OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
September 10, 2025
4:00pm

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

Viewing Access Only:
Please register for the webinar at:
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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 10, 2025

DATE: September 3, 2025

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

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

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Enclosed are the following items related to the 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

Impact of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators – Appendix C

Action Item – Vote to Prior Authorize Azmiro™ (Testosterone Cypionate) and Undecatrex™ (Testosterone Undecanoate) and Update the Approval Criteria for the Testosterone Products – Appendix D

Action Item – Vote to Prior Authorize Zevaskyn™ (Prademagene Zamikeracel) and Update the Approval Criteria for the Epidermolysis Bullosa (EB) Medications – Appendix E

Action Item – Vote to Prior Authorize Zunveyl® (Benzgalantamine) – Appendix F

Action Item – Vote to Prior Authorize Blujepa (Gepotidacin), Emblaveo™ (Aztreonam/Avibactam), Likmez™ (Metronidazole Oral Suspension), and Metronidazole 125mg Tablet and 375mg Capsule and Update the Approval Criteria for the Various Systemic Antibiotics – Appendix G

Action Item – Vote to Prior Authorize Tramadol 75mg Tablet and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications – Appendix H

Action Item – Vote to Update the Approval Criteria for the Topical Corticosteroids – Appendix I

Action Item – Vote to Prior Authorize Ryoncil® (Remestemcel-L-rknd) and Update the Approval Criteria for the Miscellaneous Cancer Medications – Appendix J

Action Item – Annual Review of Camzyos® (Mavacamten) – Appendix K

Action Item – Annual Review of Synagis® (Palivizumab) – Appendix L

Action Item – Annual Review of Jynarque® (Tolvaptan) – Appendix M

Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Datroway® (Datopotamab Deruxtecan-dlnk) and Itovebi™ (Inavolisib) – Appendix N

30-Day Notice to Prior Authorize Encelto™ (Revakinagene Taroretcel-lwey) – Appendix O

Annual Review of Hyperphosphatemia Medications and 30-Day Notice to Prior Authorize Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet – See Appendix P

Annual Review of Cystic Fibrosis (CF) Medications and 30-Day Notice to Prior Authorize Alyftrek™ (Vanzacaftor/Tezacaftor/Deutivicaftor) – Appendix Q

Annual Review of Amyloidosis Medications and 30-Day Notice to Prior Authorize Attruby™ (Acoramidis) – Appendix R

30-Day Notice to Prior Authorize Photrexa®/ Photrexa® Viscous (Riboflavin 5'-Phosphate) – Appendix S

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – September 10, 2025 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Haymore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Cassidy Blaiss –	participating in person
Mr. Kenneth Foster –	participating in person
Dr. Bret Haymore –	participating in person
Dr. Bethany Holderread –	participating in person
Dr. Matt John –	participating in person
Dr. Craig Kupiec –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Jennifer Weakley –	participating in person

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

Public Comment for Meeting:

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

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 9, 2025 DUR Board Meeting Minutes
   B. July 9, 2025 DUR Board Recommendations Memorandum
   C. August 13, 2025 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit – See Appendix B**
   A. Pharmacy Help Desk Activity for August 2025
   B. Medication Coverage Activity for August 2025

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

5. **Impact of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators – See Appendix C**
   A. Introduction
   B. CFTR Modulators
   C. CFTR Modulator Impact
   D. SoonerCare Impact
   E. Conclusions

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

6. **Action Item – Vote to Prior Authorize Azmiro™ (Testosterone Cypionate) and Undecatrex™ (Testosterone Undecanoate) and Update the Approval Criteria for the Testosterone Products – See Appendix D**
   A. Market News and Updates
   B. Product Summaries
   C. Cost Comparison: Testosterone Products
   D. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Zevaskyn™ (Prademagene Zamikeracel) and Update the Approval Criteria for the Epidermolysis Bullosa (EB) Medications – See Appendix E**
   A. Market News and Updates
   B. Zevaskyn™ (Prademagene Zamikeracel) Product Summary
   C. Cost Comparison: EB Medications
   D. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Zunveyl® (Benzgalantamine) – See Appendix F**
   A. Market News and Updates
   B. Cost Comparison: Benzgalantamine and Galantamine Products
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Blujepa (Gepotidacin), Emblaveo™ (Aztreonam/Avibactam), Likmez™ (Metronidazole Oral Suspension), and Metronidazole 125mg Tablet and 375mg Capsule and Update the Approval Criteria for the Various Systemic Antibiotics – See Appendix G**
   A. Market News and Updates
   B. Product Summaries
   C. Cost Comparison: Metronidazole Products
   D. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Tramadol 75mg Tablet and Update the Approval Criteria for the Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications – See Appendix H**
    A. Market News and Updates
    B. Cost Comparison: Tramadol
    C. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Update the Approval Criteria for the Topical Corticosteroids – See Appendix I**
    A. College of Pharmacy Recommendations

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

12. **Action Item – Vote to Prior Authorize Ryoncil® (Remestemcel-L-rknd) and Update the Approval Criteria for the Miscellaneous Cancer Medications – See Appendix J**
    A. Market News and Updates
    B. Ryoncil® (Remestemcel-L-rknd) Product Summary
    C. College of Pharmacy Recommendations

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

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

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

14. **Action Item – Annual Review of Synagis® (Palivizumab) – See Appendix L**
    A. Current Prior Authorization Criteria
    B. Utilization of Synagis® (Palivizumab)
    C. Prior Authorization of Synagis® (Palivizumab)
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Synagis® (Palivizumab)

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

15. **Action Item – Annual Review of Jynarque® (Tolvaptan) – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Jynarque® (Tolvaptan)
    C. Prior Authorization of Jynarque® (Tolvaptan)
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of Jynarque® (Tolvaptan)

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

16. **Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Datroway® (Datopotamab Deruxtecan-dlnk) and Itovebi™ (Inavolisib) – See Appendix N**
    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:

17. **30-Day Notice to Prior Authorize Encelto™ (Revakinagene Taroretcel-lwey) – See Appendix O**
    A. Introduction
    B. Encelto™ (Revakinagene Taroretcel-lwey) Product Summary
    C. College of Pharmacy Recommendations

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

18. **Annual Review of Hyperphosphatemia Medications and 30-Day Notice to Prior Authorize Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet – See Appendix P**
    A. Current Prior Authorization Criteria
    B. Utilization of Hyperphosphatemia Medications
    C. Prior Authorization of Hyperphosphatemia Medications
    D. Market News and Updates
    E. Cost Comparison: Lanthanum Carbonate Products
    F. College of Pharmacy Recommendations
    G. Utilization Details of Hyperphosphatemia Medications

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

19. **Annual Review of Cystic Fibrosis (CF) Medications and 30-Day Notice to Prior Authorize Alyftrek™ (Vanzacaftor/Tezacaftor/Deutivicaftor) – See Appendix Q**
    A. Current Prior Authorization Criteria
    B. Utilization of CF Medications
    C. Prior Authorization of CF Medications
    D. Market News and Updates
    E. Alyftrek™ (Vanzacaftor/Tezacaftor/Deutivicaftor) Product Summary
    F. College of Pharmacy Recommendations
    G. Utilization Details of CF Medications

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

20. Annual Review of Amyloidosis Medications and 30-Day Notice to Prior Authorize Attruby™ (Acoramidis) – See Appendix R

A. Current Prior Authorization Criteria
B. Utilization of Amyloidosis Medications
C. Prior Authorization of Amyloidosis Medications
D. Market News and Updates
E. Attruby™ (Acoramidis) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Amyloidosis Medications

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

21. 30-Day Notice to Prior Authorize Photrexa®/Photrexa® Viscous (Riboflavin 5'-phosphate) – See Appendix S

A. Introduction
B. Photrexa®/Photrexa® Viscous (Riboflavin 5'-phosphate) Product Summary
C. College of Pharmacy Recommendations

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

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

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

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

A. Anticoagulants and Platelet Aggregation Inhibitors
B. Allergen Immunotherapies
C. Anemia Medications
D. *Clostridium difficile (C. difficile*) Medications
E. Cushing's Disease Medications
F. Hereditary Angioedema (HAE) Medications
G. Myeloproliferative Neoplasm Medications
H. Ophthalmic Anti-Inflammatory Products
I. Targeted Immunomodulator Agents

*Future product and class reviews subject to change.

24. Adjournment

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

NOTE: Oklahoma Medicaid transitioned from a fee-for-service (FFS) pharmacy benefit to a managed care pharmacy benefit for most members on April 1, 2024. At

that time, the majority of SoonerCare members were transitioned to one of the three managed care SoonerSelect plans: Aetna, Humana, or Oklahoma Complete Health. SoonerSelect data has been provided to the College of Pharmacy and has been used in analyses throughout this DUR Board meeting packet. The data included in this DUR Board meeting packet combines FFS and managed care utilization data. The managed care utilization and prior authorization (PA) data reported in this packet is based solely on the data provided by the SoonerSelect plans. SoonerSelect PA data only includes medications billed as pharmacy claims (NDC) and does not include those billed as medical claims (HCPCS), where applicable.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING JULY 9, 2025

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

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

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

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

OTHERS PRESENT:	
Jennifer Lauper, Bristol Myers Squibb	JJ Roth, Mirum
Bobby White, Eisai	Kellie Vazzana, Alkermes
Thonda Clark, Indivior	Glenn Cornish, Alkermes
Bryan Steffan, Boehringer	Eardie Curry, Genentech
Kristen Winters, Centene	David Prather, Novo Nordisk
Brent Parker, Merck	Kenneth Berry, Alkermes
Rodney Brown, Genentech	Andi Stratton, Krystal Biotech
Lee Stout, Chiesi	David Large, Chiesi
Irene Chung, Aetna	Matt John, Otsuka
Patrick O'Neal, Millicent Pharma	David Mendoza, Otsuka
Andy Berg, Audaire Health	Christopher Fields, Abeona Therapeutics
Jenna Doerr, Artia Solutions	Marc Parker, VS Health Group
Rick Ludwico, Mayne Pharmaceuticals	Mark Kaiser, Otsuka

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**
ACTION: NONE REQUIRED

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

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT**
4A: PHARMACY HELPDESK ACTIVITY FOR JUNE 2025
4B: MEDICATION COVERAGE ACTIVITY FOR JUNE 2025
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: INTRODUCTION
5B: CONCLUSIONS
Materials included in agenda packet; presented by Dr. Travers
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE COBENFY™ (XANOMELINE/TROSPIUM), ERZOFRI® [PALIPERIDONE PALMITATE EXTENDED-RELEASE (ER) INJECTION], AND OPIPZA™ (ARIPIPRAZOLE ORAL FILM) AND**

UPDATE THE APPROVAL CRITERIA FOR THE ATYPICAL ANTIPSYCHOTIC MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: COBENFY™ (XANOMELINE/TROSPIUM) PRODUCT SUMMARY
6C: COST COMPARISONS
6D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE BUCAPSOL™ (BUSPIRONE CAPSULE), CARBAMAZEPINE 200MG CHEWABLE TABLET, FEMLYV™ [NORETHINDRONE ACETATE/ETHINYL ESTRADIOL ORALLY DISINTEGRATING TABLET (ODT)], FOCINVEZ™ (FOSAPREPITANT INJECTION), IMKELDI (IMATINIB ORAL SOLUTION), IVRA (MELPHALAN 90MG/ML INJECTION), MYHIBBIN™ (MYCOPHENOLATE MOFETIL ORAL SUSPENSION), ONDANSETRON 16MG ODT, TEZRULY™ (TERAZOSIN ORAL SOLUTION), TOPIRAMATE 50MG SPRINKLE CAPSULE, VELTASSA® (PATIROMER) 1G POWDER PACKET, AND VIGAFYDE™ (VIGABATRIN ORAL SOLUTION) AND UPDATE THE APPROVAL CRITERIA FOR THE VARIOUS SPECIAL FORMULATIONS
7A: INTRODUCTION
7B: PRODUCT SUMMARIES AND COLLEGE OF PHARMACY RECOMMENDATIONS
7C: COLLEGE OF PHARMACY ADDITIONAL RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Muñoz moved to approve; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE AVMAPKI™ FAKZYNJA™ CO-PACK (AVUTOMETINIB AND DEFACTINIB) AND UPDATE THE APPROVAL CRITERIA FOR THE GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
8A: MARKET NEWS AND UPDATES
8B: AVMAPKI™ FAKZYNJA™ CO-PACK (AVUTOMETINIB AND DEFACTINIB) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Muñoz moved to approve; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF COLORECTAL CANCER (CRC) MEDICATIONS
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF CRC MEDICATIONS
9C: PRIOR AUTHORIZATION OF CRC MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: COLLEGE OF PHARMACY RECOMMENDATIONS
9F: UTILIZATION DETAILS OF CRC MEDICATIONS
Non-presentation item; materials included in agenda packet by Dr. Sinko
ACTION: NONE REQUIRED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF DEFENCATH® (TAUROLIDINE/HEPARIN)
10A: CURRENT PRIOR AUTHORIZATION CRITERIA

10B: UTILIZATION OF DEFENCATH® (TAUROLIDINE/HEPARIN)
10C: PRIOR AUTHORIZATION OF DEFENCATH® (TAUROLIDINE/HEPARIN)
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF DEFENCATH® (TAUROLIDINE/HEPARIN)
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF CONSTIPATION AND DIARRHEA MEDICATIONS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
11C: PRIOR AUTHORIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF CONSTIPATION AND DIARRHEA MEDICATIONS
Materials included in agenda packet; presented by Dr. DeRemer
Dr. Muñoz moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF TESTOSTERONE PRODUCTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AZMIRO™ (TESTOSTERONE CYPIONATE 200MG/ML SYRINGE) AND UNDECATREX™ (TESTOSTERONE UNDECANOATE CAPSULE)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF TESTOSTERONE PRODUCTS
12C: PRIOR AUTHORIZATION OF TESTOSTERONE PRODUCTS
12D: MARKET NEWS AND UPDATES
12E: COST COMPARISON
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF TESTOSTERONE PRODUCTS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 13: ANNUAL REVIEW OF EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZEVASKYN™ (PRADEMAGENE ZAMIKERACEL)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF EB MEDICATIONS
13C: PRIOR AUTHORIZATION OF EB MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: ZEVASKYN™ (PRADEMAGENE ZAMIKERACEL) PRODUCT SUMMARY
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF EB MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ALZHEIMER'S DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ZUNVEYL® (BENZGALANTAMINE)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
14C: PRIOR AUTHORIZATION OF ALZHEIMER'S DISEASE MEDICATIONS

14D: MARKET NEWS AND UPDATES
14E: ZUNVEYL® (BENZGALANTAMINE) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF ALZHEIMER'S DISEASE MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 15: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Non-presentation item; materials included in agenda packet by Dr. DeRemer
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
16A: IRON PRODUCTS
16B: OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
16C: TOPICAL CORTICOSTEROIDS
16D: VARIOUS SYSTEMIC ANTIBITOICS
*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. 17: ADJOURNMENT
The meeting was adjourned at 4:30pm.

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

Memorandum

Date: July 10, 2025

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

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

Subject: DUR Board Recommendations from Meeting on July 9, 2025

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

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 criteria):

1. Prior authorization of Cobenfy™ (xanomeline/trospium) and Erzofri® (paliperidone palmitate ER injection) and placement into Tier-3; and
2. Prior authorization of Opipza™ (aripiprazole oral film) and placement into Tier-3 with the following additional criteria; and

3. Removing the verbiage of clozapine not counting as a Tier-1 trial from the Tier-2 and Tier-3 criteria based on the removal of the Clozapine REMS program; and
4. Updating the Lybalvi® (olanzapine/samidorphan) approval criteria based on recent data from long-term extension trials and to be consistent with clinical practice.

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

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates,

and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
*~~Clozapine does not count towards a Tier-1 trial.~~
^Use of a long-acting injectable product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
ßUnique criteria applies to Lybalvi® (olanzapine/samidorphan).
∞Unique criteria applies to Tier-3 long-acting injectable (LAI) products.

Tier-1 products are available without prior authorization for members 5 years of age and older. Prior authorization requests for members younger than 5 years of age are reviewed by an Oklahoma Health Care Authority (OHCA)- or SoonerSelect health plan-contracted child psychiatrist.

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

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

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
    a. ~~Clozapine does not count towards a Tier-1 trial; and~~
2. Trials of 2 oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Members currently stable on a Tier-3 medication may be approved for continuation of therapy; and
5. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) or requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Use of Opipza™ (aripiprazole oral film) will require a patient-specific, clinically significant reason why the member cannot use the oral tablet or oral disintegrating tablet formulation; and

7. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered quetiapine products, which are available without a prior authorization; and
8. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
9. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. ~~Member must have a positive clinical response to olanzapine and gained ≥10% from baseline body weight after starting olanzapine (baseline and current weight must be provided); or~~
4. ~~A patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain profile must be provided; and~~
5. Member must meet 1 of the following:
    a. Member has a positive clinical response to olanzapine and experienced weight gain ≥7% from baseline body weight or other metabolic complications [e.g., increased waist circumference, increased metabolic parameters, worsening diabetes (i.e., increased A1c or glucose despite optimal adherent therapy for diabetes)] after starting olanzapine (baseline and current weight must be provided or documentation of metabolic complications); or
    b. Member has a trial of one Tier-1 and one Tier-2 medication with a lower weight gain or metabolic profile (e.g., aripiprazole, ziprasidone, lurasidone), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and
6. Member must not be taking opioids or undergoing acute opioid withdrawal; and
7. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and any increase in body weight is ~~<~~ ≤10% of baseline body weight (current weight must be provided) or has had no increase or worsening in metabolic complications (documentation must be provided) while on therapy must be provided.

Recommendation 4: Vote to Prior Authorize Bucapsol™ (Buspirone Capsule), Carbamazepine 200mg Chewable Tablet, Femlyv™ [Norethindrone Acetate/Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Focinvez™ (Fosaprepitant Injection), Imkeldi (Imatinib Oral Solution), IVRA (Melphalan 90mg/mL Injection), Myhibbin™ (Mycophenolate Mofetil Oral Suspension), Ondansetron 16mg ODT, Tezruly™ (Terazosin Oral Solution), Topiramate 50mg Sprinkle Capsule, Veltassa® (Patiromer) 1g Powder Packet, and Vigafyde™ (Vigabatrin Oral Solution) and Update the Approval Criteria for the Various Special Formulations

MOTION CARRIED by unanimous approval.

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

Bucapsol™ (Buspirone Capsule) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use buspirone tablets, even when the tablets are crushed, must be provided.

