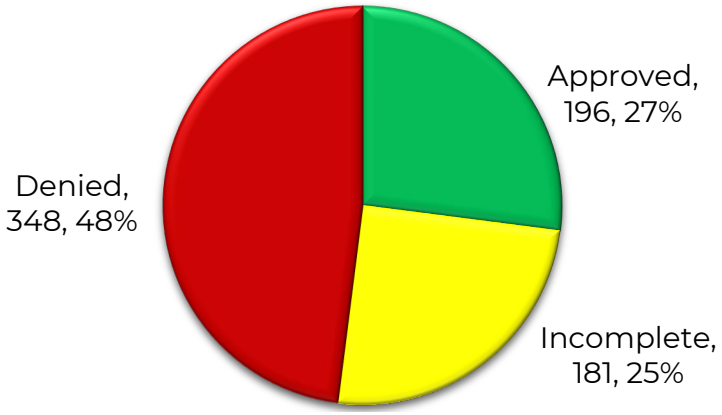
Top Prescriber Specialties of Systemic Antihistamine Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Systemic Antihistamine Medications

There were 725 prior authorization requests submitted for systemic antihistamine medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	97	31%	116	37%	101	32%	**314**
Aetna	42	21%	28	14%	133	66%	**203**
Humana	3	23%	8	62%	2	15%	**13**
OCH	54	28%	29	15%	112	57%	**195**
Total	**196**	**27%**	**181**	**25%**	**348**	**48%**	**725**

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

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Xyzal® (levocetirizine dihydrochloride oral solution): October 2027

Cost Comparison: Cetirizine Products

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
cetirizine 5mg/5mL oral sol unit-dose cup	**$0.40**	**$120.00**	**$1,440.00**
cetirizine 1mg/mL oral solution	$0.03	**$9.00**	$108.00
cetirizine 10mg tablet	$0.05	$1.50	$18.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the use of 10mg per day for each product.
Sol = solution; Unit = each tablet or milliliter

Recommendations

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

1. Prior authorization of cetirizine oral solution UDCs and placement into Tier-3 with additional criteria shown below; and
2. Moving levocetirizine tablets from Tier-2 to Tier-1 based on net cost; and
3. Moving desloratadine tablets from Tier-3 to Tier-2 based on net cost; and
4. Updating the Tier-2 and Tier-3 approval criteria to lengthen the previous trial duration period based on the addition of new trial options in lower Tiers and to clarify the trial requirements for age-appropriate dosage formulations.

Oral Antihistamine Medications		
Tier-1⁺	**Tier-2**	**Tier-3**
OTC cetirizine (Zyrtec®) **sol, tab**	**desloratadine (Clarinex®) tab**	**cetirizine sol UDC**
OTC levocetirizine (Xyzal®) tab	OTC levocetirizine (Xyzal®)* **sol**	clemastine **syr, tab**
OTC loratadine (Claritin®) **ODT, sol, tab**		desloratadine (Clarinex®)¥ **ODT, sol**

⁺Tier-1 products are covered for pediatric members with no authorization necessary. OTC products are only covered for pediatric members.
*~~Xyzal® is only covered for members 0 to 20 years of age.~~ Xyzal® solution is available for children 6 months to 6 years of age.
¥An age restriction of 6 years to 11 years of age applies for Clarinex® ODT ~~RediTabs®~~.
ODT = orally disintegrating tablet; OTC = over-the-counter; sol = solution; syr = syrup; tab = tablet; UDC = unit-dose cup

Oral Antihistamine Medications Tier-2 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of all age-appropriate Tier-1 products within the last ~~30~~ 60 days; and
3. Approvals will be for the duration of 1 year.

Oral Antihistamine Medications Tier-3 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of all age-appropriate Tier-1 and Tier-2 products within the last ~~60~~ 90 days (unless no age-appropriate Tier-2 product exists); and
   a. Requests for cetirizine unit-dose cups (UDCs) will require a patient-specific, clinically significant reason why the member cannot use cetirizine bulk solution, which is available without a prior authorization; and
3. Approvals will be for the duration of 1 year.