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

Carbamazepine 200mg Chewable Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all other forms of carbamazepine that are available without a prior authorization, including using 2 of the 100mg chewable tablets to achieve the 200mg dose, must be provided; and
2. A quantity limit of 720 chewable tablets per 90 days will apply.

The College of Pharmacy recommends the prior authorization of Femlyv™ (norethindrone acetate/ethinyl estradiol ODT) with criteria similar to Nextstellis® (drospirenone/estetrol tablet) and Slynd® (drospirenone tablet) with the following criteria (shown in red):

Femlyv™ [Norethindrone Acetate/Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Nextstellis® (Drospirenone/Estetrol Tablet), and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without a prior authorization must be provided.

The College of Pharmacy recommends the prior authorization of Focinvez™ (fosaprepitant) with criteria similar to Anzemet® (dolasetron), Cinvanti® and Emend® (aprepitant), Emend® IV (fosaprepitant), and Kytril® and Sancuso®

(granisetron) with the following additional updates to be consistent with clinical practice and net costs (changes shown in red):

Anzemet® (Dolasetron), Cinvanti® and Emend® (Aprepitant), Emend® IV (Fosaprepitant), Focinvez™ (Fosaprepitant), and Kytril® and Sancuso® (Granisetron) Approval Criteria:

1. An FDA approved diagnosis; and
2. A recent trial of ondansetron (within the past 6 months) used for at least 3 days or 1 cycle that resulted in an inadequate response is required for authorization in members receiving moderately emetogenic chemotherapy; and
3. No ondansetron trial is required for authorization ~~of Emend® (aprepitant)~~ in members receiving highly emetogenic chemotherapy; and
4. For Emend® (aprepitant) oral suspension, an age restriction of 6 years and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. For Cinvanti® [aprepitant intravenous (IV) emulsion] and Focinvez™ (fosaprepitant), a previously failed trial of IV fosaprepitant (Emend® IV) that resulted in an inadequate response or a patient-specific, clinically significant reason why IV fosaprepitant (Emend® IV) cannot be used must be provided; and
6. Approval length will be based on duration of need.

The College of Pharmacy recommends the prior authorization of Imkeldi (imatinib oral solution) with the following criteria (shown in red):

Imkeldi (Imatinib Oral Solution) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use imatinib tablets, which are available without a prior authorization, must be provided. Imatinib tablets may be dispersed in a glass of water or apple juice to form a suspension for members who cannot swallow the film-coated tablets.

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

IVRA (Melphalan 90mg/mL) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason why the member cannot use generic melphalan 50mg/10mL vial which is available without a prior authorization.

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

Myhibbin™ (Mycophenolate Mofetil Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use generic Cellcept® (mycophenolate mofetil for oral suspension), which is available without a prior authorization, must be provided.

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

Ondansetron 16mg Orally Disintegrating Tablet (ODT) Approval Criteria:

1. An FDA approved indication for the prevention of postoperative nausea and vomiting (PONV); and
2. A patient-specific, clinically significant reason why the member cannot use 2 of the 8mg ODTs to achieve the 16mg dose must be provided.

The College of Pharmacy also recommends the prior authorization of Tezruly™ (terazosin oral solution) with placement into the Special Prior Authorization (PA) Tier of the Benign Prostatic Hyperplasia (BPH) Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

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/tadalafil 5mg/5mg (Entadfi®)*
dutasteride (Avodart®)	silodosin (Rapaflo®)	**terazosin oral solution (Tezruly™)***
finasteride (Proscar®)		
tamsulosin (Flomax®)		
terazosin (Hytrin®)		

*Unique criteria applies

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.

The College of Pharmacy recommends the prior authorization of topiramate 50mg sprinkle capsule with the following criteria (shown in red):

Topiramate 50mg Sprinkle Capsule Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use other available generic topiramate products, including using 2 topiramate 25mg sprinkle capsules to achieve the 50mg dose, must be provided; and
3. Members 12 years of age and older will require a patient-specific, clinically significant reason why a special formulation product is needed; and
4. A quantity limit of 240 capsules per 30 days will apply.

The College of Pharmacy recommends the prior authorization of Veltassa® (patiromer) 1 gram packet with criteria similar to the other Veltassa® strengths with the following additional criteria (changes shown in red):

Veltassa® (Patiromer) Approval Criteria:

1. An FDA approved diagnosis of hyperkalemia; and
2. Medications known to cause hyperkalemia [e.g., aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the lowest effective dose where clinically appropriate; and
3. A trial of a potassium-eliminating diuretic or documentation why a diuretic is not appropriate for the member; and
4. Documentation of a low potassium diet; and
5. For members 18 years of age and older, a patient-specific, clinically significant reason why the member cannot use Lokelma® (sodium zirconium cyclosilicate) must be provided; and
6. Quantity limits will apply as follows:
    a. 1g Packets: A quantity limit of 120 packets per 30 days will apply; or
    b. 8.4g, 16.8g, and 25.2g Packets: A quantity limit of 30 packets per month will apply.

The College of Pharmacy recommends the prior authorization of Vigafyde™ (vigabatrin oral solution) with the following criteria and updating the Sabril® (vigabatrin) criteria based on the Vigafyde™ FDA approval (changes shown in red):

Vigafyde™ (Vigabatrin Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of infantile spasms in children 1 month to 2 years of age; and
2. A patient-specific, clinically significant reason why the member cannot use brand name Sabril® (vigabatrin) for oral solution must be provided; and
3. Prescription must be written by, or in consultation with, a neurologist; and
4. Member, prescriber, and pharmacy must all register in the Vigabatrin REMS program and maintain enrollment throughout therapy.

Sabril® (Vigabatrin) Approval Criteria:

1. An FDA approved diagnosis of refractory complex seizures in adults and pediatric patients 2 years of age or older, or infantile spasms in children 1 month to 2 years of age; and
2. Authorization of generic vigabatrin (in place of brand Sabril®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
3. Members with refractory complex seizures must have previous trials of at least three other antiepileptic medications; or
4. Prescription must be written by, or in consultation with a neurologist; and
5. Member, prescriber, and pharmacy must all register in the Vigabatrin ~~SABRIL~~ REMS program and maintain enrollment throughout therapy.

The College of Pharmacy recommends updating the Jylamvo™ (methotrexate oral solution) based on the FDA label expansion to allow use of Jylamvo™ in pediatric patients for a diagnosis of acute lymphoblastic leukemia (ALL) or polyarticular juvenile idiopathic arthritis (pJIA) (changes shown in red):

Jylamvo™ (Methotrexate Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Treatment of adults and pediatric members with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen; or
   b. Treatment of adults with mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or
   c. Treatment of pediatric members with polyarticular juvenile idiopathic arthritis (pJIA); or
   d. Treatment of adults with relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or
   e. Treatment of adults with rheumatoid arthritis; or
   f. Treatment of adults with severe psoriasis; and

~~2. Member must be 18 years of age or older; and~~

3. A patient-specific clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.

Finally, the College of Pharmacy recommends removal of SoonerCare coverage and of the prior authorization criteria for Aspruzyo Sprinkle™ due to product discontinuation (shown in red):

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

~~1. An FDA approved diagnosis of chronic angina; and~~

~~2. A patient-specific, clinically significant reason why the member cannot use ranolazine ER tablets must be provided.~~

Recommendation 5: Vote to Prior Authorize Avmapki™ Fakzynja™ Co-Pack (Avutometinib and Defactinib) 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 Avmapki™ Fakzynja™ Co-Pack (avutometinib and defactinib) with the following criteria (shown in red):

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

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

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

Cabometyx® (Cabozantinib) Approval Criteria:

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

b. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

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

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

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

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

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

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

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

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

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

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

3. As a single agent.

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

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

1. Diagnosis of metastatic, high-risk, CSPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Recommendation 6: Fiscal Year 2024 Annual Review of Colorectal Cancer (CRC) Medications

NO ACTION REQUIRED.

Recommendation 7: Fiscal Year 2024 Annual Review of Defencath® (Taurolidine/Heparin)

MOTION CARRIED by unanimous approval.

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

Defencath® (Taurolidine/Heparin) Approval Criteria:

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

a. For requests exceeding the quantity limit, supporting documentation (e.g., HD schedule, number of CVC lumens, CVC lumen volumes) must be provided for a quantity limit override; and

7. Approvals will be granted for 1 year.

Recommendation 8: Fiscal Year 2024 Annual Review of Constipation and Diarrhea Medications

MOTION CARRIED by unanimous approval.

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

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

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

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

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

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

Ibsrela® (Tenapanor) Approval Criteria:

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

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

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

Linzess® (Linaclotide) Approval Criteria:

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

6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 capsules per 30 days will apply.

Motegrity® (Prucalopride) Approval Criteria:

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

Movantik® (Naloxegol) Approval Criteria:

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

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

Pizensy™ (Lactitol) Approval Criteria:

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

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

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

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

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

Relistor® (Methylnaltrexone) Tablets Approval Criteria:

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

Symproic® (Naldemedine) Approval Criteria:

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

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

Trulance® (Plecanatide) Approval Criteria:

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

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

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

Motofen® (Difenoxin/Atropine) Approval Criteria:

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

Recommendation 9: Fiscal Year 2024 Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Azmiro™ (Testosterone Cypionate) and Undecatrex™ (Testosterone Undecanoate)

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

Recommendation 10: Fiscal Year 2024 Annual Review of Epidermolysis Bullosa (EB) Medications and 30-Day Notice to Prior Authorize Zevaskyn™ (Prademagene Zamikeracel)

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

Recommendation 11: Fiscal Year 2024 Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Zunveyl® (Benzgalantamine)

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

Recommendation 12: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

Recommendation 13: Future Business

No live DUR Board meeting is scheduled for August 2025. August 2025 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 15, 2025

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

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

Subject: DUR Board Recommendations from Packet Meeting on August 13, 2025

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 2024 Annual Review of Iron Products

NO ACTION REQUIRED.

Recommendation 4: Fiscal Year 2024 Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Ryoncil® (Remestemcel-L-rknd)

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

Recommendation 5: Fiscal Year 2024 Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Tramadol 75mg Tablet

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

Recommendation 6: Fiscal Year 2024 Annual Review of Topical Corticosteroids

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

Recommendation 7: Fiscal Year 2024 Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Blujepa (Gepotidacin), Emblaveo™ (Aztreonam/Avibactam), Likmez™ (Metronidazole Oral Suspension), and Metronidazole 125mg Tablet and 375mg Capsule

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

Recommendation 8: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

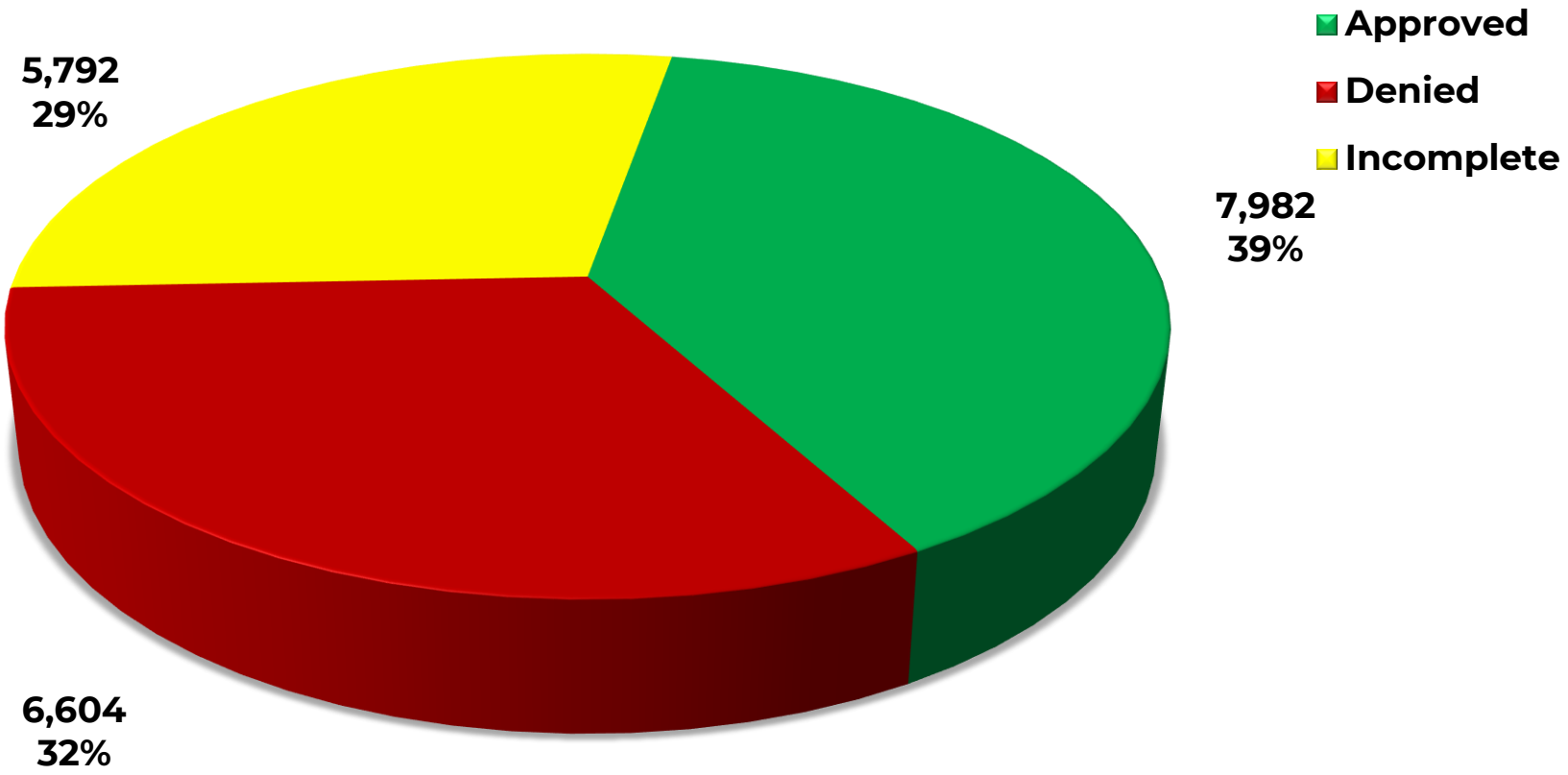
NO ACTION REQUIRED.

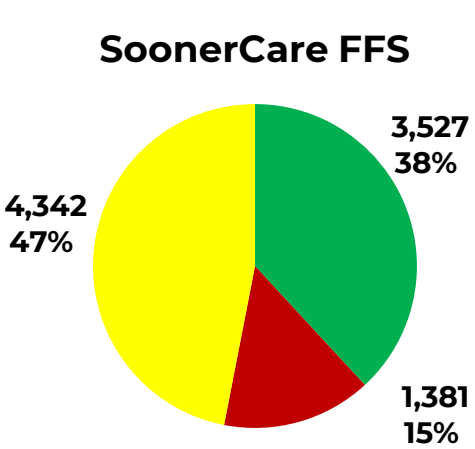
Recommendation 9: Future Business

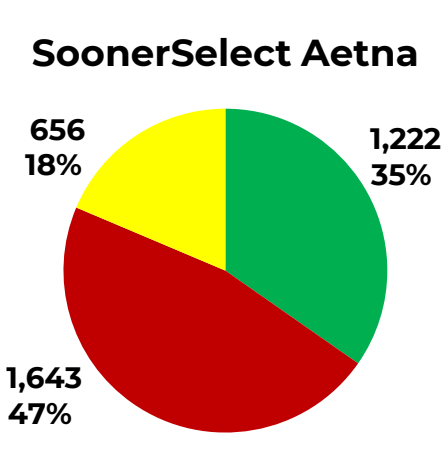
NO ACTION REQUIRED.

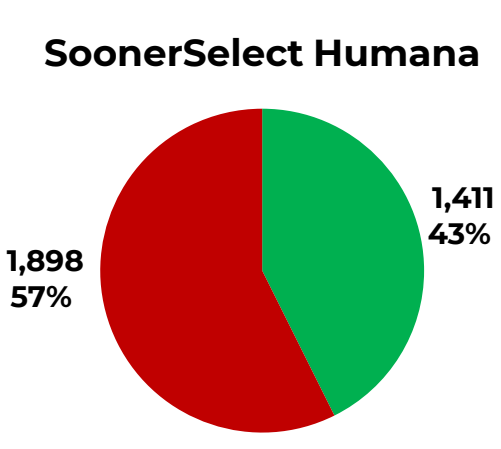
Appendix B

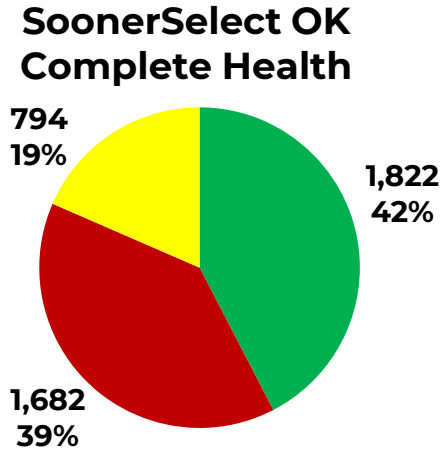
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: AUGUST 2025