Utilization Details of Systemic Antihistamine Medications:
Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CETIRIZINE PRODUCTS						
CETIRIZINE SOL 1MG/ML	75,953	37,786	$1,195,674.02	$15.74	2.01	48.16%
CETIRIZINE TAB 10MG	55,952	25,172	$632,109.03	$11.30	2.22	25.46%
CETIRIZINE SOL 5MG/5ML	10,404	6,031	$162,137.11	$15.58	1.73	6.53%
CETIRIZINE TAB 5MG	2,944	1,401	$34,441.24	$11.70	2.1	1.39%
ALL DAY ALLG SOL 1MG/ML	2,742	1,523	$68,184.94	$24.87	1.8	2.75%
ALLERGY REL TAB 10MG	2,488	1,052	$30,437.19	$12.23	2.37	1.23%
ALLERGY REL SOL 1MG/ML	735	480	$10,389.32	$14.14	1.53	0.42%
ALL DAY ALLG SOL 5MG/5ML	417	248	$6,476.51	$15.53	1.68	0.26%
FT ALLG CHILD SOL 1MG/ML	269	177	$3,914.36	$14.55	1.52	0.16%
ALLERGY REL TAB 5MG	105	51	$1,315.81	$12.53	2.06	0.05%
FT ALLERGY TAB 10MG	57	38	$718.70	$12.61	1.5	0.03%
ALL DAY ALLG TAB 10MG	54	33	$732.39	$13.56	1.64	0.03%
GNP ALL DAY TAB ALLG	8	7	$116.60	$14.58	1.14	0.00%
CETIRIZINE CHW 10MG	1	1	$77.61	$77.61	1	0.00%
CETIRIZINE CHW 5MG	1	1	$139.06	$139.06	1	0.01%
SUBTOTAL	**152,130**	**74,001**	**$2,146,863.89**	**$14.11**	**2.06**	**86.47%**
LORATADINE PRODUCTS						
LORATADINE TAB 10MG	11,592	4,885	$114,943.11	$9.92	2.37	4.63%
LORATADINE SOL 5MG/5ML	11,437	5,073	$164,428.58	$14.38	2.25	6.62%
ALLERGY CHILD SOL 5MG/5ML	390	186	$6,548.97	$16.79	2.1	0.26%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALLERGY REL LIQ CHILD	330	133	$5,259.74	$15.94	2.48	0.21%
ALLERGY REL TAB 10MG	277	107	$3,716.75	$13.42	2.59	0.15%
FT ALLERGY TAB 10MG	211	82	$2,393.78	$11.34	2.57	0.10%
ALLERGY REL SOL 5MG/5ML	86	63	$1,532.18	$17.82	1.37	0.06%
LORATADINE TAB 10MG	60	34	$1,588.98	$26.48	1.76	0.06%
SM ALLERGY SOL 5MG/5ML	3	1	$59.01	$19.67	3	0.00%
SUBTOTAL	**24,386**	**10,564**	**$300,471.10**	**$12.32**	**2.31**	**12.10%**
TIER-1 SUBTOTAL	**176,516**	**78,570***	**$2,447,334.99**	**$13.86**	**2.25**	**98.57%**
TIER-2 PRODUCTS						
LEVOCETIRIZINE PRODUCTS						
LEVOCETIRIZINE TAB 5MG	1,608	368	$20,710.47	$12.88	4.37	0.83%
LEVOCETIRIZINE SOL 2.5MG/5ML	472	130	$13,730.04	$29.09	3.63	0.55%
TIER-2 SUBTOTAL	**2,080**	**492***	**$34,440.51**	**$16.56**	**4.23**	**1.39%**
TIER-3 PRODUCTS						
DESLORATADINE PRODUCTS						
DESLORATADINE TAB 5MG	44	22	$887.08	$20.16	2	0.04%
DESLORATADINE TAB 2.5 ODT	1	1	$146.99	$146.99	1	0.01%
TIER-3 SUBTOTAL	**45**	**23***	**$1,034.07**	**$22.98**	**1.96**	**0.04%**
TOTAL	**178,641**	**78,940***	**$2,482,809.57**	**$13.90**	**2.26**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ALLG = allergy; CHW = chewable; LIQ = liquid; ODT = orally disintegrating tablet; REL = relief; SOL = solution; TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

[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 08/2026. Last accessed 08/14/2026.

Appendix U

Fiscal Year 2026 Annual Review of Benign Prostatic Hyperplasia (BPH) Medications

Oklahoma Health Care Authority
September 2026

Current Prior Authorization Criteria

Benign Prostatic Hyperplasia (BPH) Medications		
Tier-1	**Tier-2**	**Tier-3**
alfuzosin (Uroxatral®)	doxazosin (Cardura XL®)	tadalafil 5mg (Cialis®)
doxazosin (Cardura®)	dutasteride/tamsulosin (Jalyn®)	finasteride 5mg/ tadalafil 5mg (Entadfi®)*
dutasteride (Avodart®)	silodosin (Rapaflo®)	terazosin (Tezruly™) oral solution*
finasteride (Proscar®)		
tamsulosin (Flomax®)		
terazosin (Hytrin®)		

*Unique criteria applies

BPH Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A 4-week trial of 2 Tier-1 medications from different pharmacological classes within the past 90 days; or
3. Documented adverse effect, drug interaction, or contraindication to all available Tier-1 medications.

BPH Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH); and
2. A 4-week trial of at least 2 Tier-1 medications from different pharmacological classes; and
3. A 4-week trial of all Tier-2 medications within the past 5 months; or
4. Documented adverse effect, drug interaction, contraindication, or lack of efficacy to all available Tier-1 and Tier-2 medications; and
5. Authorizations for Cialis® (tadalafil) will be granted for the 5mg tablets only.

Entadfi® (Finasteride 5mg/Tadalafil 5mg) Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH); and
2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and

3. A patient-specific, clinically significant reason why the member cannot use the individual components (finasteride and tadalafil) must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply; and
5. Maximum treatment duration of 26 weeks will apply.