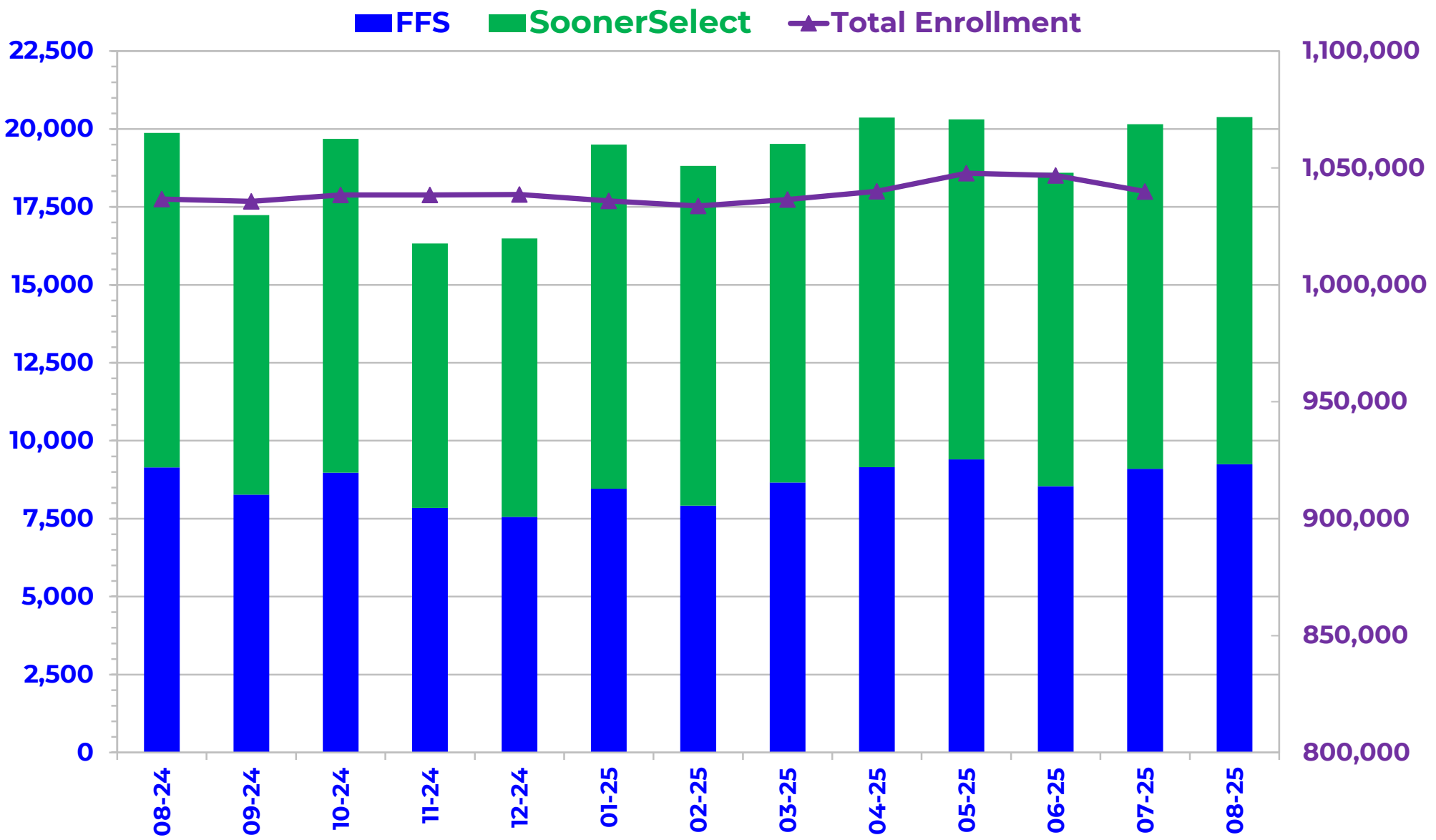






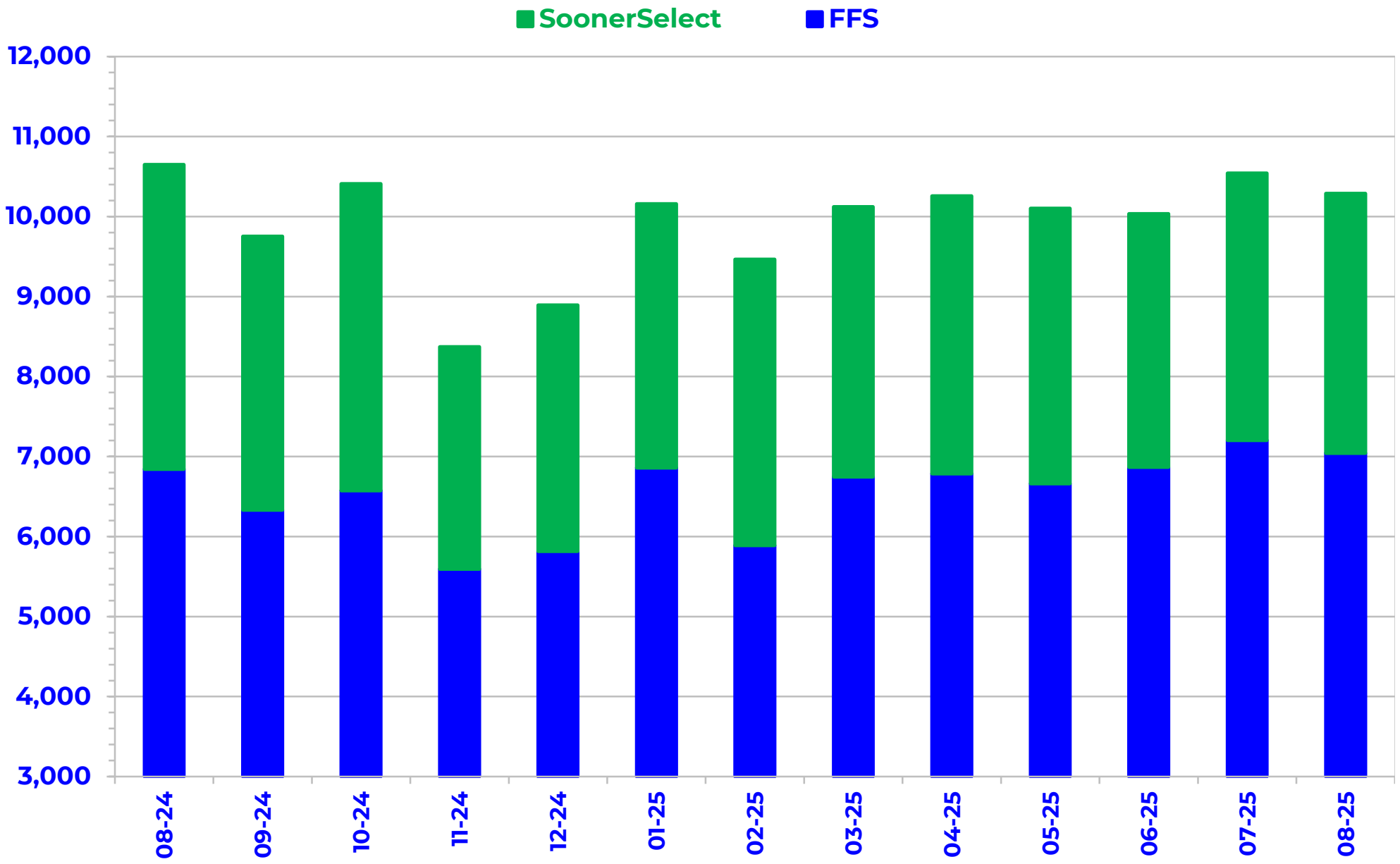
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: AUGUST 2024 – AUGUST 2025



SoonerCare FFS Prior Authorization Activity

8/1/2025 Through 8/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	0	1	0
Amphetamines	800	411	52	337	351
Analgesics - Anti-Inflammatory	208	83	29	96	308
Analgesics - Nonnarcotic	6	0	0	6	0
Analgesics - Opioid	316	125	31	160	136
Androgens - Anabolic	74	19	20	35	359
Anorectal and Related Products	2	0	2	0	0
Antacids	2	2	0	0	361
Anthelmintics	10	0	2	8	0
Anti-Infective Agents - Misc.	36	12	4	20	135
Anti-Obesity Agents	108	6	80	22	137
Antianginal Agents	3	2	0	1	362
Antianxiety Agents	28	3	2	23	299
Antiarrhythmics	7	2	0	5	360
Antiasthmatic and Bronchodilator Agents	504	98	95	311	334
Antibiotics	29	10	2	17	187
Anticoagulants	19	5	2	12	246
Anticonvulsants	208	101	14	93	341
Antidepressants	249	77	36	136	298
Antidiabetics	1,308	366	232	710	354
Antidotes and Specific Antagonists	2	0	0	2	0
Antiemetics	17	0	3	14	0
Antifungals	6	2	0	4	14
Antihistamines	29	8	6	15	318
Antihyperlipidemics	56	9	19	28	339
Antihypertensives	14	6	2	6	317
Antimalarials	1	0	0	1	0
Antineoplastics and Adjunctive Therapies	241	165	10	66	190
Antiparkinson and Related Therapy Agents	10	1	4	5	358
Antipsychotics/Antimanic Agents	350	112	35	203	346
Antivirals	23	8	3	12	29
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	234	157	16	61	340
Beta Blockers	12	3	3	6	361
Calcium Channel Blockers	14	5	2	7	360
Cardiovascular Agents - Misc.	93	34	11	48	343
Contraceptives	29	13	3	13	358
Corticosteroids	15	2	4	9	147
Dermatologicals	463	145	118	200	242
Diagnostic Products	63	19	10	34	200
Dietary Products/Dietary Management Products	1	0	1	0	0
Digestive Aids	5	3	0	2	358

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Diuretics	13	5	2	6	291
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	0	1	1	0
Emergency PA	1	1	0	0	0
Endocrine and Metabolic Agents - Misc.	184	79	24	81	230
Estrogens	6	1	0	5	360
Gastrointestinal Agents - Misc.	295	73	71	151	269
Genitourinary Agents - Misc.	9	6	1	2	302
Gout Agents	15	3	3	9	359
Hematological Agents - Misc.	18	8	1	9	334
Hematopoietic Agents	62	26	10	26	155
Histamine H3-Receptor Antagonist/Inverse Agonists	2	2	0	0	183
Hypnotics/Sedatives/Sleep Disorder Agents	59	11	14	34	261
Laxatives	19	11	1	7	178
Medical Devices and Supplies	332	55	77	200	302
Migraine Products	429	90	96	243	226
Minerals and Electrolytes	7	0	1	6	0
Miscellaneous Therapeutic Classes	66	25	7	34	333
Multivitamins	3	0	1	2	0
Musculoskeletal Therapy Agents	35	7	7	21	131
Nasal Agents - Systemic and Topical	22	2	6	14	87
Neuromuscular Agents	68	34	21	13	350
Ophthalmic Agents	62	10	10	42	200
Other*	74	34	5	35	148
Otic Agents	78	35	7	36	31
Passive Immunizing and Treatment Agents	3	1	0	2	87
Progestins	3	0	1	2	0
Psychotherapeutic and Neurological Agents - Misc.	222	86	30	106	231
Respiratory Agents - Misc.	32	15	2	15	311
Stimulants - Misc.	222	105	22	95	347
Thyroid Agents	14	2	4	8	353
Ulcer Drugs/Antispasmodics/Anticholinergics	79	18	11	50	163
Urinary Antispasmodics	53	9	9	35	359
Vaginal and Related Products	3	0	2	1	0
Vitamins	31	1	22	8	70
Total	**8,119**	**2,769**	**1,322**	**4,028**	

Overrides					
Brand	26	7	1	18	359
Compound	14	12	0	2	15
Diabetic Supplies	1	1	0	0	12
Dosage Change	163	152	0	11	18
High Dose	3	2	0	1	359
Ingredient Duplication	1	1	0	0	7
Lost/Broken Rx	49	45	1	3	24
MAT Override	21	15	2	4	79

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
NDC vs Age	173	102	18	53	280
NDC vs Sex	35	27	3	5	266
Nursing Home Issue	57	55	0	2	12
Opioid MME Limit	66	22	5	39	132
Opioid Quantity	23	14	2	7	154
Other	70	42	6	22	21
Quantity vs Days Supply	342	224	15	103	259
STBS/STBSM	11	5	1	5	114
Step Therapy Exception	11	4	5	2	277
Third Brand Request	65	28	0	37	13
Overrides Total	**1,131**	**758**	**59**	**314**	
Total Regular PAs + Overrides	**9,250**	**3,527**	**1,381**	**4,342**	

Denial Reasons	
Unable to verify required trials.	3,796
Does not meet established criteria.	1,421
Lack required information to process request.	540
Other PA Activity	
Duplicate Requests	1,023
Letters	40,064
No Process	6
Helpdesk Initiated Prior Authorizations	388
PAs Missing Information	374
Pharmacotherapy	120
Changes to Existing PAs	587

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

SoonerSelect Aetna Prior Authorization Activity

8/1/2025 Through 8/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	346	159	158	29	364
Analgesics - Anti-Inflammatory	110	72	31	7	354
Analgesics - Nonnarcotic	4	1	2	1	184
Analgesics - Opioid	160	79	50	31	197
Androgens - Anabolic	72	17	54	1	365
Anthelmintics	6	2	4	0	18
Antianginal Agents	2	0	0	2	0
Antianxiety Agents	26	10	10	6	365
Antiarrhythmics	1	0	0	1	0
Antiasthmatic and Bronchodilator Agents	165	39	103	23	300
Antibiotics	12	0	5	7	0
Anticoagulants	6	2	1	3	184
Anticonvulsants	47	12	24	11	367
Antidepressants	196	55	85	56	308
Antidiabetics	545	164	299	82	304
Antidotes and Specific Antagonists	1	0	0	1	0
Antiemetics	6	2	2	2	116
Antifungals	1	0	1	0	0
Antihistamines	9	1	8	0	365
Antihyperlipidemics	33	4	13	16	274
Antihypertensives	24	2	2	20	198
Anti-Infective Agents - Misc.	8	6	1	1	196
Antineoplastics and Adjunctive Therapies	43	14	2	27	343
Anti-Obesity Agents	93	6	79	8	28
Antiparkinson and Related Therapy Agents	10	1	5	4	365
Antipsychotics/Antimanic Agents	118	29	56	33	347
Antivirals	7	1	6	0	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	85	69	11	5	357
Beta Blockers	27	2	4	21	365
Calcium Channel Blockers	18	4	3	11	365
Cardiovascular Agents - Misc.	51	26	17	8	314
Chemicals	2	2	0	0	274
Contraceptives	13	2	10	1	365
Corticosteroids	24	16	5	3	113
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	292	109	142	41	260
Diagnostic Products	43	19	7	17	349
Dietary Products/Dietary Management Products	2	0	0	2	0
Diuretics	10	0	0	10	0
Endocrine and Metabolic Agents - Misc.	45	19	21	5	255
Estrogens	10	9	1	0	334
Gastrointestinal Agents - Misc.	92	31	56	5	201
General Anesthetics	2	0	2	0	0
Gout Agents	21	14	6	1	95
Hematopoietic Agents	14	4	10	0	365
Hypnotics/Sedatives/Sleep Disorder Agents	35	3	17	15	244
Laxatives	11	2	9	0	138

*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	78	21	37	20	344
Migraine Products	168	55	104	9	213
Minerals and Electrolytes	11	1	0	10	364
Miscellaneous Therapeutic Classes	12	7	5	0	365
Multivitamins	3	2	1	0	365
Musculoskeletal Therapy Agents	35	4	13	18	147
Nasal Agents - Systemic and Topical	12	0	8	4	0
Neuromuscular Agents	11	9	1	1	365
Ophthalmic Agents	18	3	12	3	136
Other	18	5	2	11	365
Otic Agents	15	1	14	0	14
Passive Immunizing and Treatment Agents	5	5	0	0	304
Progestins	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	42	18	15	9	304
Respiratory Agents - Misc.	5	3	1	1	244
Stimulants - Misc.	101	67	24	10	364
Thyroid Agents	2	1	1	0	184
Ulcer Drugs/Antispasmodics/Anticholinergics	84	6	44	34	254
Urinary Antispasmodics	15	0	10	5	0
Vaccines	1	1	0	0	365
Vaginal and Related Products	6	0	4	2	0
Vitamins	29	4	25	0	271
****Total**	**3,521**	**1,222**	**1,643**	**656**	

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

Overrides					
Brand	1	1	0	0	92
Other	657	1	0	656	0
Quantity Level Limit	25	25	0	0	294
Step Therapy Met	4	4	0	0	198
Overrides Total	**687**	**31**	**0**	**656**	

Denial Reason	
Benefit	64
Experimental/Investigational	149
Medical Necessity	1,319
Lack required information to process request	111
Other PA Activity	
Duplicate Requests	21
Letters	4,562
No Process	257
Changes to existing PAs	0
Helpdesk initiated PA	2
PAs missing info	11

*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

8/1/2025 Through 8/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	1	0	0	184
Analgesics - Anti-Inflammatory	54	37	17	0	318
Analgesics - Nonnarcotic	3	0	3	0	0
Analgesics - Opioid	69	33	36	0	253
Androgens - Anabolic	38	11	27	0	209
Anthelmintics	10	5	5	0	287
Antiasthmatic and Bronchodilator Agents	129	36	93	0	219
Antibiotics	4	0	4	0	0
Anticonvulsants	12	6	6	0	340
Antidepressants	48	20	28	0	298
Antidiabetics	319	144	175	0	253
Antiemetics	8	3	5	0	125
Antihistamines	1	0	1	0	0
Antihyperlipidemics	22	10	12	0	173
Anti-Infective Agents - Misc.	4	4	0	0	282
Antineoplastics and Adjunctive Therapies	35	33	2	0	217
Anti-Obesity Agents	60	5	55	0	142
Antiparkinson and Related Therapy Agents	1	0	1	0	0
Antipsychotics/Antimanic Agents	2	2	0	0	365
Antivirals	5	4	1	0	113
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	7	6	1	0	365
Beta Blockers	2	1	1	0	365
Calcium Channel Blockers	3	1	2	0	365
Cardiovascular Agents - Misc.	31	10	21	0	372
Contraceptives	35	28	7	0	334
Corticosteroids	3	0	3	0	0
Dermatologicals	158	60	98	0	200
Diagnostic Products	16	11	5	0	349
Diuretics	4	2	2	0	364
Endocrine and Metabolic Agents - Misc.	41	25	16	0	239
Estrogens	5	1	4	0	146
Gastrointestinal Agents - Misc.	92	29	63	0	193
Gout Agents	2	2	0	0	274
Hematopoietic Agents	23	5	18	0	238
Hypnotics/Sedatives/Sleep Disorder Agents	3	1	2	0	365
Medical Devices and Supplies	91	80	11	0	396
Migraine Products	136	76	60	0	194
Minerals and Electrolytes	1	0	1	0	0
Miscellaneous Therapeutic Classes	3	2	1	0	365
Musculoskeletal Therapy Agents	9	6	3	0	365
Nasal Agents - Systemic and Topical	1	0	1	0	0
Neuromuscular Agents	31	26	5	0	292
Ophthalmic Agents	18	7	11	0	282
Other	4	1	3	0	730
Progestins	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	22	13	9	0	253
Respiratory Agents - Misc.	6	4	2	0	324
Stimulants - Misc.	12	7	5	0	328

*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
Thyroid Agents	5	0	5	0	0
Ulcer Drugs/Antispasmodics/Anticholinergics	14	4	10	0	324
Urinary Antispasmodics	15	1	14	0	446
Vaginal and Related Products	2	0	2	0	0
Vitamins	32	0	32	0	0
Total	**1,653**	**764**	**889**	**0**	
Overrides					
Ingredient Duplication	135	75	60	0	238
NDC vs Age	355	207	148	0	212
Opioid MME Limit	8	7	1	0	292
Opioid Quantity	3	3	0	0	292
Other	164	58	106	0	129
Quantity vs Days Supply	207	137	70	0	257
STBS/STBSM	470	28	442	0	24
Step Therapy Exception	314	132	182	0	153
Overrides Total	**1,656**	**647**	**1,009**	**0**	
Total Regular PAs + Overrides	**3,309**	**1,411**	**1,898**	**0**	
Denial Reasons					
Benefit					850
Medical Necessity					1,048

*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

8/1/2025 Through 8/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	7	0	5	2	0
Amebicides	1	0	1	0	0
Amphetamines	359	153	122	84	268
Analgesics - Anti-Inflammatory	108	54	31	23	358
Analgesics - Nonnarcotic	6	1	4	1	124
Analgesics - Opioid	343	131	158	54	178
Androgens - Anabolic	80	15	53	12	346
Anorectal and Related Products	4	0	1	3	0
Anorexiants Non-Amphetamine	1	0	0	1	0
Anthelmintics	5	1	4	0	365
Antianxiety Agents	25	4	15	6	365
Antiasthmatic and Bronchodilator Agents	225	53	134	38	229
Antibiotics	19	6	6	7	318
Anticoagulants	8	4	3	1	193
Anticonvulsants	57	27	26	4	289
Antidepressants	124	46	56	22	306
Antidiabetics	759	400	268	91	310
Antidotes and Specific Antagonists	1	1	0	0	125
Antiemetics	13	3	2	8	243
Antifungals	4	2	1	1	134
Antihistamines	21	5	14	2	365
Antihyperlipidemics	15	2	12	1	365
Antihypertensives	3	1	2	0	365
Anti-Infective Agents - Misc.	13	5	7	1	207
Antineoplastics and Adjunctive Therapies	62	30	12	20	204
Anti-Obesity Agents	81	4	33	44	196
Antiparkinson and Related Therapy Agents	5	2	3	0	249
Antipsychotics/Antimanic Agents	131	73	40	18	331
Antivirals	9	2	4	3	30
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	111	68	34	9	319
Beta Blockers	11	8	3	0	177
Calcium Channel Blockers	5	2	1	2	365
Cardiovascular Agents - Misc.	27	9	13	5	326
Contraceptives	17	5	11	1	365
Corticosteroids	10	5	2	3	319
Cough/Cold/Allergy	1	1	0	0	145
Dermatologicals	353	130	141	82	202
Diagnostic Products	58	35	11	12	343
Digestive Aids	5	2	0	3	256
Diuretics	1	0	0	1	0
Endocrine and Metabolic Agents - Misc.	60	25	28	7	259
Estrogens	11	3	6	2	285
Gastrointestinal Agents - Misc.	113	40	58	15	229
Hematological Agents - Misc.	23	17	6	0	312
Hematopoietic Agents	30	16	9	5	222
Histamine H3-Receptor Antagonist/Inverse Agonists	3	1	0	2	365
Hypnotics/Sedatives/Sleep Disorder Agents	27	13	12	2	203
Laxatives	5	0	3	2	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	147	98	20	29	306
Migraine Products	182	65	89	28	222
Minerals and Electrolytes	1	0	1	0	0
Miscellaneous Therapeutic Classes	34	19	6	9	313
Mouth/Throat/Dental Agents	1	0	1	0	0
Multivitamins	11	3	5	3	229
Musculoskeletal Therapy Agents	28	3	18	7	146
Nasal Agents - Systemic and Topical	13	1	11	1	90
Neuromuscular Agents	30	10	11	9	365
Ophthalmic Agents	52	16	26	10	226
Other	44	18	3	23	284
Otic Agents	35	4	26	5	365
Passive Immunizing and Treatment Agents	1	1	0	0	145
Progestins	5	0	4	1	0
Psychotherapeutic and Neurological Agents - Misc.	51	13	20	18	233
Respiratory Agents - Misc.	12	9	3	0	338
Stimulants - Misc.	197	113	48	36	259
Thyroid Agents	42	30	7	5	227
Ulcer Drugs/Antispasmodics/Anticholinergics	35	10	20	5	275
Urinary Antispasmodics	12	2	7	3	246
Vaccines	1	1	0	0	134
Vaginal and Related Products	1	0	1	0	0
Vasopressors	1	0	0	1	0
Vitamins	2	1	0	1	139
****Total**	**4,298**	**1,822**	**1,682**	**794**	

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

Denial Reasons	
Medical Necessity	1,682

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

Appendix C

Impact of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators

Oklahoma Health Care Authority
September 2025

Introduction[1,2]

Cystic fibrosis (CF) is an inherited autosomal recessive disease caused by mutations in the *CFTR* gene. A normal *CFTR* gene encodes the CFTR protein that controls the movement of chloride and sodium across cell membranes and is primarily active in the cells lining the airways, gastrointestinal tract, pancreas, sweat glands, and genitourinary system. Mutations in the *CFTR* gene lead to the creation of a dysfunctional CFTR protein or a deficiency or absence of CFTR protein at the cell surface, causing cells to produce mucus that is abnormally thick and sticky.

CF affects approximately 100,000 individuals worldwide and occurs predominately among Caucasians but can occur in other ethnicities. Approximately 40,000 people in the United States have been diagnosed with CF, and 1,000 new cases are diagnosed each year, with males and females affected equally. More than 75% of individuals with CF are diagnosed by 2 years of age, and more than half of CF patients are 18 years of age or older.

CF is progressive and affects multiple organs, with the greatest impact being on the lungs and pancreas. The abnormal mucus can build up in the lungs and lead to blockages in the airway, which can lead to inflammation, infections, and respiratory failure. Over time, significant lung damage can occur, leading to scarring of the airways, progressive deterioration in lung function, and ultimately respiratory failure. CF can also cause pancreatic insufficiency when mucus builds up in the pancreatic ducts. This can prevent pancreatic enzymes from reaching the intestines, interfering with the breakdown and absorption of food and nutrients, and can then lead to malabsorption resulting in a variety of nutritional deficiencies in affected individuals, such as failure to thrive and low levels of fat-soluble vitamins.

Cystic fibrosis is a complex condition with symptoms and severity differing from person to person, requiring individualized treatment plans. Patients with CF complete a combination of daily therapies, such as airway clearance, inhaled mucolytics, inhaled and oral antibiotics, pancreatic enzyme supplements, individualized fitness plans, and CFTR modulators. There have been numerous advancements in the care of CF patients over the years that have helped increase their quality of life, as well as life expectancy.

CFTR Modulators[3,4,5]

CFTR modulators are a class of drugs that are designed to correct the malfunctioning CFTR protein made by the *CFTR* gene. How well CFTR modulators work correlates to the specific mutations a patient has in their *CFTR* genes. The most common *CFTR* mutation is the *F508del* mutation; however, there are over 1,700 known *CFTR* mutations. Before prescribing a CFTR modulator therapy, the patient's mutation must be identified as the current available CFTR modulators have only been U.S. Food and Drug Administration (FDA) approved for specific *CFTR* mutations.

There are currently 5 CFTR modulators that are FDA approved and available on the market:

- Kalydeco® (ivacaftor): Approved in 2012
- Orkambi® (lumacaftor/ivacaftor): Approved in 2015
- Symdeko® (tezacaftor/ivacaftor and ivacaftor): Approved in 2018
- Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor): Approved in 2019
- Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor): Approved in 2024

Among these CFTR modulators, there are 2 main types based on their mechanisms of action - potentiators and correctors:

- Potentiators hold the protein gate open so chloride can flow through the cell membrane. Current available potentiators include ivacaftor and deutivacaftor.
- Correctors help the CFTR protein form the correct 3-D shape so that it can move to the cell surface. About 85% of the CF population has at least 1 copy of the *F508del* mutation, which prevents the CFTR protein from folding into the correct shape. Current available correctors include vanzacaftor, tezacaftor, elexacaftor, and lumacaftor.
- Even with correctors, only some of the CFTR protein reaches the cell surface. Additionally, the proteins that do reach the cell surface do not open sufficiently to allow chloride to pass out of the cell. If a corrector is used in combination with a potentiator to hold the gate on the CFTR protein open, enough chloride can then flow to reduce the symptoms of CF.

CFTR Modulator Impact[6,7,8,9,10]

Over time, there have been substantial improvements in the survival of patients with CF. The development of CFTR modulators represent a significant advancement in the treatment of CF and are one of the factors contributing to a longer life expectancy for many patients with CF. The median survival for patients with CF has continued to increase over the years from a median age of 38 years in 2005-2009 to 65 years in 2020-2024;

however, the survival age is lower for those who are ineligible for CFTR modulators. Along with increased life expectancy, other health improvements have been observed in the United States, such as decreased lung transplants (249 in 2019 vs. 61 in 2024), decreases in airway infections with *Pseudomonas aeruginosa* (43% in 2019 vs. 23% in 2024), improvements in lung function, and decreased exacerbations (adults: 40% in 2019 vs. 15% in 2024; children: 21% in 2019 vs. 9% in 2024).

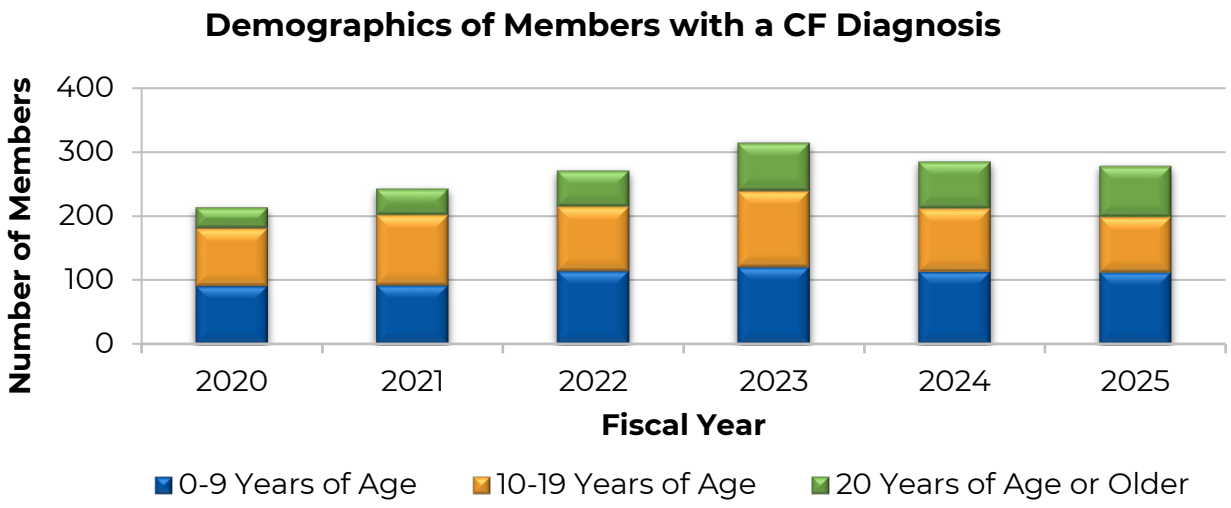
The number of patients with CF who are using CFTR modulator therapies continues to increase. In 2022, more than 21,000 patients in the United States were using CFTR modulator therapies. By the end of 2024, there were more than 25,000 patients taking a CFTR modulator, with 76% of those patients being on Trikafta®. However, as of 2024 there are still about 2,400 patients with CF who are ineligible for current CFTR modulator therapy.

The expanded approval of Trikafta® for children with CF from 2 to 5 years of age in April 2023 resulted in approximately 2,500 patients in the United States becoming eligible for treatment. Additionally, in December 2024, Trikafta® received a label expansion that added 94 additional non-*F508del* mutations to the label, allowing approximately 300 additional patients with CF in the United States to be eligible for a CFTR modulator. Alyftrek™, which was FDA approved in December 2024, demonstrated efficacy in 31 additional mutations that allowed approximately 150 patients with CF to be eligible for a CFTR modulator.

SoonerCare Impact

In August 2025, a claims analysis was performed to assess the impact CFTR modulators have had on the SoonerCare population. The claims were reviewed from 07/01/2019 to 06/30/2025 to allow for a comparison across 6 fiscal years (FY) of data. Members were included in the analysis if they had >1 medical claim with a reported diagnosis of CF. These members were assessed for CFTR modulator therapy utilization, inpatient (IP) and/or emergency department (ED) visits, and inhaled antibiotic utilization.

During this 6-year time period, there were 515 unique SoonerCare members with a reported diagnosis of CF with an average age of 12 years. Of these 515 members, 46.8% were 0-9 years of age, 30.5% were 10-19 years of age, and 22.7% were 20 years of age or older. The following graph shows the number of members per FY from 2020 to 2025 by age group.



The number of members on CFTR modulator therapy increased from FY2020 to FY2024 and then a slight decrease was seen in FY2025. From FY2022 to FY2023, there was a 16% increase in total members, and this was primarily due to the age expansion of Trikafta® in April 2023. From FY2020 to FY2025, there was a 58% increase in total members and a 99% increase in total cost. The results of the pharmacy claims analysis can be seen in Table 1.

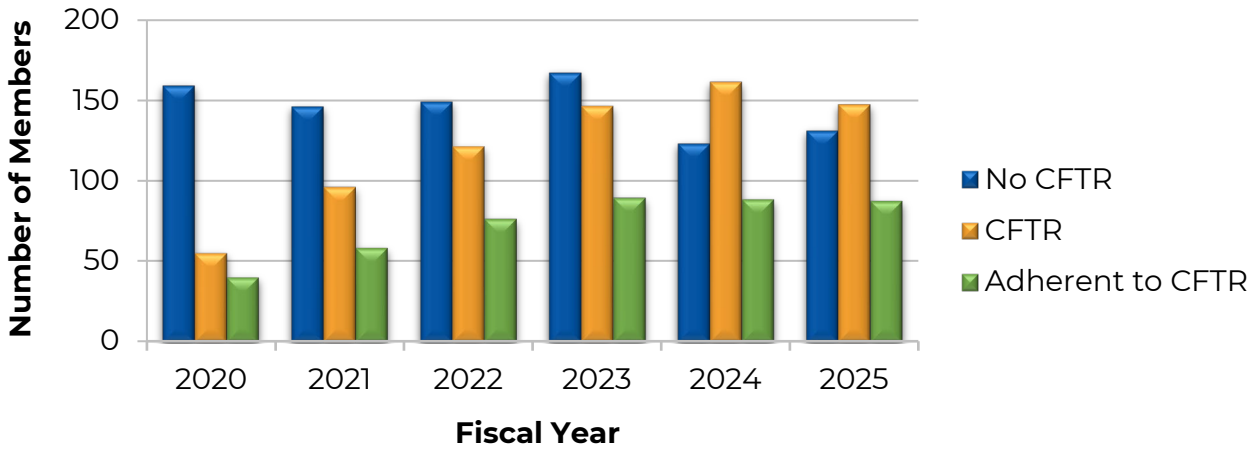
Table 1: Pharmacy Claims for CFTR Modulators by Fiscal Year

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Member	Claims/ Member
2020	107	925	$20,667,086.31	$22,342.80	$193,150.34	8.64
2021	125	1,140	$25,819,981.14	$22,649.11	$206,559.85	9.12
2022	148	1,491	$34,632,572.53	$23,227.75	$234,003.87	10.07
2023	172	1,652	$39,274,276.53	$23,773.78	$228,338.82	9.6
2024	178	1,704	$42,761,973.25	$25,095.05	$240,235.80	9.57
2025	169	1,562	$41,074,376.62	$26,296.02	$243,043.65	9.24

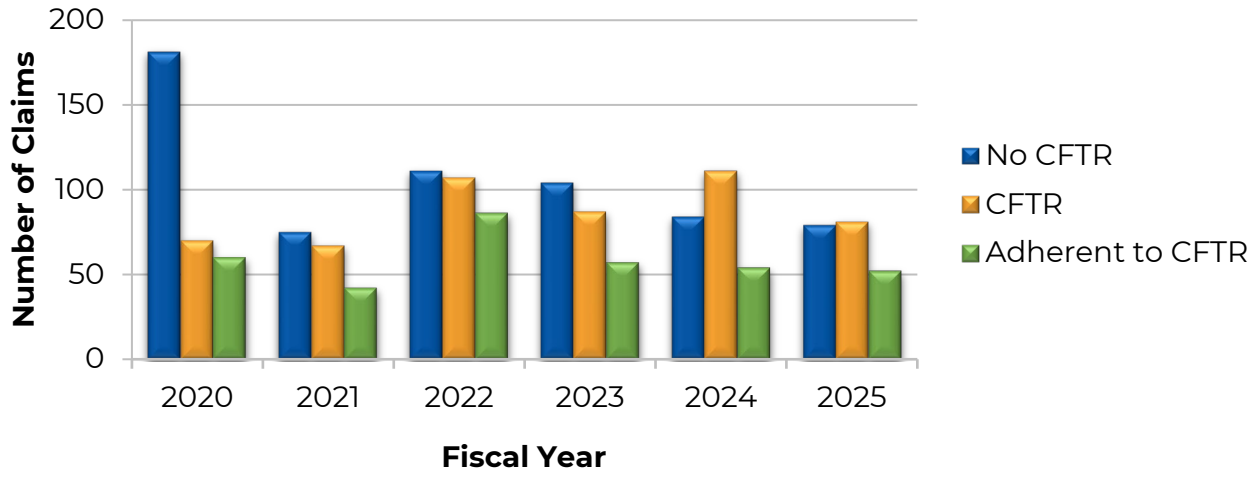
CFTR = cystic fibrosis transmembrane conductance regulator

IP hospitalizations and/or ED visits and utilization of inhaled antibiotics related to the member's CF diagnosis were also assessed in this analysis. Members were categorized into 3 cohorts: 1) no CFTR (i.e., members not currently utilizing CFTR modulator therapy or who started therapy mid-year), 2) CFTR (i.e., members currently utilizing a CFTR modulator since the beginning of the fiscal year or prior to the first day of the fiscal year), and 3) adherent to CFTR [i.e., those who are adherent to CFTR modulator therapy, defined as ≥80% proportion of days covered (PDC)]. The results of these claims analyses can be seen in the following 4 graphs below.