Tezruly™ (Terazosin Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH) or hypertension (HTN); and
2. A patient specific, clinically significant reason why the member cannot use terazosin capsules must be provided; and
3. For a diagnosis of BPH, a patient specific, clinically significant reason why the member cannot use Rapaflo® (silodosin), which may be opened and sprinkled on applesauce for patients with difficulties swallowing, must be provided; and
4. A quantity limit of 600mL per 30 days will apply.

Utilization of BPH Medications: Fiscal Year 2026

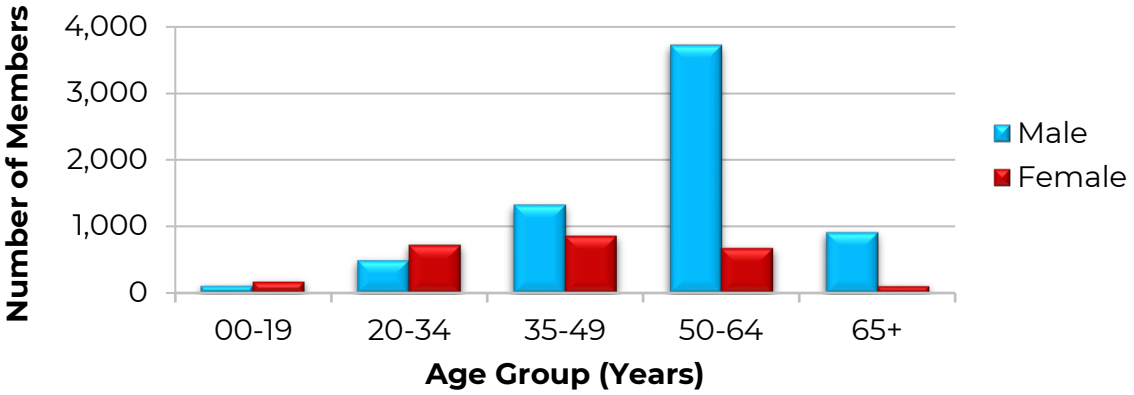
The following utilization data includes BPH medications used for all diagnoses and does not differentiate between a BPH diagnosis and other diagnoses, for which use may be appropriate. Tier-1 medications are available without prior authorization.

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

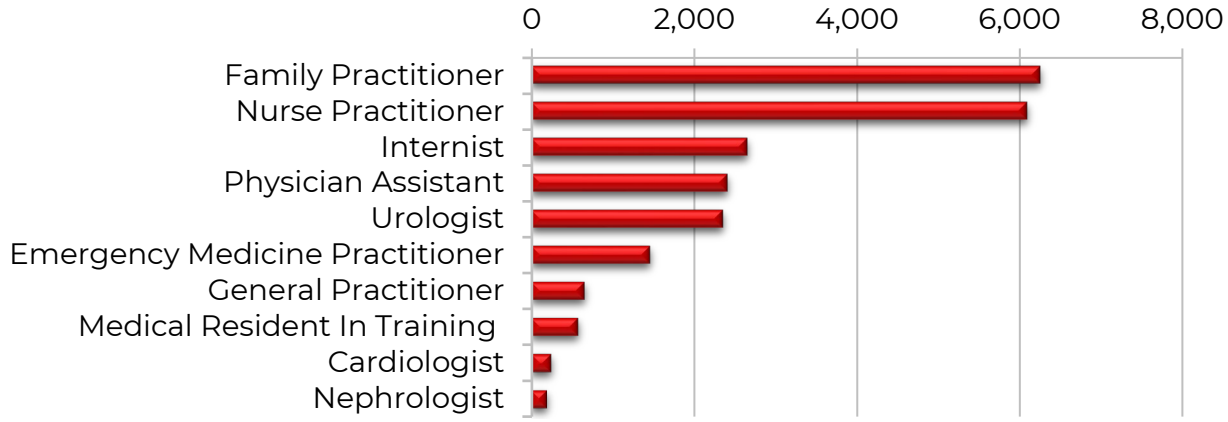
Plan Type	Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2025							
FFS	4,153	12,263	$162,597.83	$13.26	$0.28	649,035	576,420
Aetna	1,452	2,985	$44,656.07	$14.96	$0.28	172,662	158,696
Humana	1,965	4,446	$65,707.15	$14.78	$0.28	258,383	235,174
OCH	1,466	2,821	$42,749.48	$15.15	$0.26	175,843	161,920
2025 Total	**8,483**	**22,515**	**$315,710.53**	**$14.02**	**$0.28**	**1,255,923**	**1,132,210**
Fiscal Year 2026							
FFS	4,470	12,935	$218,776.14	$16.91	$0.37	663,070	594,961
Aetna	1,579	3,225	$48,055.38	$14.90	$0.27	194,926	176,547
Humana	2,035	4,611	$68,674.01	$14.89	$0.27	278,038	249,952
OCH	1,680	3,294	$49,208.68	$14.94	$0.26	204,236	186,319
2026 Total	**9,105**	**24,065**	**$384,714.21**	**$15.99**	**$0.32**	**1,340,270**	**1,207,779**
% Change	**7.30%**	**6.90%**	**21.90%**	**14.10%**	**14.30%**	**6.70%**	**6.70%**
Change	**622**	**1,550**	**$69,003.68**	**$1.97**	**$0.04**	**84,347**	**75,569**