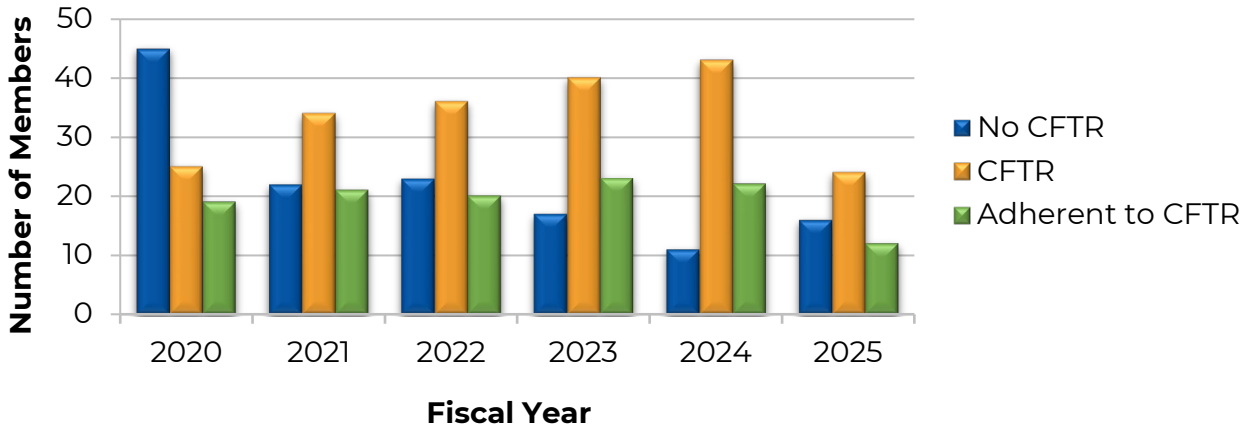
Number of CF Members with IP and/or ED Claims

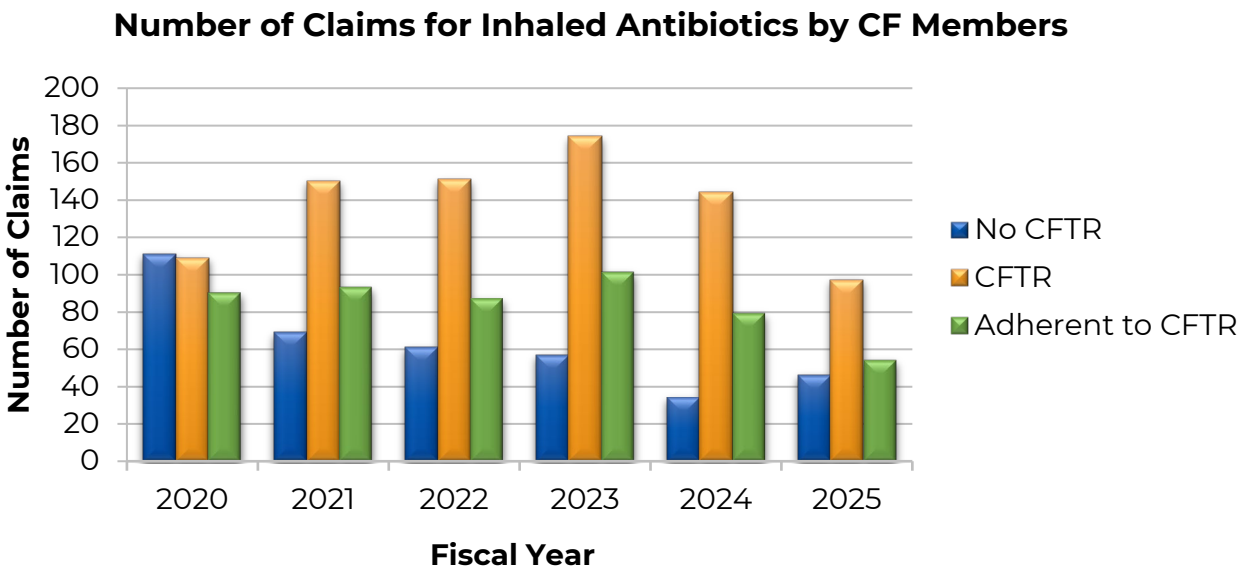


Number of IP and/or ED Claims by CF Members



Number of CF Members with Inhaled Antibiotic Pharmacy Claims





Conclusions[11,12]

Since the first CFTR modulator was approved by the FDA in 2012, utilization in the SoonerCare population has generally increased, and more members are becoming eligible for CFTR modulator therapy earlier in life due to the FDA approval of new therapies and various age expansions over the years. Members adherent to their CFTR modulator therapy were shown to have fewer IP and/or ED visits through fiscal years 2020-2025; however, utilization for inhaled antibiotics had variable results between the 3 cohorts. Some fiscal years showed members on CFTR modulator therapy having more claims for inhaled antibiotics; however, the number of claims from fiscal years 2023 to 2025 did decrease, suggesting improvement.

CF is a very complex disease state. Symptoms and treatment are highly individualized, as the patients' specific mutations correlate to disease severity. This analysis was based on SoonerCare claims only and, due to the complexity of CF, there are various reasons why members on CFTR modulator therapy could have increased IP and/or ED claims and inhaled antibiotic claims that were not able to be assessed in this analysis by claims alone. Patients with CF who develop chronic infections, such as chronic *Pseudomonas aeruginosa*, will typically be on inhaled antibiotics as part of their maintenance regimen and are not always recommended to discontinue them even when starting CFTR modulator therapy.

CFTR modulator therapy utilization is expected to increase over time and improve SoonerCare members' quality and length of life. The College of Pharmacy will continue to monitor the utilization of CFTR modulator therapy in the SoonerCare population and assess the impact of these therapies over time.

[1] National Organization for Rare Disorders (NORD). Cystic Fibrosis. Available online at: https://rarediseases.org/rare-diseases/cystic-fibrosis/. Last revised 01/17/2025. Last accessed 08/14/2025.
[2] Cystic Fibrosis Foundation. About Cystic Fibrosis. Available online at: https://www.cff.org/intro-cf/about-cystic-fibrosis. Last accessed 08/14/2025.
[3] Cystic Fibrosis Foundation. CFTR Modulator Types. Available online at: https://www.cff.org/cftr-modulator-types. Last accessed 08/14/2025.
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Appendix D

Vote to Prior Authorize Azmiro™ (Testosterone Cypionate) and Undecatrex™ (Testosterone Undecanoate) and Update the Approval Criteria for the Testosterone Products

Oklahoma Health Care Authority
September 2025

Market News and Updates[1,2,3]

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

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

News:

- **September 2024:** Undecatrex™ (testosterone undecanoate) is an NDA authorized generic of Kyzatrex® (testosterone undecanoate). According to the FDA's NDC Directory, the marketing start date for Undecatrex™ was in September 2024.

Azmiro™ (Testosterone Cypionate) Product Summary[4]

Therapeutic Class: Androgen

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

- Primary hypogonadism (congenital or acquired): Testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins [follicle stimulating hormone (FSH), luteinizing hormone (LH)] above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

- **Limitation(s) of Use:**
  - Safety and efficacy of Azmiro™ in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
  - Safety and effectiveness in pediatric patients younger than 12 years of age have not been established.

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

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

Undecatrex™ (Testosterone Undecanoate) Product Summary[5]

Therapeutic Class: Androgen

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

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

Dosing and Administration:
- The recommended starting dose is 200mg twice daily with food.
- Serum testosterone should be measured 7 days after initiation (or after dosage adjustment), and dose should be adjusted as necessary.

- The minimum recommended dose is 100mg once daily in the morning.
- The maximum recommended dose is 400mg twice daily.
- See the full *Prescribing Information* for specific dosage adjustment recommendations, based on serum testosterone concentrations.

Cost Comparison: Testosterone Products

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Azmiro™ (testost cyp) 200mg/mL syr	**$250.00**	**$1,000.00***	**$13,000.00**
Undecatrex™ (testost undec) 200mg cap	**$15.78**	**$1,893.60[Δ]**	**$22,723.20**
testosterone 1% gel 5g tube (generic)	$0.72	$216.00[¥]	$2,592.00
testosterone 1% gel 5g packet (generic)	$0.57	$171.00[¥]	$2,052.00
testosterone 30mg/1.5mL solution (generic)	$0.69	$124.20[€]	$1,490.40
testosterone 1.62% gel pump (generic)	$0.44	$66.00[§]	$792.00
testosterone cyp 200mg/mL vial (generic)	$12.46[+]	$49.84*	$647.92

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month based on the max FDA approved dose of 400mg every 2 weeks.
[Δ]Cost per month based on the max FDA approved dose of 400mg twice daily.
[¥]Cost per month based on the max FDA approved dose of 100mg (10g of gel) once daily.
[€]Cost per month based on the max FDA approved dose of 120mg (6mL of solution) once daily.
[§]Cost per month based on the max FDA approved dose of 81mg (5g of gel) once daily.
[+]Cost varies by NDC
Unit = each capsule, gram, or milliliter
cap = capsule; cyp = cypionate; syr = syringe; testost = testosterone; undec = undecanoate

Recommendations

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

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

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

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

[1] U.S. Food and Drug Administration (FDA). NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/216318Orig1s000ltr.pdf. Issued 06/02/2022. Last accessed 08/15/2025.
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[4] Azmiro™ (Testosterone Cypionate) Prescribing Information. Azurity Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/216318s005lbl.pdf. Last revised 07/2025. Last accessed 08/15/2025.
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Appendix E

Vote to Prior Authorize Zevaskyn™ (Prademagene Zamikeracel) and Update the Approval Criteria for the Epidermolysis Bullosa (EB) Medications

Oklahoma Health Care Authority
September 2025

Market News and Updates[1]

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

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

Zevaskyn™ (Prademagene Zamikeracel) Product Summary[2,3]

Therapeutic Class: Autologous cell sheet-based gene therapy

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

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

Dosing and Administration:

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

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

- Key Inclusion Criteria:
  - ≥6 years of age
  - Clinical diagnosis of RDEB
  - 2 confirmed mutations in the *COL7A1* gene with recessive inheritance patterns (or confirmation that the parents do not have any evidence of dominant disease)

    - 1 pair of matched, large (at least 1 wound ≥20cm^2 for treatment and at least 1 wound ≥20cm^2 for control), stage 2 (partial thickness), chronic wounds (≥6 months) associated with RDEB
- Intervention: Matched wound pairs were randomized in a 1:1 ratio to receive either Zevaskyn™ (up to 6 sheets) or control treatment (standard of care wound dressing)
- Primary Outcome(s):
    - Proportion of randomized wound pairs ≥50% healing at 6 months with confirmation of wound healing 2 weeks later as assessed using baseline digital photography
    - Pain reduction as assessed by the mean differences in patient-reported pain scores using the Wong-Baker FACES scale between randomized wound pairs at 6 months
- Secondary Outcome(s):
    - Proportion of randomized wound pairs with complete wound healing defined as reepithelialization with no drainage or erosion and presence of only minor crusting from baseline at 3 months and 6 months with confirmation of wound healing 2 weeks later
- Results:
    - Proportion of randomized wound pairs healed ≥50% from baseline at 6 months: 35 (81%) in the Zevaskyn™ treated wounds vs. 7 (16%) in the control wounds (P<0.0001)
    - Mean pain reduction from baseline at 6 months [standard deviation (SD)]: -3.07 (3.19) in the Zevaskyn™ treated wounds vs. -0.90 (2.73) in the control wounds (P=0.0002)
    - Proportion of randomized wound pairs completely healed from baselined at 3 months: 6 (14%) in the Zevaskyn™ treated wounds vs. 0 (0%) in the control groups (P=0.0316)
    - Proportion of randomized wound pairs completely healed from baseline at 6 months: 7 (16%) in the Zevaskyn™ treated wounds vs. 0 (0%) in the control groups (P=0.0160)

Cost Comparison: EB Medications

Product	Cost
Zevaskyn™ (prademagene zamikeracel)	**$3,100,000.00±**
Vyjuvek® (beremagene geperpavec-svdt)	$1,311,960.00*
Filsuvez® (birch triterpenes 10% topical gel)	$647,974.08α

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
±Cost is per treatment cycle for Zevaskyn™. Depending on the size and number of wounds, patients may need more than 1 cycle.
*Cost is per year for Vyjuvek® and is based on the FDA maximum recommended weekly dose, which would require 1 carton (2.5mL) per week regardless of dose.
αCost is per year for Filsuvez® and is based on the use of 1 tube (23.4g) daily.

Recommendations

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

Zevaskyn™ (Prademagene Zamikeracel) Approval Criteria*:

1. An FDA approved indication for the treatment of wounds in members with recessive dystrophic epidermolysis bullous (RDEB); and
2. Diagnosis must be confirmed by biallelic pathogenic variants in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of the genetic testing must be submitted); and
3. Zevaskyn™ must be prescribed by a dermatologist at a qualified treatment center with expertise in the treatment of RDEB; and
4. Member must have the presence of partial-thickness RDEB wounds open chronically for ≥6 months; and
5. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
6. Prescriber must confirm that the member has been counseled and will not use other epidermolysis bullous products (e.g., Vyjuvek®, Filsuvez®) on wounds treated with Zevaskyn™; and
7. Zevaskyn™ must be administered at a Zevaskyn™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zevaskyn™ from receipt to storage to administration; and
8. Approval will be granted for 1 year for 1 treatment cycle; and
9. A new prior authorization may be considered for any previously untreated wounds. For consideration, the prescriber must attest Zevaskyn™ will not be used on wounds previously treated by Zevaskyn™ and the member responded well to treatment with Zevaskyn™ as indicated by the presence of wound healing; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's response to therapy and ongoing treatment plan.

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

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

1. An FDA approved indication for the treatment of wounds in members 6 months of age and older with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB); and

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

Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB); and

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

a. Clinical documentation (i.e., recent office notes) must be submitted with every request documenting the member's response to treatment and ongoing treatment plan; and
b. Vyjuvek® must continue to be administered by an HCP. Approvals will not be granted for self-administration. Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health).

[1] Abeona Therapeutics. U.S. FDA Approves Zevaskyn™ (Prademagene Zamikeracel), the First and Only Cell-Based Gene Therapy for Patients with Recessive Dystrophic Epidermolysis Bullosa (RDEB). Available online at: https://investors.abeonatherapeutics.com/press-releases/detail/303/u-s-fda-approves-zevaskyn-prademagene-zamikeracel. Issued 04/29/2025. Last accessed 08/07/2025.
[2] Zevaskyn™ (Prademagene Zamikeracel) Prescribing Information. Abeona Therapeutics Inc. Available online at: https://d1io3yog0oux5.cloudfront.net/_97c62242a52d17e584a3147d26ed2790/abeonatherapeutics/files/ZEVASKYN_Final_Label_30Apr2025.pdf. Last revised 04/2025. Last accessed 08/07/2025.
[3] Phase 3, Open-label Clinical Trial of EB-101 for the Treatment of Recessive Dystrophic Epidermolysis Bullosa (RDEB). *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/study/NCT04227106. Last revised 12/05/2022. Last accessed 08/07/2025.

Appendix F

Vote to Prior Authorize Zunveyl® (Benzgalantamine)

Oklahoma Health Care Authority
September 2025

Market News and Updates[1,2,3]

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

- **July 2024:** The FDA approved Zunveyl® (benzgalantamine) DR tablets for the treatment of mild to moderate dementia of the Alzheimer's type in adults. Zunveyl® is a prodrug of galantamine and is expected to release galantamine after bypassing the stomach. The efficacy of Zunveyl® was based on 3 bioavailability studies in healthy adults comparing Zunveyl® to galantamine immediate-release tablets and galantamine ER capsules where Zunveyl® was found to be bioequivalent to both formulations of galantamine. Zunveyl® is available as an oral DR tablet in 3 strengths (5mg, 10mg, and 15mg), and the recommended starting dose is 5mg twice daily for at least 4 weeks with a maximum recommended dose of 15mg twice daily. In March 2025, Alpha Cognition announced the launch of Zunveyl®.

Cost Comparison: Benzgalantamine and Galantamine Products

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Zunveyl® (benzgalantamine) DR 15mg tablet	**$12.48**	**$748.80***	**$8,985.60**
galantamine 12mg tablet (generic)	$0.60	$36.00⁺	$432.00
galantamine ER 24mg capsule (generic)	$1.05	$31.50⁺	$378.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
DR = delayed-release; ER = extended-release; Unit = capsule or tablet
*Cost per month based on the maximum FDA approved dosing of 15mg twice daily.
⁺Cost per month based on the maximum FDA recommended dose of 24mg per day.

Recommendations

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

Zunveyl® (Benzgalantamine) Approval Criteria:

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

[1] Zunveyl® (Benzgalantamine) – New drug approval. *OptumRx*®. Available online at: https://professionals.optumrx.com/content/dam/noindex-resources/business/support-documents/drug-approvals/drugapproval_zunveyl_2024-0729.pdf. Issued 07/29/2024. Last accessed 08/13/2025.

[2] U.S. FDA. Zunveyl® (Benzgalantamine) Summary Review. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/218549Orig1s000SumR.pdf. Issued 07/25/2024. Last accessed 08/13/2025.

[3] Alpha Cognition. Alpha Cognition Announces the Commercial Launch of Zunveyl® (Benzgalantamine) for the Treatment of Mild to Moderate Alzheimer's Disease. *Businesswire*. Available online at: https://www.businesswire.com/news/home/20250319665873/en/Alpha-Cognition-Announces-the-Commercial-Launch-of-ZUNVEYL-Benzgalantamine-for-the-Treatment-of-Mild-to-Moderate-Alzheimers-Disease. Issued 03/18/2025. Last accessed 08/13/2025.

Appendix G

Vote to Prior Authorize Blujepa (Gepotidacin), Emblaveo™ (Aztreonam/Avibactam), Likmez™ (Metronidazole Oral Suspension), and Metronidazole 125mg Tablet and 375mg Capsule and Update the Approval Criteria for the Various Systemic Antibiotics

Oklahoma Health Care Authority
September 2025

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

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

- **September 2023:** The FDA approved Likmez™ (metronidazole oral suspension) for the indications of trichomoniasis in adults, amebiasis in adults and pediatric patients, and anaerobic bacterial infections in adults. Likmez™ is available as a 500mg/5mL oral suspension with a strawberry peppermint flavor.
- **February 2025:** The FDA approved the monobactam/beta-lactamase inhibitor combination antibiotic therapy, Emblaveo™ (aztreonam/avibactam). When used in combination with metronidazole, Emblaveo™ is indicated for the treatment of complicated intra-abdominal infections (cIAI), including those caused by susceptible gram-negative bacteria (e.g., *Klebsiella oxytoca, Enterobacter cloacae complex, Citrobacter freundii complex, Serratia marcescens*), in patients 18 years of age or older who have limited or no alternative treatment options. According to package labeling, the FDA approved this indication based on limited clinical safety and efficacy data.
- **March 2025:** The FDA approved Blujepa (gepotidacin) for the treatment of uncomplicated urinary tract infection (uUTI) caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii* complex, *Staphylococcus saprophyticus* and *Enterococcus faecalis*. Blujepa is approved for female adult and pediatric patients 12 years of age and older and weighing at least 40kg. Blujepa is a first-in-class, bactericidal triazaacenaphthylene antibiotic that inhibits 2 different topoisomerase enzymes, thereby inhibiting bacterial deoxyribonucleic acid (DNA) replication.

News:

- **February 2024:** Generic metronidazole 375mg capsules were brought to market under an Abbreviated New Drug Application (ANDA).

- **January 2025:** Generic metronidazole 125mg tablets were brought to market under an ANDA.

Guideline Update(s):

- **American College of Gastroenterology (ACG) Guideline Update(s):** In September 2024, the ACG released an update to the 2017 guidelines for the treatment of *Helicobacter pylori* (*H. pylori)* infection. Changes to the recommended first-line regimens are based on data indicating increasing rates of *H. pylori* resistance to clarithromycin and levofloxacin in North America. The guidelines state that the rising resistance rates greatly reduce the efficacy of clarithromycin- and levofloxacin-based regimens. First-line regimens for treatment-naïve patients include:
  - Optimized bismuth quadruple therapy (BQT) for 14 days as the preferred option when the antibiotic susceptibility profile is unknown. BQT consists of a standards dose proton pump inhibitor (PPI), bismuth subcitrate or subsalicylate, tetracycline, and metronidazole.
  - Rifabutin triple therapy or potassium channel acid blocker (PCAB) dual therapy for 14 days can be suitable alternatives in patients without a penicillin allergy. The rifabutin triple therapy regimen consists of omeprazole, amoxicillin, and rifabutin while the PCAB dual therapy regimen consists of vonoprazan and amoxicillin (available as Voquezna® DualPak®).
  - In patients with unknown antibiotic susceptibility and no history of macrolide exposure or penicillin allergy, PCAB-clarithromycin triple therapy for 14 days is preferable to PPI-clarithromycin triple therapy when no other obvious first-line treatment option is available.

Blujepa (Gepotidacin) Product Summary[7,8]

Therapeutic Class: Triazaacenaphthylene bacterial type II topoisomerase inhibitor

Indication(s): Treatment of female adult and pediatric patients 12 years of age and older and weighing at least 40kg with uUTI caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Citrobacter freundii* complex, *Staphylococcus saprophyticus* and *Enterococcus faecalis*

How Supplied: 750mg film-coated tablet

Dosing and Administration: 1,500mg (2 tablets) orally twice daily after a meal for 5 days

Efficacy: The safety and efficacy of Blujepa was supported by 2 Phase 3 multicenter, double-blind, double-dummy, non-inferiority trials, designated as Trial 1 and Trial 2 in the *Prescribing Information*.

- Key Inclusion Criteria:
  - Female ≥12 years of age and weighing ≥40kg
  - At least 2 symptoms consistent with uUTI (e.g., dysuria, frequency, urgency, lower abdominal pain)
  - At least 1 baseline qualifying uropathogen [$\geq 10^5$ colony-forming units (CFU)/mL]
- Key Exclusion Criteria:
  - Medical condition or presentation suggestive of cUTI (e.g., pyelonephritis, urosepsis)
  - Baseline uropathogen not susceptible to nitrofurantoin
- Intervention(s):
  - Both trials compared Blujepa 1,500mg orally twice daily with food for 5 days vs. nitrofurantoin 100mg orally twice daily for 5 days
- Primary Endpoint(s):
  - Composite of clinical cure (resolution of all signs and symptoms) and microbiological response (reduction of baseline pathogen to $<10^3$ CFU/mL) at the Test-of-Cure (TOC) visit on day 10 to 13
  - -10% prespecified non-inferiority margin for the composite endpoint
- Results:
  - Both trials demonstrated non-inferiority of Blujepa to nitrofurantoin
  - Trial 1: 51.8% (174/336) of participants who received Blujepa achieved the composite response vs. 47% (140/298) of participants who received nitrofurantoin [difference: 5.3; 95% confidence interval (CI): -2.4, 13.0)
  - Trial 2: 58.9% (172/292) of participants who received Blujepa achieved the composite response vs. 44% (121/275) of participants who received nitrofurantoin (difference: 14.4; 95% CI: 6.4, 22.4)

Cost: The Wholesale Acquisition Cost (WAC) of Blujepa is not available at this time to allow for a cost analysis.

Emblaveo™ (Aztreonam/Avibactam) Product Summary[2]

Therapeutic Class: Monobactam antibacterial and beta-lactamase inhibitor combination

Indication(s): Treatment of cIAI caused by designated susceptible gram-negative microorganisms in patients 18 years of age and older; used in combination with metronidazole

How Supplied: 2 gram single-dose vial (SDV) containing 1.5 grams of aztreonam and 0.5 grams of avibactam as a lyophilized powder for reconstitution and dilution

Dosing and Administration: The recommended dose of Emblaveo™ is a loading dose of 2.67 grams by IV infusion followed by a maintenance dose of 2 grams every 6 hours via IV infusion in adults with an estimated creatinine clearance (CrCl) >50mL/min.

- See package labeling for dose adjustments for adults with CrCl ≤50mL/min.
- The recommended treatment duration is 5 to 14 days.

Efficacy: According to the *Prescribing Information*, the safety and efficacy of Emblaveo™ were supported in part by previously published findings regarding the safety and efficacy of the aztreonam component for cIAI and, for the avibactam component, by established *in vitro* and animal models of infection. Emblaveo™ was studied in a randomized, active-controlled multicenter trial in patients with cIAI or hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP) (not an FDA-approved indication); this trial was not designed with any formal hypotheses for inferential testing against the active comparator.

Cost: The Wholesale Acquisition Cost (WAC) of Emblaveo™ is $327 per 2g SDV, resulting in a cost of $694 for the loading dose and $327 for each maintenance dose. The cost of a 14-day regimen, with a 2.67 gram loading dose followed by maintenance dosing of 2 grams IV every 6 hours, would be $18,639.

Cost Comparison: Metronidazole Products

Product	Cost Per Unit	Cost Per Day*
metronidazole 125mg tablet (generic)	**$13.27**	**$159.24**
metronidazole 375mg capsule (generic)	**$6.56**	**$26.24**
Likmez™ (metronidazole 500mg/5mL oral suspension)	**$2.73**	**$40.95**
metronidazole 500mg tablet (generic)	$0.10	$0.30
metronidazole 250mg tablet (generic)	$0.09	$0.54

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 1,500mg per day.
Unit = capsule, milliliter, or tablet

Recommendations

The College of Pharmacy recommends the prior authorization of Blujepa (gepotidacin), Emblaveo™ (aztreonam/avibactam) and Likmez™ (metronidazole oral suspension) with the following criteria (shown in red):

Blujepa (Gepotidacin) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by designated microorganisms (culture/sensitivity results must be submitted); and
2. Member must be a female 12 years of age or older and weigh ≥40kg; and
3. Member must have an estimated glomerular filtration rate (eGFR) >30mL/min/1.73m^2) and must not be on dialysis; and
4. Member must not have severe hepatic impairment (Child Pugh C); and
5. 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
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 duration 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 quantity limit of 20 tablets per 5 days will apply.

Emblaveo™ (Aztreonam/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of complicated intra-abdominal infections (cIAI) caused by susceptible gram-negative microorganisms (e.g., *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca*,

Enterobacter cloacae complex, *Citrobacter freundii* complex, *Serratia marcescens*) in adults who have limited or no alternative treatment options (culture/sensitivity results must be submitted); and
2. Member must 18 years of age or older; and
3. Must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use 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, a fluoroquinolone (e.g., ciprofloxacin or levofloxacin) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. A quantity limit of 57 vials per 14 days will apply.

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

1. 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.

Additionally, the College of Pharmacy recommends the prior authorization of metronidazole 125mg tablets and 375mg capsules based on net costs within the Oral Antibiotic Special Formulation Approval Criteria (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

Lastly, based on the 2024 ACG guideline updates, the College of Pharmacy recommends updating the Tetracycline 250mg and 500mg Capsule and Tablet Approval Criteria to remove the prior authorization requirement from tetracycline 250mg and 500mg capsules for the diagnosis of *H. pylori* infection (changes shown in red):

Tetracycline 250mg and 500mg Capsule and Tablet Approval Criteria:

1. ~~Approval requires a patient-specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s).~~
2. For the capsule formulation, a quantity of 56 capsules for 14 days is available without a prior authorization for a diagnosis of *Helicobacter pylori* (*H. pylori*) infection; or
3. For the tablet formulation, approval ~~also~~ requires a patient-specific, clinically significant reason why the member requires the tablet formulation and cannot use the capsule formulation, which is available without prior authorization; and
4. A quantity limit of 56 capsules or tablets per 14 days will apply; and
    a. A quantity limit override for longer durations of therapy for indications other than for the eradication of *H. pylori* infection will require a patient specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s).

[1] Likmez™ (Metronidazole Oral Suspension) Prescribing Information. Saptalis Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216755s003lbl.pdf. Last revised 09/22/2023. Last accessed 08/11/2025.
[2] Emblaveo™ (Aztreonam/Avibactam) Prescribing Information. AbbVie. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/217906Orig1s000lbl.pdf. Last revised 02/07/2025. Last accessed 08/11/2025.
[3] GSK. Blujepa (Gepotidacin) Approved by US FDA for Treatment of Uncomplicated Urinary Tract Infections (uUTIs) in Female Adults and Pediatric Patients 12 Years of Age and Older. Available online at: https://www.gsk.com/en-gb/media/press-releases/blujepa-gepotidacin-approved-by-us-fda-for-treatment-of-uncomplicated-urinary-tract-infections/. Issued 03/25/2025. Last accessed 08/11/2025.
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Appendix H

Vote to Prior Authorize Tramadol 75mg Tablet and Update the Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications

Oklahoma Health Care Authority
September 2025

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

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

- **April 2024:** The FDA approved a new strength of tramadol in a 75mg tablet through an Abbreviated New Drug Application (ANDA).
- **February 2025:** The FDA approved a label change to allow a rapid initiation protocol for Sublocade® [buprenorphine extended-release (ER) injection] which can now be initiated after a single dose of transmucosal buprenorphine and a 1-hour observation period to confirm tolerability. The rapid initiation protocol was supported by a non-inferiority study of Sublocade® in 729 patients randomized at a 2:1 ratio to rapid initiation [receiving a single dose of 4mg transmucosal buprenorphine (TM-BUP), followed by a Sublocade® injection within 1 hour] or to the standard induction (daily TM-BUP for at least 7 days before receiving the first injection of Sublocade®). The results showed the rapid induction was effective with 66.4% of patients receiving the second injection in the rapid induction arm compared to 54.5% in the standard induction arm.
- **May 2025:** The Suboxone® (buprenorphine/naloxone SL tablet and film) and Zubsolv® (buprenorphine/naloxone SL tablet) labels were modified to clarify there is no maximum daily dosage. Both products' maintenance dosing states higher doses "may be appropriate for some patients". This update aligns with the American Society of Addiction Medicine's Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-Potency Synthetic Opioids, which was published in 2023. This document stated that some patients may need higher doses of buprenorphine (>24mg/day) if they are using high-potency synthetic opioids, such as fentanyl.

Cost Comparison: Tramadol[5]

Product	Cost Per Tablet	Cost Per 30 Days*
tramadol 75mg tablet (generic)	**$4.34**	**$520.80**
tramadol 50mg tablet (generic)	$0.02	$3.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the FDA approved dose of 75mg four times daily.

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. Adding tramadol 75mg tablet to the Special PA Tier with the following additional criteria; and
2. Moving oxycodone tablet (RoxyBond™) to the Special PA Tier with the following additional criteria; and
3. Making hydrocodone ER capsule (Hysingla® ER) brand preferred; and
4. Moving tramadol ER tablet (Ultram® ER) to Tier 1.

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®)	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**	tramadol ER cap (ConZip®)
	tramadol ER tab (~~**Ultram® ER,**~~ Ryzolt®)	hydromorphone ER tab (Exalgo®)	
		methadone tab (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		oxycodone ER cap (Xtampza® ER)	
Short-Acting			
APAP/butalbital/ caff/codeine cap 50/325/40/30mg (Fioricet® with Codeine)	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)	dihydrocodeine/ APAP/caff cap (Trezix®)	APAP/butalbital/ caff/codeine cap 50/300/40/30mg (Fioricet® with Codeine)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)	~~**oxycodone tab (RoxyBond™)**~~	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™)			**oxycodone tab (RoxyBond™)**
hydromorphone tab & soln (Dilaudid®)			oxycodone/APAP tab (Nalocet®)
meperidine tab & soln (Demerol®)			oxycodone/APAP tab & soln (Prolate®)
morphine IR tab & soln (MSIR®)			tramadol 25mg**, 75mg,** & 100mg tab
oxycodone/APAP tab & soln (Percocet®)			tramadol soln (Qdolo™)
oxycodone/ASA tab (Percodan®)			
oxycodone IR cap (Oxy IR®)			
oxycodone IR tab & soln (Roxicodone®)			***Oncology Only:***
tramadol 50mg tab (Ultram®)			fentanyl buccal tab (Fentora®)
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® and Fentora® are 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. 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.
9. 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.
10. Oxymorphone ER Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other available extended-release opioid analgesic must be provided.
11. 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.
12. 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 (changes shown in red):

1. Removing the prior authorization of Subutex® (buprenorphine SL tablet) based on net cost and to increase access and decrease barriers to opioid use disorder (OUD) treatment; and
2. Updating the Brixadi® (buprenorphine ER injection) and Sublocade® (buprenorphine ER injection) approval criteria based on the FDA label expansion of Sublocade®.

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

1. Generic buprenorphine/naloxone SL tablet and buprenorphine SL tablet ~~is~~ are the preferred product~~s~~. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why ~~generic buprenorphine/naloxone SL tablets~~ the preferred SL tablets are not appropriate.
2. ~~Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and~~
3. Member must have an FDA approved diagnosis of opioid abuse/ dependence [i.e., opioid use disorder (OUD)]; and
4. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
5. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
6. 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.
i. Zubsolv® 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.

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

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder (OUD); and
2. ~~For Sublocade®, member must have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days; or~~
3. ~~For Brixadi®,~~ Member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
4. Concomitant treatment with opioids (including tramadol) will be denied; and
5. Medication should only be prepared and administered by a health care provider; and
6. 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
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 to allow for concurrent medication monitoring; and
9. ~~A quantity limit of 1 monthly dose per 28 days or 4 weekly doses per 28 days will apply.~~
10. The following quantity limits will apply:
    a. Brixadi® 8mg/0.16mL, 16mg/0.32mL, 24mg/0.48mL, and 32mg/0.64mL: 4 weekly doses per 28 days
    b. Brixadi® 64mg/0.18mL, 96mg/0.27mL, and 128mg/0.36mL: 1 monthly dose per 28 days
    c. 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.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations Product Details for Abbreviated New Drug Application (ANDA) 208708. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=208708#22539. Last revised 08/2025. Last accessed 08/07/2025.

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[3] Sublocade® (Buprenorphine Extended-Release) Prescribing Information. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/209819s031lbl.pdf. Last revised 02/2025. Last accessed 08/07/2025.

[4] American Society of Addiction Medicine (ASAM). New Buprenorphine OUD Labels Clarify Higher Doses Appropriate for Some Patients. Available online at: https://www.asam.org/news/detail/2025/06/09/new-buprenorphine-for-oud-labels-clarify-higher-doses-appropriate-for-some-patients. Issued 06/09/2025. Last accessed 08/07/2025.

[5] Tramadol Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=93b12089-3a0f-4b57-abb1-2429cf31995d. Last revised 09/06/2024. Last accessed 08/07/2025.

Appendix I

Vote to Update the Approval Criteria for the Topical Corticosteroids

Oklahoma Health Care Authority
September 2025

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. Move amcinonide 0.1% cream from Tier-2 to Tier-3; and
   b. Move augmented betamethasone dipropionate 0.05% (Diprolene®) lotion from Tier-2 to Tier-1; and
2. Medium-High to Medium Potency:
   a. Move hydrocortisone valerate 0.2% (Westcort®) ointment from Tier-3 to Tier-2.

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®) Diprolene AF®)	C,**L,**O	~~**amcinonide 0.1%**~~	~~**C**~~	**amcinonide 0.1%**	**C**
betamethasone dipropionate 0.05% (Diprosone®)	C,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G~~,L~~	clobetasol propionate 0.025% (Impoyz®)	C
clobetasol propionate 0.05% (Olux®)	F	clobetasol propionate 0.05% (Clobex®)	L,Sh,Spr	clobetasol propionate 0.05% (Olux-E®, Tovet®)	F
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	desoximetasone 0.25% (Topicort®)	Spr
desoximetasone 0.25% (Topicort®)	C,O	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
fluocinonide 0.05%	C,O,So	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon E®)	C
fluocinonide 0.1% (Vanos®)	C	halobetasol propionate 0.05% (Ultravate®)	L	halcinonide 0.1% (Halog®)	C,So
halobetasol propionate 0.05% (Ultravate®)	C,O			halobetasol propionate 0.01% (Bryhali®)	L
				halobetasol propionate 0.05%	F
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	fluocinonide emollient 0.05% (Lidex E®)	C	fluticasone propionate 0.05% (Cutivate®)	L
mometasone furoate 0.1% (Elocon®)	C,L,O, So	hydrocortisone butyrate 0.1%	O, So	hydrocortisone butyrate 0.1%	C,L
triamcinolone acetonide 0.025%	O	hydrocortisone probutate 0.1% (Pandel®)	C	~~**hydrocortisone valerate 0.2% (Westcort®)**~~	~~**O**~~
triamcinolone acetonide 0.1%	C,L,O	**hydrocortisone valerate 0.2% (Westcort®)**	**O**	triamcinolone acetonide 0.147mg/g	Spr

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
triamcinolone acetonide 0.5%	C,O	triamcinolone acetonide 0.05% (Trianex®)	O		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C,O	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	fluocinolone acetonide 0.01% (Synalar®)	C	hydrocortisone 2.5% (Texacort®)	So
hydrocortisone acetate 2.5%	C,L,O				
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

Additionally, the College of Pharmacy recommends removing the prior authorization of Cortifoam® (hydrocortisone acetate 10% rectal foam) and recommends the prior authorization of Proctofoam® HC (hydrocortisone/ pramoxine 1%/1% rectal foam) based on net costs (changes shown in red):

~~**Cortifoam® (Hydrocortisone Acetate 10% Rectal Foam) Approval Criteria:**~~

~~1. A patient-specific, clinically significant reason why the member cannot use other strengths and rectal formulations of hydrocortisone must be provided.~~

Proctofoam® HC (Hydrocortisone/Pramoxine 1%/1% Rectal Foam) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Epifoam® (hydrocortisone/pramoxine 1%/1% rectal foam) or other rectal formulations of hydrocortisone available without a prior authorization must be provided.