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 2025 = 07/01/2024 to 06/30/2025; Fiscal Year 2026 = 07/01/2025 to 06/30/2026

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



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



Prior Authorization of BPH Medications

There were 404 prior authorization requests submitted for BPH medications during fiscal year 2026. The following charts show the status of the submitted petitions for fiscal year 2026.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	38	35%	46	43%	24	22%	**108**
Aetna	0	0%	9	9%	87	91%	**96**
Humana	2	2%	42	44%	52	54%	**96**
OCH	5	5%	60	58%	39	38%	**104**
Total:	**45**	**11%**	**157**	**39%**	**202**	**50%**	**404**

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

Recommendations

The College of Pharmacy does not recommend any changes to the BPH Medications Product Based Prior Authorization (PBPA) category at this time.

Utilization Details of BPH Medications: Fiscal Year 2026

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
TAMSULOSIN CAP 0.4MG	18,137	7,697	$280,446.81	$15.46	2.36	72.90%
FINASTERIDE TAB 5MG	2,108	745	$38,132.39	$18.09	2.83	9.91%
DOXAZOSIN TAB 2MG	780	251	$10,290.06	$13.19	3.11	2.67%
DOXAZOSIN TAB 4MG	704	220	$14,635.92	$20.79	3.2	3.80%
ALFUZOSIN TAB 10MG ER	387	176	$6,267.19	$16.19	2.2	1.63%
DOXAZOSIN TAB 1MG	379	130	$5,610.34	$14.80	2.92	1.46%
DUTASTERIDE CAP 0.5MG	314	108	$6,152.55	$19.59	2.91	1.60%
DOXAZOSIN TAB 8MG	214	71	$3,210.56	$15.00	3.01	0.83%
TERAZOSIN CAP 1MG	208	81	$3,328.18	$16.00	2.57	0.87%
TERAZOSIN CAP 2MG	172	67	$3,160.65	$18.38	2.57	0.82%
TERAZOSIN CAP 5MG	139	52	$2,521.40	$18.14	2.67	0.66%
TERAZOSIN CAP 10MG	86	30	$1,632.12	$18.98	2.87	0.42%
SUBTOTAL	**23,628**	**9,628**	**$375,388.17**	**$15.89**	**2.45**	**97.58%**
TIER-2 UTILIZATION						
SILODOSIN CAP 8MG	73	20	$1,997.92	$27.37	3.65	0.52%
SILODOSIN CAP 4MG	40	13	$927.67	$23.19	3.08	0.24%
DUTAST/TAMSU CAP 0.5/0.4 MG	12	4	$1,682.51	$140.21	3	0.44%
CARDURA XL TAB 4MG	1	1	$210.67	$210.67	1	0.05%
SUBTOTAL	**126**	**38**	**$4,818.77**	**$38.24**	**3.32**	**1.25%**
TIER-3 UTILIZATION						
TADALAFIL TAB 5MG	311	169	$4,507.27	$1.84	0.51	1.17%
SUBTOTAL	**311**	**169**	**$4,507.27**	**$1.84**	**1.84**	**1.17%**
TOTAL	**24,065**	**9,105***	**$384,714.21**	**$15.99**	**2.64**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DUTAST/TAMSU = dutasteride/tamsulosin; ER = extended-release; TAB = tablet
Fiscal Year 2026 = 07/01/2025 to 06/30/2026

Appendix V

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: August 28, 2026

FDA Approves First Drug of Its Kind for Polycythemia Vera, a Rare Blood Disorder

The FDA approved Mimrylo™ (rusfertide), a new treatment for adults with polycythemia vera, a rare blood disorder that causes the body to make too many red blood cells. The excess cells can thicken the blood and increase the risk of cardiovascular issues, such as blood clots, stroke and heart attack.

Mimrylo™ offers a new treatment approach for patients whose disease has not been adequately controlled with existing therapies. It is the first approved treatment for polycythemia vera that mimics hepcidin, a hormone that naturally regulates iron in the body. By limiting the iron available to make new red blood cells, Mimrylo™ helps reduce their overproduction and keep red blood cell levels under control. This novel approach offers a new option for patients who have not achieved adequate control with existing therapies.

A key goal of treatment for polycythemia vera is keeping the proportion of hematocrit below 45% to reduce cardiovascular risks. This often requires phlebotomy, a procedure that removes blood from a vein to lower the number of red blood cells in the body. However, some patients continue to need frequent phlebotomies despite treatment, creating an ongoing burden. The safety and efficacy of Mimrylo™ were evaluated in the VERIFY trial, a multicenter, randomized, double-blind, placebo-controlled phase 3 study of 293 adults with polycythemia vera who required frequent phlebotomies despite ongoing standard-of-care therapy. Patients were randomized 1:1 to receive either Mimrylo™ or placebo over 32 weeks. Mimrylo™ treatment started at 19 mg, administered subcutaneously once weekly, and was titrated to maintain hematocrit levels below 45%.