Appendix J

Vote to Prior Authorize Ryoncil® (Remestemcel-L-rknd) and Update the Approval Criteria for the Miscellaneous Cancer Medications

Oklahoma Health Care Authority
September 2025

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

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

- **December 2024:** The FDA approved Ryoncil® (remestemcel-L-rknd) for the treatment of steroid-refractory acute graft versus host disease (aGVHD) in pediatric patients 2 months of age and older.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines allow the use of toripalimab-tpzi for the treatment of locally unresectable or medically inoperable, advanced or metastatic anal carcinoma, colorectal cancer, or small bowel adenocarcinoma that is deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype.

Ryoncil® (Remestemcel-L-rknd) Product Summary[6]

Therapeutic Class: Allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy

Indication(s): Treatment of steroid-refractory aGVHD in pediatric patients 2 months of age and older

How Supplied:

- Cell suspension for intravenous (IV) infusion in a target concentration of 6.68 X 10^6 MSCs per mL in 3.8mL contained in a 6mL cryovial
- Supplied as a customized kit containing a variable number of vials to meet dosing requirements for a single dose for each patient, based on the patient's weight

Dosing and Administration:

- The recommended dosage of Ryoncil® is 2 X 10^6 MSCs/kg body weight per IV infusion given twice a week for 4 consecutive weeks for a total of 8 infusions.
- Infusions should be administered at least 3 days apart.

- Treatment response should be assessed 28 ± 2 days after the first dose, and further treatment may be administered based on day 28 response.
- For a partial or mixed response at day 28, Ryoncil® administration may be repeated once weekly for an additional 4 weeks (4 infusions total).
- For recurrence of GVHD after a complete response, Ryoncil® administration may be repeated twice weekly for an additional 4 consecutive weeks (8 infusions total).

Cost: The Wholesale Acquisition Cost (WAC) is $194,000 per infusion, regardless of weight. For the initial treatment course of 8 infusions, this would result in an estimated cost of $1,552,000. If a partial or mixed response is achieved after the initial treatment, the cost of 4 additional infusions would be $776,000, and the total cost for that member would be $2,328,000.

Recommendations

The College of Pharmacy recommends the prior authorization of Ryoncil® (remestemcel-l-rknd) with the following criteria (shown in red):

Ryoncil® (Remestemcel-L-rknd) Approval Criteria [Acute Graft Versus Host Disease (aGVHD) Diagnosis]:

1. Diagnosis of aGVHD; and
2. Disease is steroid refractory; and
3. Member is 2 months of age to younger than 18 years of age; and
4. Member is an allogeneic hematopoietic stem cell transplant (HSCT) recipient; and
5. Initial approvals will be for a maximum of 8 infusions; and
6. Subsequent approvals for additional infusions will require repeat authorization and clinical documentation must be submitted to support the need for additional infusions; and
    a. All requests for subsequent approvals will require review by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician.

Additionally, the College of Pharmacy recommends updating the Loqtorzi® (toripalimab-tpzi) approval criteria based on NCCN recommendations with the following changes (shown in red):

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

1. Diagnosis of anal carcinoma, CRC, or small bowel adenocarcinoma; and
2. Disease is locally unresectable, medically inoperable, advanced, or metastatic; and
3. Must meet 1 of the following:
    a. Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H); or

   b. Polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb]; and
4. No prior treatment with a checkpoint inhibitor; and
5. Used as a single agent; and
6. Dose as follows:
   a. 3mg/kg every 2 weeks.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves Remestemcel-L-rknd for Steroid-Refractory Acute Graft Versus Host Disease in Pediatric Patients. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-remestemcel-l-rknd-steroid-refractory-acute-graft-versus-host-disease-pediatric. Issued 12/18/24. Last accessed 08/25/2025.
[2] National Comprehensive Cancer Network (NCCN). Anal Carcinoma Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Last revised 05/30/2025. Last accessed 08/25/2025.
[3] 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 06/27/2025. Last accessed 08/25/2025.
[4] National Comprehensive Cancer Network (NCCN). Rectal Cancer Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Last revised 03/31/2025. Last accessed 08/25/2025.
[5] National Comprehensive Cancer Network (NCCN). Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology. Available online at: https://www.nccn.org/professionals/physician_gls/pdf/small_bowel.pdf. Last revised 03/31/2025. Last accessed 08/25/2025.
[6] Ryoncil® (Remestemcel-L-rknd) Prescribing Information. Mesoblast, Inc. Available online at: https://www.ryoncil.com/pdfs/prescribing-information.pdf. Last revised 01/2025. Last accessed 08/25/2025.

Appendix K

Fiscal Year 2025 Annual Review of Camzyos® (Mavacamten)

Oklahoma Health Care Authority
September 2025

Current Prior Authorization Criteria

Camzyos® (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or nondihydropyridine calcium channel blockers; and
7. Member must not be taking concurrent moderate to strong CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole, fluvoxamine), strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir), moderate to strong CYP2C19 inducers (e.g., rifampicin, carbamazepine), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and
8. 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
9. 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
10. Prescriber, pharmacy, and member must be enrolled in the Camzyos® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
11. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment; and
12. Subsequent approvals will be for the duration of 1 year.

Utilization of Camzyos® (Mavacamten): Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

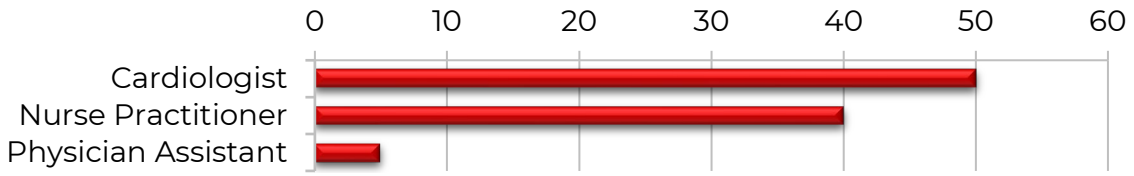
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	7	22	$177,839.65	$8,083.62	$269.45	660	660
Aetna	1	2	$16,407.38	$8,203.69	$273.46	60	60
Humana	3	7	$57,425.83	$8,203.69	$273.46	210	210
OCH	1	2	$16,407.38	$8,203.69	$273.46	60	60
2024 Total	**9**	**33**	**$268,080.24**	**$8,123.64**	**$270.79**	**990**	**990**
Fiscal Year 2025							
FFS	5	12	$96,892.69	$8,074.39	$280.85	345	345
Aetna	3	22	$184,536.33	$8,388.02	$279.60	660	660
Humana	4	36	$274,976.87	$7,638.25	$279.16	985	985
OCH	4	25	$210,341.94	$8,413.68	$280.46	750	750
2025 Total	**14**	**95**	**$766,747.83**	**$8,071.03**	**$279.83**	**2,740**	**2,740**
% Change	**55.60%**	**187.90%**	**186.00%**	**-0.60%**	**3.30%**	**176.80%**	**176.80%**
Change	**5**	**62**	**$498,667.59**	**-$52.61**	**$9.04**	**1,750**	**1,750**

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

Demographics of Members Utilizing Camzyos® (Mavacamten): Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing Camzyos® (mavacamten) during fiscal year 2025, detailed demographic information could not be provided.

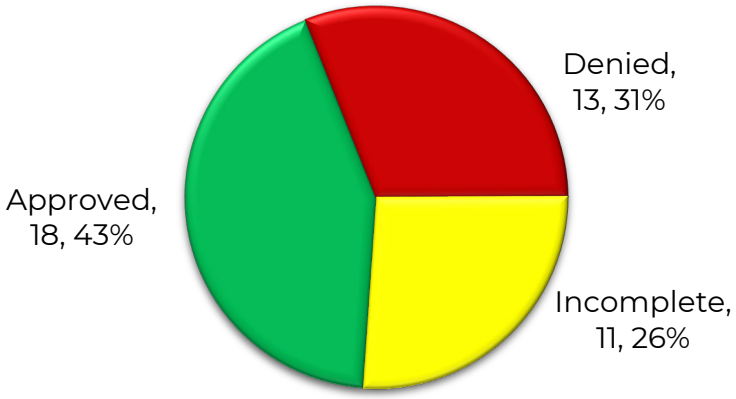
Top Prescriber Specialties of Camzyos® (Mavacamten) by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Camzyos® (Mavacamten)

There were 42 prior authorization requests submitted for Camzyos® (mavacamten) during fiscal year 2025. The following chart shows the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	6	30%	10	50%	4	20%	**20**
Aetna	4	67%	1	17%	1	17%	**6**
Humana	7	64%	0	0%	4	36%	**11**
OCH	1	20%	0	0%	4	80%	**5**
Total	**18**	**43%**	**11**	**26%**	**13**	**31%**	**42**

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

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

Anticipated Patent Expiration(s):

- Camzyos® (mavacamten): June 2034

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

- **April 2025:** The FDA approved updates to the Camzyos® (mavacamten) *Prescribing Information* and Risk Evaluation and Mitigation Strategy (REMS) program based on a supplemental new drug application (sNDA) that included data from long-term clinical trials and real-world evidence. Notable changes include the following:
  - Removal of contraindications for moderate CYP2C19 inhibitors and strong CYP3A4 inhibitors
  - Updated descriptions of contraindicated medications and concomitant medications requiring dose adjustment:
    - The dose of Camzyos® should be reduced to the next lower daily (mg) dose level in patients who intend to initiate a weak to moderate CYP2C19 inhibitor or moderate to strong CYP3A4 inhibitor.
    - Initiation of a weak to moderate CYP2C19 inhibitor or moderate to strong CYP3A4 inhibitor should be avoided in

patients who are stable on the 2.5mg dose of Camzyos® because a lower dose is not available.
    - Camzyos® may be interrupted for short-term (e.g., 1 week) use of a weak to moderate CYP2C19 inhibitor or a moderate to strong CYP3A4 inhibitor when Camzyos® dose modification is not feasible.
- Reduction of recommended frequency of echocardiogram monitoring from every 12 weeks to every 3 to 6 months for patients on a stable dose of Camzyos® in the maintenance phase
- Addition that a post-exercise left ventricular outflow tract (LVOT) gradient assessment may be considered to further titrate symptomatic patients with normal or near normal Valsalva gradients

Pipeline:

- **Aficamten:** Cytokinetics announced in May 2025 that the FDA extended the Prescription Drug User Fee (PDUFA) date for its experimental therapeutic product, aficamten, to December 26, 2025 to conduct a full review of the proposed REMS program. The New Drug Application (NDA) for aficamten is seeking approval for the treatment of patients with obstructive hypertrophic cardiomyopathy (HCM). Aficamten is an oral, small molecule cardiac myosin inhibitor designed to reduce hypercontractility associated with HCM and was evaluated in the Phase 3 SEQUOIA-HCM clinical trial. In the Phase 3 trial, treatment with aficamten resulted in significantly greater improvement in peak oxygen uptake in patients with symptomatic obstructive HCM as compared to placebo.
- **Inpefa® (Sotagliflozin):** In May 2025, Lexicon Pharmaceuticals announced the study design for SONATA-HCM, a Phase 3 clinical trial designed to evaluate Inpefa® (sotagliflozin) for the treatment of obstructive and non-obstructive HCM. The trial is currently enrolling participants at study sites in 20 countries.

Recommendations

The College of Pharmacy recommends the following changes to the Camzyos® (mavacamten) approval criteria based on the FDA-approved updates to the package labeling and REMS program (changes shown in red):

Camzyos® (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and

4. Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or nondihydropyridine calcium channel blockers; and
7. ~~Member must not be taking concurrent moderate to strong CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole, fluvoxamine), strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir), moderate to strong CYP2C19 inducers (e.g., rifampicin, carbamazepine), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and~~
8. 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
9. 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
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. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment; and
14. Subsequent approvals will be for the duration of 1 year.

Utilization Details of Camzyos® (Mavacamten): Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CAMZYOS CAP 5MG	43	12	$350,001.58	$8,139.57	3.58	45.65%
CAMZYOS CAP 2.5MG	25	3	$209,139.40	$8,365.58	8.33	27.28%
CAMZYOS CAP 10MG	19	4	$140,134.08	$7,375.48	4.75	18.28%
CAMZYOS CAP 15MG	8	2	$67,472.77	$8,434.10	4	8.8%
TOTAL	**95**	**14***	**$766,747.83**	**$8,071.03**	**6.79**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2025. Last accessed 08/25/2025.
[2] U.S. FDA. Camzyos® Supplement Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/214998Orig1s010ltr.pdf. Issued 04/17/2025. Last accessed 08/25/2025.
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Appendix L

Fiscal Year 2025 Annual Review of Synagis® (Palivizumab)

Oklahoma Health Care Authority
September 2025

Current Prior Authorization Criteria[1,2]

Prior authorization is required for all members who receive palivizumab in an outpatient setting. Palivizumab is approved for members who meet the established prior authorization criteria, which is based on the American Academy of Pediatrics (AAP) 2014 guidelines for palivizumab prophylaxis.

Synagis® (Palivizumab) Approval Criteria:

A. Member Selection:
   1. Infants younger than 12 months of age at the start of respiratory syncytial virus (RSV) season:
      a. Born before 29 weeks, 0 days gestation; or
      b. Born before 32 weeks, 0 days gestation and develop chronic lung disease (CLD) of prematurity (require >21% oxygen supplementation for ≥28 days after birth); or
      c. Have hemodynamically significant congenital heart disease [acyanotic heart disease and receiving medication to control congestive heart failure (CHF) and will require surgical procedures, or have moderate-to-severe pulmonary hypertension]; or
      d. May be considered for:
         i. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough; or
         ii. Infants who undergo cardiac transplantation during RSV season; or
         iii. Infants who are profoundly immunocompromised during RSV season; or
         iv. Infants with cystic fibrosis with clinical evidence of CLD and/or who are nutritionally compromised; or
   2. Infants 12 to 24 months of age at the start of RSV season:
      a. Born before 32 weeks, 0 days gestation and have CLD of prematurity (required ≥28 days of oxygen after birth) and continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) during the 6 months before the start of the RSV season; or

b. May be considered for:
    i. Infants who undergo cardiac transplantation during RSV season; or
    ii. Infants who are profoundly immunocompromised during RSV season; or
    iii. Infants with cystic fibrosis with manifestations of severe lung disease or weight for length less than the 10th percentile.

B. Product Selection: A patient-specific, clinically significant reason why the member cannot receive Beyfortus® (nirsevimab-alip), as recommended by the CDC, must be provided. Additionally, the prescriber must confirm the member has not already received Beyfortus® for the current RSV season. Concomitant use with Beyfortus® will not be approved.

C. Length of Treatment: Palivizumab is approved for use only during RSV season in Oklahoma as determined by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System or other credible statewide monitoring system. The threshold for determining RSV seasonality is 10% of positive tests. RSV is determined to be in season once the percentage of positive tests is >10%; however, due to a potential lag in reporting data, palivizumab coverage will begin when the percentage of positive tests is consistently increasing and approaching the 10% threshold. RSV season is determined to be at an end when the percentage of positive tests is consistently <10%. Initial and subsequent approvals will be for the duration of 1 month until RSV season ends. A separate prior authorization request will be required for consideration of initial approval and for each subsequent approval. Members initially approved for palivizumab will require a patient-specific, clinically significant reason why the member still cannot receive Beyfortus® (nirsevimab-alip).

D. Units Authorized: The member's current weight (taken within the last 3 weeks) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling. Doses are to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as 1 of the approved total.

E. Dose-Pooling: To avoid unnecessary risk to the member, multiple members are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Utilization of Synagis® (Palivizumab): Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	57	136	$406,229.04	$2,986.98	$99.57	122	4,080
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**57**	**136**	**$406,229.04**	**$2,986.98**	**$99.57**	**122**	**4,080**
Fiscal Year 2025							
FFS	0	0	$0.00	$0.00	$0.00	0	0
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	**0**	**0**	**$0.00**	**$0.00**	**$0.00**	**0**	**0**
% Change	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**
Change	**-57**	**-136**	**-$406,229.04**	**-$2,986.98**	**-$99.57**	**-122**	**-4,080**

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

Comparison of Fiscal Years: Medical Claims (All Plans)

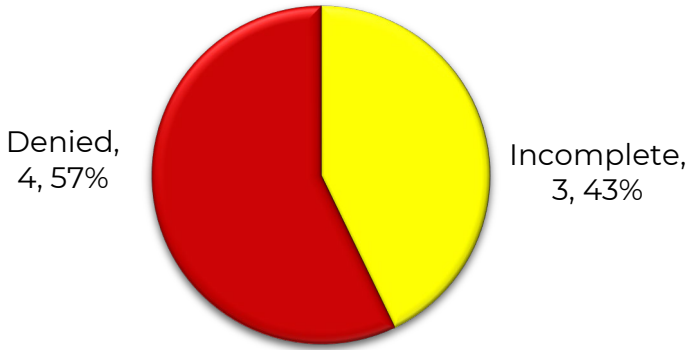
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	1	1	$3,568.50	$3,568.50	1
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**1**	**1**	**$3,568.50**	**$3,568.50**	**1**
Fiscal Year 2025					
FFS	0	0	$0.00	$0.00	0
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2025 Total	**0**	**0**	**$0.00**	**$0.00**	**0**
% Change	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**
Change	**-1**	**-1**	**-$3,568.50**	**-$3,568.50**	**-1**

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

Prior Authorization of Synagis® (Palivizumab)

There were 7 palivizumab prior authorization requests submitted during fiscal year 2025. This is a significant decrease in requests compared to fiscal year 2024 when there were 253 requests submitted. The following chart shows the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

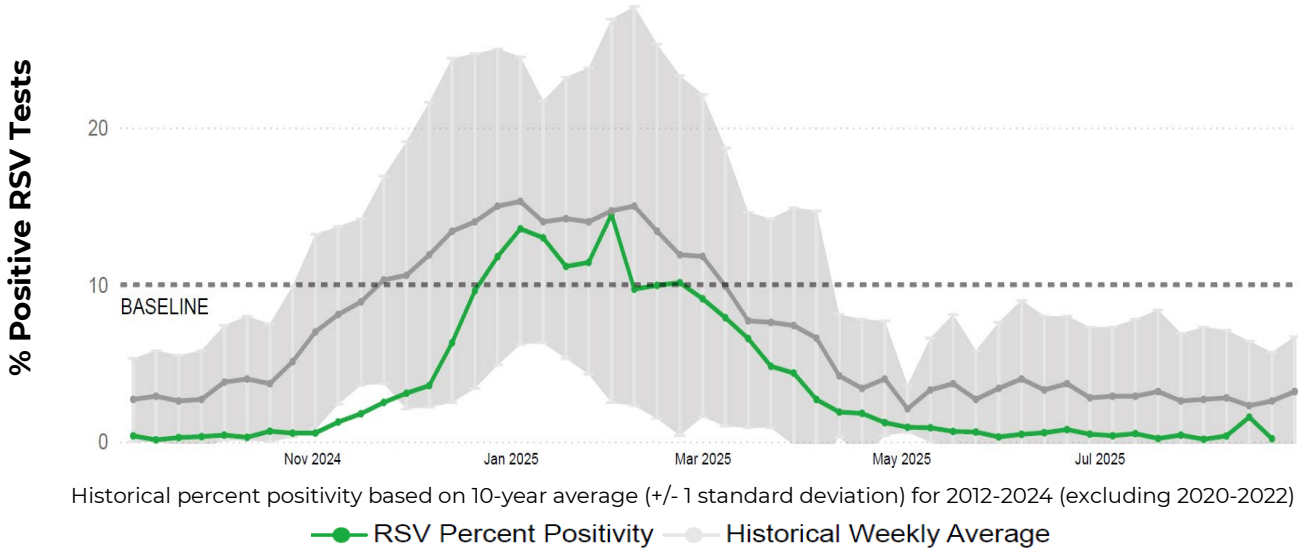
Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	0	0%	1	33%	2	67%	**3**
Aetna	0	0%	2	50%	2	50%	**4**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**0**	**0%**	**3**	**43%**	**4**	**57%**	**7**

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

RSV Season Comparison[3,4]

The following chart contains the weekly percentage of laboratory positive RSV tests in Oklahoma as reported by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System. The chart shows the percent positivity for the 2024-2025 RSV season compared to a 10-year historical average. RSV is determined to be in season once the percentage of positive tests is >10% for 2 consecutive weeks. Similarly, the season is determined to be at an end when the percentage of positive tests is <10% for 2 consecutive weeks.