Efficacy was measured by the proportion of patients who did not meet criteria for phlebotomy between weeks 20 and 32 of the study. Overall, 76.9% of patients on Mimrylo™ required no phlebotomies during the 32-week period compared to 32.9% on placebo. The most common adverse reactions were injection site reactions and anemia.

Mimrylo™ received priority review. The approval was granted to Takeda Pharmaceuticals America, Inc.

FDA NEWS RELEASE

For Immediate Release: August 27, 2026

FDA Approves First Oral Drug Indicated to Treat Dermatomyositis in Adults

The FDA approved Lisraya™ (brepocitinib) tablets for the treatment of dermatomyositis in adults. For decades, dermatomyositis patients have had limited treatment options to manage their symptoms. The approval of Lisraya™ offers patients an important new alternative by providing an effective oral treatment option.

Dermatomyositis is a rare autoimmune disease in which the immune system attacks the muscles and skin, causing chronic inflammation, progressive muscle weakness, and distinctive skin rashes. Lisraya™ is a once-daily oral tablet that works as a Janus kinase (JAK/TYK2) inhibitor. By blocking JAK pathways, which play a key role in the body's immune and inflammatory responses, Lisraya™ helps reduce the harmful inflammation that damages the muscles and skin, offering an effective new option for disease control.

The efficacy and safety of Lisraya™ were evaluated in a phase 3 randomized, double-blind, multicenter, placebo-controlled study (NCT05437263) that included 241 adults with dermatomyositis. Participants were randomized to receive Lisraya™ (brepocitinib) 30 mg once daily, brepocitinib 15 mg once daily, or placebo for a 52-week treatment period. The study measured Total Improvement Score (TIS) at week 52, a standardized scoring tool that tracks changes across six areas (muscle strength, physical function, skin and other disease activity, muscle enzymes, and both physician and patient assessments of overall health) to assess how much a patient’s dermatomyositis has improved.

Participants treated with Lisraya™ 30 mg had a higher average TIS score indicating greater clinical response and disease control at week 52 compared to those who received a placebo. They also showed improvements in physical function and skin disease activity and were more likely to reduce corticosteroid use by week 48.

Some of the most common adverse reactions to Lisraya™ were upper respiratory tract infection, headache, fatigue, urinary tract infection, and nausea. Discontinuation due to adverse reactions occurred in 6% of participants treated with Lisraya™ 30 mg, compared with 11% of those given a placebo. Lisraya™ carries a boxed warning for serious infections, increased all-cause mortality, malignancies, major adverse cardiovascular events, and thrombosis.

The FDA granted Lisraya™ Orphan Drug and Priority Review designations. The approval of Lisraya™ for the treatment of dermatomyositis was granted to Priovant Therapeutics Inc.

FDA NEWS RELEASE

For Immediate Release: August 26, 2026

FDA Approves First in Class Targeted Therapy for Metastatic Pancreatic Cancer

The FDA approved Rasonque™ (daraxonrasib), a RAS inhibitor for the most common form of pancreatic cancer—delivering a new treatment option to patients with advanced pancreatic cancer months ahead of schedule.

This action demonstrates the agency's commitment to moving with urgency, reducing unnecessary delays and advancing innovative treatments that can make a meaningful difference in the lives of American patients and their families.

Rasonque™, a tablet taken once daily, targets multiple forms of a protein called RAS, a key driver of tumor growth in most patients with pancreatic adenocarcinoma, which arises from cells lining the ducts of the pancreas.

The approval is for the treatment of adults with metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or are not candidates for multiagent systemic therapy.

Approximately 90% to 95% of the 67,000 new cases of pancreatic cancer diagnosed in the United States each year are pancreatic adenocarcinoma, according to the National Cancer Institute. Despite representing roughly 3.2% of all cancer diagnoses, pancreatic adenocarcinoma accounts for a disproportionately high share of cancer deaths, owing to its typically late detection, aggressive disease course, and historically limited treatment options.

In a randomized, open-label, multicenter clinical trial involving 500 adults with previously treated metastatic pancreatic adenocarcinoma, Rasonque™ improved median overall survival to 13.2 months compared to 6.7 months for standard chemotherapy.

The FDA granted Rasonque™ Breakthrough Therapy and Orphan Drug designations. Rasonque™ received Priority Review for this indication. The application was also reviewed under the Commissioner's National Priority Voucher pilot program, which is intended to help accelerate the review of therapies that address national public health priorities.

In May, the FDA issued a "safe to proceed" letter allowing the sponsor to initiate an expanded access treatment protocol for Rasonque™, enabling patient access to the investigational drug prior to approval under applicable FDA regulations.

The most common side effects of the drug are rash, diarrhea, stomatitis, nausea, fatigue, vomiting, abdominal pain, edema, decreased appetite, and hemorrhage.

The FDA granted the approval to Revolution Medicines, Inc.

FDA NEWS RELEASE

For Immediate Release: August 19, 2026

FDA Approves First Therapy for Patients aged 8 years and older with Glycogen Storage Disease Type Ia

The FDA issued an accelerated approval for Genglycos™ (pariglasgene brecaparvovec-opnr) to reduce daily cornstarch intake as an adjunct to nutritional management in adults and pediatric patients 8 years of age and older with glycogen storage disease type Ia (GSDIa), a rare, inherited genetic disorder caused by a deficiency of the enzyme glucose-6-phosphatase, which prevents the body from properly breaking down stored glycogen into glucose. Genglycos™ is the first approved treatment for this condition.

The accelerated approval pathway allows the FDA to approve certain drugs or biologics intended to treat a serious or life-threatening disease or condition if the agency determines the treatment influences a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit.

The agency based this accelerated approval on clinical trial data showing Genglycos™ helps reduce daily cornstarch intake, when taken with an appropriate diet. Reducing cornstarch intake is the surrogate endpoint, and the manufacturer must complete additional clinical trials to confirm the effectiveness of Genglycos™.

GSDIa is caused by a genetic mutation that results in a missing enzyme called glucose-6-phosphatase (G6PC). This enzyme normally releases free glucose from the liver and kidneys into the bloodstream, helping to maintain stable blood sugar levels during fasting and between meals. This enzyme deficiency causes the blood sugar to drop dangerously low whenever a person goes too long without eating. The condition can lead to long-term metabolic complications that can impair normal function in certain organs and tissues. GSDIa is typically managed through careful medical monitoring, frequent meals, avoidance of certain foods containing simple sugars, and daily, strict, around-the-clock dietary supplementation of uncooked or specially formulated cornstarch to prevent hypoglycemia.

Genglycos™ is a one-time adeno-associated virus 8 based gene therapy designed to deliver a functional G6PC gene to the liver, aiming to restore the deficient enzyme required to release stored glucose and ensure stable blood sugar levels when a person is fasting.

The effectiveness of Genglycos™ was evaluated in a randomized, double-blind, placebo-controlled study in patients with GSDIa followed over 48 weeks after dosing. Patients treated with Genglycos™ demonstrated a statistically significant mean reduction from baseline in daily cornstarch intake of 31% compared to placebo, the study's primary endpoint. A mean reduction from baseline of one cornstarch dose per day was seen in the Genglycos™ group compared to placebo, the study's secondary endpoint. Genglycos™-treated patients experienced a numerical (mean 3%) increase in

the percentage of glucose values in the hypoglycemic range (< 70 mg/dL) compared to placebo.

Across two clinical studies of Genglycos™ including the randomized clinical study, serious adverse reactions reported in Genglycos™-treated patients included anaphylaxis, adrenal insufficiency, high lactate levels, and hypoglycemia. The most commonly reported adverse reactions included increased transaminases, nausea, headache, constipation, and hyperglycemia. Genglycos™-treated patients had a higher rate of hypertriglyceridemia, a metabolic marker of GSDIa, compared to placebo-treated patients (29% vs 8%). The prescribing information contains warnings about the risks of anaphylaxis, liver toxicity, adrenal insufficiency, and risk of tumorigenicity. Genglycos™ should not be used during pregnancy.

The application for Genglycos™ received a Rare Pediatric Disease Priority Review Voucher. The FDA granted Genglycos™ regenerative medicine advanced therapy (RMAT) and Fast Track designations.

The FDA granted accelerated approval of Genglycos™ to Ultragenyx Pharmaceutical, Inc.

FDA NEWS RELEASE

For Immediate Release: August 6, 2026

FDA Approves New Engineered Viral Immunotherapy for Patients with Treatment-Resistant Advanced Melanoma

The FDA granted accelerated approval to Tudriqev™ (vusolimogene oderparepvec-wtpg), a genetically modified oncolytic viral therapy for the treatment of advanced, refractory melanoma. Tudriqev™ is indicated in combination with nivolumab for the treatment of adult patients with unresectable advanced cutaneous melanoma who experienced disease progression with a programmed death receptor-1 (PD-1)-blocking antibody-based regimen.

The approval is supported by data from a clinical trial showing that 1 in 4 patients responded to treatment, with responses lasting a median of nearly 14 months, offering clinicians a meaningful new tool for a patient population. In reaching this decision, the FDA also considered input from clinical experts and patient advocates who emphasized the urgent need for effective options in this refractory population.

Anti-PD-1 refractory melanoma is advanced skin cancer that no longer responds to a widely used class of immunotherapy drugs. Despite treatment, the cancer may continue to grow because of developed mechanisms to evade the immune system's ability to detect and destroy it.

Tudriqev™ is an oncolytic viral therapy based on a modified herpes simplex virus type 1 (HSV-1) that is engineered to selectively target and destroy cancer cells. Once inside a tumor, the virus replicates and breaks cancer cells apart, while simultaneously triggering the body's immune system to recognize and attack the cancer. When used in combination with

nivolumab, an anti-PD-1 immunotherapy, Tudriqev™ may help restore an anti-tumor immune response in patients whose cancer had previously stopped responding to immunotherapy.

Tudriqev™ is injected directly into tumors once every 2 weeks for 8 consecutive doses, with the dosage amount determined by the size of the tumor. A lower concentration is used for the first dose, followed by a higher concentration for all remaining doses. A second drug, nivolumab, is given intravenously beginning at week 3 of treatment.

The safety and effectiveness of Tudriqev™ were evaluated in an open-label, multiregional, single-arm trial enrolling 140 adult patients with Stage IIIB, IIIC or IV unresectable advanced melanoma who experienced disease progression on at least 8 consecutive weeks of prior anti-PD-1-based therapy. In the trial, 91 patients were evaluated and 24% of patients achieved an objective response. Responses had a median duration of 14.1 months.

The most common adverse reactions reported in more than 10% of patients were fatigue, fever, infections, chills, musculoskeletal pain, nausea, diarrhea, injection site reaction, headache, cough, influenza-like illness, rash, vomiting, itching, arthralgia, constipation, decreased appetite, dizziness, dyspnea, hemorrhage, edema, and abdominal pain. Important safety warnings include the risk of accidentally spreading a herpes infection to close contacts, the possibility of a herpes infection developing or reactivating in the patient, and complications related to injection procedure.

On July 30, 2026, the FDA convened the Cellular, Tissue, and Gene Therapies Advisory Committee Meeting for this application. The meeting included a public hearing section to hear from patients, patient advocates, clinicians and independent experts and a session for discussion and deliberation among committee members. The application was granted Breakthrough Therapy and Priority Review designations.

FDA granted the approval of Tudriqev™ to Replimune, Inc. The approval is granted under the FDA's accelerated approval pathway based on objective response rate and duration of response. As a condition of accelerated approval, Replimune, Inc., is required to conduct post-approval trial(s) to verify and describe the clinical benefit of Tudriqev™. Continued approval may be contingent upon verification of clinical benefit in confirmatory trial(s).

FDA NEWS RELEASE

For Immediate Release: August 5, 2026

FDA Approves First Drug to Treat the Full Range of Narcolepsy Type 1 Symptoms

The FDA approved Orzeyful™ (oveporexton) tablets for the treatment of narcolepsy type 1 in adults. Orzeyful™ is the first medicine approved for narcolepsy type 1 as a complete disorder — addressing the full range of

symptoms that define the condition — and the first to work by directly targeting the loss of orexin signaling that causes the disease.

Narcolepsy type 1 is a rare, lifelong neuropsychiatric sleep disorder affecting an estimated 1 in 2,000 people in the United States. It is caused by the loss of brain cells that produce orexin, a chemical messenger that regulates wakefulness, sleep, and muscle tone. Without orexin, the brain struggles to maintain alertness or to control the boundary between sleep and waking. The result is a cluster of disabling symptoms, including excessive daytime sleepiness, cataplexy, sleep paralysis, hallucinations at the edge of sleep or waking, and disrupted nighttime sleep. Until today, no medicine had been approved for narcolepsy type 1 as a unified disorder, and none acted on the orexin system.

Rather than masking symptoms with stimulants or sedatives, Orzeyful™ directly activates the same brain receptor that the body's own orexin would normally stimulate, restoring the missing signal. The medicine is taken as an oral tablet twice daily.

The effectiveness and safety of Orzeyful™ were evaluated in 2 randomized, double-blind, placebo-controlled 12-week studies enrolling 273 adults with narcolepsy type 1. Across both studies, patients taking Orzeyful™ 2mg showed improvements in their ability to stay awake during the day compared with those receiving placebo. Patients also reported substantially less daytime sleepiness, a significant reduction in cataplexy episodes, and meaningful improvement across the full spectrum of narcolepsy symptoms, including sleep paralysis, hallucinations, and disrupted nighttime sleep.

The most common side effects were insomnia, increased urinary frequency, urgency to urinate, and increased saliva production. The rate of participants stopping treatment due to side effects was low. Patients should inform their healthcare professionals about all medicines they are currently taking, as Orzeyful™ should not be used at the same time as strong CYP3A inhibitors. The safety and effectiveness of Orzeyful™ have not been established in patients under 18 years of age. Orzeyful™ has been recommended for scheduling under the Controlled Substances Act and will be lawful to market following the scheduling decision issued by the Drug Enforcement Agency (DEA).

Orzeyful™ received Breakthrough Therapy designation and Priority Review.

The approval of Orzeyful™ for the treatment of narcolepsy type 1 was granted to Takeda Pharmaceuticals America, Inc.

FDA NEWS RELEASE

For Immediate Release: July 29, 2026

FDA Licenses First-Ever Freeze-Dried Plasma Product in the U.S.

The FDA licensed Ezplaz™ Freeze Dried Plasma (FDP), making it the first FDP product licensed for use in the United States. Ezplaz™ is intended

for transfusion in adult patients who need plasma and for whom other plasma products are not available.

Ezplaz™ is a FDP product derived from a single unit of fresh frozen plasma collected from FDA-licensed blood establishments. It is available in Group AB and Group A with low-titer anti-B blood types, chosen to mitigate risk of giving to patients in emergencies before their blood type is determined.

Unlike conventional plasma products that must be stored frozen and thawed before use, Ezplaz™ can be stored at room temperature, is stable after exposure to temperature fluctuations, and is rapidly reconstituted. It is packaged in a plastic bag rather than a glass bottle, reducing the risk of breakage during handling and transport. The FDA expects that these features will make the use of Ezplaz™ compatible with austere environments, potentially including combat zones, remote areas, and disaster response settings.

Ezplaz™ is indicated for transfusion in adults when plasma is required and other plasma products are not available, including bleeding patients, patients needing massive transfusion, or certain patients on warfarin who are bleeding.

Each Ezplaz™ kit is a complete, self-contained package containing: 1 unit of FDP sealed in an outer foil pouch, one 250 mL bag of sterile water for injection, 1 sterile fluid transfer set, and 1 sterile blood transfusion set.

FDP was among the first products identified under Public Law 115-92, enacted in December 2017, which authorized the DoD (now DoW)-FDA collaboration for assistance to expedite the development and review of products for serious or life-threatening conditions facing American military personnel. Accordingly, the FDA-issued guidance in 2019 to assist manufacturers developing dried plasma products for transfusion.

For uses of Ezplaz™ that are approved under the license, the FDA has found that the benefits of Ezplaz™ transfusion outweigh the risks. The safety profile of Ezplaz™ is consistent with other plasma products used for transfusion. As with all plasma products, patients and healthcare providers should be aware of risks associated with transfusion. Healthcare providers should review the full prescribing information before use.

The FDA granted the biologics license to Vascular Solutions, LLC, a subsidiary of Teleflex.

FDA NEWS RELEASE

For Immediate Release: July 22, 2026

FDA Announces First Participant Selected for TEMPO for Digital Health Devices Pilot

The FDA announced the first manufacturer selected for the Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot. The participating manufacturer intends to offer a device

for use in providing care expected to be covered by the Centers for Medicare & Medicaid Services (CMS) Innovation Center's ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model and intended to improve health outcomes for Americans managing certain chronic diseases.

The FDA selected Dexcom, Inc., as the first participant in the TEMPO pilot. The Dexcom Glucose Health Program, which the FDA will continue to evaluate for its intended use during the pilot, is intended to address 2 clinical use areas in the ACCESS Model.

The Dexcom Glucose Health Program is intended to enable patients aligned to the ACCESS model and their healthcare professionals or caregivers to monitor metabolic and nutritional status, receive tailored guidance, and access real-time data and AI insights for informed decision-making and behavioral modifications. The program is intended as an aid in the screening for prediabetes and type 2 diabetes through integrated digital health metrics. It may also contribute to improving glycemic control and lowering HbA1c in people with prediabetes.

Manufacturers participating in the TEMPO pilot will collect, monitor, and report real-world data (RWD) relating to the intended uses of their devices to improve patient outcomes, whether the device is offered by the manufacturer itself as an ACCESS participant or by another participating ACCESS organization. The TEMPO pilot will help the FDA and CMS better understand how digital health technologies perform in real-world settings and how they may support efforts to improve care for people living with chronic diseases.

The FDA plans to select up to about 10 TEMPO pilot participants in each of 4 ACCESS model clinical use areas who reflect a broad spectrum of manufacturers and are based in the United States. The FDA also intends to select participants in alignment with the TEMPO pilot's strategic goals of promoting patient access, safeguarding patient safety, and generating meaningful RWD in connection with the ACCESS model. The FDA's considerations include, among other things, potential risks to patient health, safety, or welfare; whether there is a reasonable expectation that the device could provide patient benefit; plans for RWD collection, monitoring, analysis, and reporting; and alignment with outcomes to be measured in the ACCESS model.

The FDA, in connection with the ACCESS model, launched the TEMPO pilot to align with the rapid and iterative nature of the development of digital health devices and expand patient access to innovative technologies for specific clinical use areas while safeguarding patient safety. The ACCESS model, whose first cohort began in July 2026, aims to expand access to new technology-supported care options, such as the use of devices selected for the TEMPO pilot, to help people improve their health and prevent and manage common chronic conditions, including certain cardio-kidney-metabolic, musculoskeletal, and behavioral health conditions.

The FDA continues to consider statements of interest for participation in the pilot and intends to continue sending follow-up requests to certain potential pilot participants. There is no specified deadline for when the FDA will stop accepting statements of interest for participation in the TEMPO pilot.

Current Drug Shortages Index (as of September 1, 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.

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***
Ifosfamide 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***
Penicillin G Benzathine Injection	***Currently in Shortage***
Pentostatin 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***
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***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***

Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***