OSDH: Percent of Positive RSV Tests Reported by Sentinel Providers by Week Compared to 10-Year Historical RSV Percent Positivity, 2024-2025



Market News and Updates[5,6,7,8,9,10,11]

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

- **June 2025:** The FDA approved Enflonsia™ (clesrovimab-cfor) for the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season. Enflonsia™ is supplied as a 105mg/0.7mL single-dose prefilled syringe, and the recommended dosing is 105mg administered as a single intramuscular (IM) injection by a health care provider. For neonates and infants born during the RSV season, Enflonsia™ should be administered once starting from birth. For infants born outside the RSV season, Enflonsia™ should be administered once prior to the start of their first RSV season considering the duration of protection provided by Enflonsia™.

News:

- **June 2024:** The Advisory Committee on Immunization Practices (ACIP) voted to recommend Enflonsia™ as an option for prevention of RSV disease in infants younger than 8 months of age who are born during or entering their first RSV season. Additionally, ACIP voted to add Enflonsia™ as a new option for RSV prevention within the Vaccines for Children (VFC) program.
- **August 2025:** Sobi, the manufacturer of Synagis® (palivizumab), has announced that Synagis® will be discontinued as of 12/31/2025. They stated that patients should contact their health care provider with any questions.

- **August 2025:** The American Academy of Pediatrics (AAP) released updated recommendations for the prevention of RSV disease in infants and children. The AAP recommends both nirsevimab and clesrovimab as first-line recommended RSV immunization products. Palivizumab is no longer routinely recommended for use.

Recommendations

The College of Pharmacy recommends updating the Synagis® (palivizumab) approval criteria to be more consistent with current AAP recommendations for RSV prophylaxis with the following changes (shown in red):

Prior authorization is required for all members who receive palivizumab in an outpatient setting. Palivizumab is approved for members who meet the established prior authorization criteria, which is based on the American Academy of Pediatrics (AAP) 2014 guidelines for palivizumab prophylaxis and AAP's updated *Red Book 2024-2027* recommendations for RSV monoclonal antibody prophylaxis.

Synagis® (Palivizumab) Approval Criteria:

A. Member Selection:
   1. Infants younger than 12 months of age at the start of respiratory syncytial virus (RSV) season:
      a. Born before 29 weeks, 0 days gestation; or
      b. Born before 32 weeks, 0 days gestation and develop chronic lung disease (CLD) of prematurity (require >21% oxygen supplementation for ≥28 days after birth); or
      c. Have hemodynamically significant congenital heart disease [acyanotic heart disease and receiving medication to control congestive heart failure (CHF) and will require surgical procedures, or have moderate-to-severe pulmonary hypertension]; or
      d. May be considered for:
         i. Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough; or
         ii. Infants who undergo cardiac transplantation during RSV season; or
         iii. Infants who are profoundly immunocompromised during RSV season; or
         iv. Infants with cystic fibrosis with clinical evidence of CLD and/or who are nutritionally compromised; or
   2. Infants 12 ~~to 24~~ through 19 months of age at the start of RSV season:

a. Born before 32 weeks, 0 days gestation and have CLD of prematurity (required ≥28 days of oxygen after birth) and continue to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) during the 6 months before the start of the RSV season; or
b. May be considered for:
    i. Infants who undergo cardiac transplantation during RSV season; or
    ii. Infants who are profoundly immunocompromised during RSV season; or
    iii. Infants with cystic fibrosis with manifestations of severe lung disease or weight for length less than the 10th percentile.

B. Product Selection: A patient-specific, clinically significant reason why the member cannot receive Beyfortus® (nirsevimab-alip) and Enflonsia™ (clesrovimab-cfor), as recommended by the CDC, must be provided. Per AAP recommendations, palivizumab is not recommended for routine use. Additionally, the prescriber must confirm the member has not already received Beyfortus® or Enflonsia™ for the current RSV season. Concomitant use with Beyfortus® or Enflonsia™ will not be approved.
C. Length of Treatment: Palivizumab is approved for use only during RSV season in Oklahoma as determined by the Oklahoma State Department of Health (OSDH) Viral Respiratory Illness Sentinel Surveillance System or other credible statewide monitoring system. The threshold for determining RSV seasonality is 10% of positive tests. RSV is determined to be in season once the percentage of positive tests is >10%; however, due to a potential lag in reporting data, palivizumab coverage will begin when the percentage of positive tests is consistently increasing and approaching the 10% threshold. RSV season is determined to be at an end when the percentage of positive tests is consistently <10%. Initial and subsequent approvals will be for the duration of 1 month until RSV season ends. A separate prior authorization request will be required for consideration of initial approval and for each subsequent approval. Members initially approved for palivizumab will require a patient-specific, clinically significant reason why the member still cannot receive Beyfortus® and Enflonsia™.
D. Units Authorized: The member's current weight (taken within the last 3 weeks) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling. Doses are to be administered no more often than every 30 days. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered

prior to the member's discharge from a hospital will be counted as 1 of the approved total.

E. Dose-Pooling: To avoid unnecessary risk to the member, multiple members are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

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[1] Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. RSV Policy Statement – Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics* 2014; 134(2):415–420. doi: 10.1542/peds.2014-1665.

[2] Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. RSV Technical Report – Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. *Pediatrics* 2014; 134(2):e620–e638. doi: 10.1542/peds.2014-1666.

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[5] Merck. U.S. FDA Approves Merck's Enflonsia™ (Clesrovimab-cfor) for Prevention of Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease in Infants Born During or Entering Their First RSV Season. Available online at: https://www.merck.com/news/u-s-fda-approves-mercks-enflonsia-clesrovimab-cfor-for-prevention-of-respiratory-syncytial-virus-rsv-lower-respiratory-tract-disease-in-infants-born-during-or-entering-their-fir/. Issued 06/09/2025. Last accessed 08/18/2025.

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[7] Merck. ACIP Recommends Use of Merck's Enflonsia™ (Clesrovimab-cfor) for Prevention of Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease in Infants Younger than 8 Months of Age Born During or Entering Their First RSV Season. Available online at: https://www.merck.com/news/acip-recommends-use-of-mercks-enflonsia-clesrovimab-cfor-for-prevention-of-respiratory-syncytial-virus-rsv-lower-respiratory-tract-disease-in-infants-younger-than-8-months-of-age/. Issued 06/26/2025. Last accessed 08/18/2025.

[8] Synagis® (Palivizumab) Website. Synagis® to be Discontinued. Available online at: https://www.synagis.com/index.html. Last accessed 08/25/2025.

[9] American Academy of Pediatrics (AAP). Sobi Discontinues RSV Injection Synagis®. Available online at: https://publications.aap.org/aapnews/news/32817/Sobi-discontinues-RSV-injection-Synagis. Issued 08/12/2025. Last accessed 08/25/2025.

[10] AAP Committee on Infectious Diseases. Recommendations for the Prevention of RSV Disease in Infants and Children: Policy Statement. *Pediatrics* 2025; doi: 10.1542/peds.2025-073923.

[11] AAP. Nirsevimab Frequently Asked Questions. Available online at: https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-frequently-asked-questions/. Last revised 08/20/2025. Last accessed 08/25/2025.

Appendix M

Fiscal Year 2025 Annual Review of Jynarque® (Tolvaptan)

Oklahoma Health Care Authority
September 2025

Current Prior Authorization Criteria

Jynarque® (Tolvaptan) Approval Criteria:

1. An FDA approved indication to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD); and
2. Member must be 18 years of age or older; and
3. Member must not have any contraindications to taking Jynarque® including the following:
    a. Taking any concomitant strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. History of signs or symptoms of significant liver impairment or injury (does not include uncomplicated polycystic liver disease); and
    c. Uncorrected abnormal blood sodium concentrations; and
    d. Unable to sense or respond to thirst; and
    e. Hypovolemia; and
    f. Hypersensitivity to tolvaptan or any of its components; and
    g. Uncorrected urinary outflow obstruction; and
    h. Anuria; and
4. Member must not be taking any of the following medications concomitantly with Jynarque®:
    a. Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. Strong CYP3A inducers (e.g., rifampin); and
    c. OATP1B1/3 and OAT3 transporter substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and
    d. BCRP transporter substrates (e.g., rosuvastatin); and
    e. V2-receptor agonists (e.g., desmopressin); and
5. Jynarque® must be prescribed by a nephrologist or specialist with expertise in the treatment of ADPKD (or an advanced care practitioner with a supervising physician who is a nephrologist or specialist with expertise in the treatment of ADPKD); and
6. Prescriber must agree to assess ALT, AST, and bilirubin prior to initiation of Jynarque®, at 2 weeks and 4 weeks after initiation, then monthly for 18 months, and every 3 months thereafter; and

7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Prescriber, pharmacy, and member must be enrolled in the Jynarque® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

Utilization of Jynarque® (Tolvaptan): Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

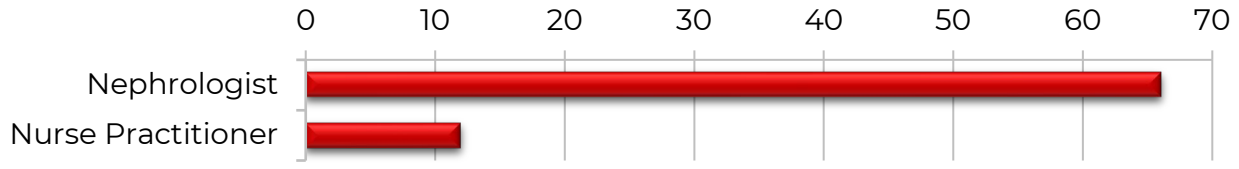
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	12	64	$1,100,931.63	$17,202.06	$614.36	3,584	1,792
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	2	6	$115,267.02	$19,211.17	$686.11	336	168
OCH	4	10	$192,111.70	$19,211.17	$686.11	560	280
2024 Total	**12**	**80**	**$1,408,310.35**	**$17,603.88**	**$628.71**	**4,480**	**2,240**
Fiscal Year 2025							
FFS	7	40	$806,240.87	$20,156.02	$719.86	2,240	1,120
Aetna	1	1	$21,582.34	$21,582.34	$770.80	56	28
Humana	1	13	$267,812.19	$20,600.94	$735.75	728	364
OCH	3	24	$479,686.54	$19,986.94	$713.82	1,344	672
2025 Total	**12**	**78**	**$1,575,321.94**	**$20,196.44**	**$721.30**	**4,368**	**2,184**
% Change	**0.00%**	**-2.50%**	**11.90%**	**14.70%**	**14.70%**	**-2.50%**	**-2.50%**
Change	**0**	**-2**	**$167,011.59**	**$2,592.56**	**$92.59**	**-112**	**-56**

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

Demographics of Members Utilizing Jynarque® (Tolvaptan): Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing Jynarque® (tolvaptan) during fiscal year 2025, detailed demographic information could not be provided.

Top Prescriber Specialties of Jynarque® (Tolvaptan) by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Jynarque® (Tolvaptan):

There were 20 prior authorization requests submitted for Jynarque® (tolvaptan) during fiscal year 2025. The following chart shows the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	8	53%	5	33%	2	13%	**15**
Aetna	0	0%	1	100%	0	0%	**1**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	2	50%	1	25%	1	25%	**4**
Total	**10**	**50%**	**7**	**35%**	**3**	**15%**	**20**

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

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

Anticipated Patent Expiration(s):

- Jynarque® (tolvaptan): April 2030

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

- **October 2020:** The FDA approved a supplemental New Drug Application (sNDA) for Jynarque® (tolvaptan) to remove drug interactions with OATP1B1/3, OAT3, and BCRP transporter substrates from the package labeling. Based on results of post marketing trials, it was determined that coadministration did not show a clinically significant reduction in exposure when tolvaptan was used concomitantly with these transporter substrates.
- **April 2025:** The FDA approved an abbreviated new drug application (ANDA) for tolvaptan tablets, an AB-rated generic version of Jynarque® tablets. In May 2025, Lupin announced the launch of tolvaptan tablets and was granted 180 days of generic exclusivity.

Guideline Update(s):

- **Kidney Disease Improving Global Outcomes (KDIGO) 2025 Clinical Practice Guideline Update:** The KDIGO 2025 Clinical Practice Guideline for the Evaluation, Management, and Treatment of Autosomal Dominant Polycystic Kidney Disease (ADPKD) is the first KDIGO guideline on this subject and provides information on various topics such as diagnosis, prevalence, and treatment for ADPKD. Some notable recommendations and practice points include:
  - Abdominal imaging by ultrasound is recommended to be used when screening adults at risk of ADPKD, in the context of the family history, kidney function, and comorbidities. A follow-up with magnetic resonance imaging (MRI), computed tomography (CT) imaging, and/or genetic testing may clarify the diagnosis and further characterize the disease.
  - Genetic testing can diagnose ADPKD in people with or without a known family history and provide prognostic information. However, genetic testing is not required to make an initial diagnosis of ADPKD in a person with a typical presentation.
  - Mayo Imaging Classification (MIC) is recommended to predict future decline in kidney function and the timing of kidney failure.
  - Initiating tolvaptan treatment is recommended in adults with ADPKD with an estimated glomerular filtration rate (eGFR) ≥25mL/min/1.73m^2 who are at risk for rapidly progressive disease.
  - Patients who are currently being treated with tolvaptan can be continued when they reach an age >55 years or if their eGFR falls below 25mL/min/1.73m^2.
  - Tolvaptan use should be discontinued prior to pregnancy, during lactation, and prior to the commencement of kidney replacement therapy (KRT).
    - Treatment with tolvaptan can be maintained close to the initiation of KRT, and the timing of withdrawal is dependent on individual patient circumstances.

Recommendations

The College of Pharmacy recommends updating the Jynarque® (tolvaptan) approval criteria based on the new FDA approved label update, KDIGO guideline updates, and net costs (changes shown in red):

Jynarque® (Tolvaptan) Approval Criteria:

1. An FDA approved indication to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD); and
2. Member must be 18 years of age or older; and

3. Member must have a baseline (prior to treatment with tolvaptan) estimated glomerular filtration rate (eGFR) of ≥25mL/min/1.73m^2; and
4. Member is not currently receiving renal replacement therapy (i.e., dialysis, kidney transplant); and
5. Member must not have any contraindications to taking Jynarque® including the following:
    a. Taking any concomitant strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. History of signs or symptoms of significant liver impairment or injury (does not include uncomplicated polycystic liver disease); and
    c. Uncorrected abnormal blood sodium concentrations; and
    d. Unable to sense or respond to thirst; and
    e. Hypovolemia; and
    f. Hypersensitivity to tolvaptan or any of its components; and
    g. Uncorrected urinary outflow obstruction; and
    h. Anuria; and
6. Member must not be taking any of the following medications concomitantly with Jynarque®:
    a. Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. Strong CYP3A inducers (e.g., rifampin); and
    ~~c. OATP1B1/3 and OAT3 transporter substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and~~
    ~~d. BCRP transporter substrates (e.g., rosuvastatin); and~~
    e. V2-receptor agonists (e.g., desmopressin); and
7. Jynarque® must be prescribed by a nephrologist or specialist with expertise in the treatment of ADPKD (or an advanced care practitioner with a supervising physician who is a nephrologist or specialist with expertise in the treatment of ADPKD); and
8. Prescriber must agree to assess ALT, AST, and bilirubin prior to initiation of Jynarque®, at 2 weeks and 4 weeks after initiation, then monthly for 18 months, and every 3 months thereafter; and
9. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
10. Jynarque® is brand preferred. Requests for generic tolvaptan will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
11. Prescriber, pharmacy, and member must be enrolled in the Jynarque® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

Utilization Details of Jynarque® (Tolvaptan): Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
JYNARQUE PAK 45-15MG	28	4	$558,619.84	$19,950.71	7	35.46%
JYNARQUE PAK 60-30MG	23	4	$463,743.85	$20,162.78	5.75	29.44%
JYNARQUE PAK 15MG	21	2	$428,163.87	$20,388.76	10.5	27.18%
JYNARQUE PAK 30-15MG	4	2	$86,329.36	$21,582.34	2	5.48%
JYNARQUE PAK 90-30MG	1	1	$21,582.34	$21,582.34	1	1.37%
TOLVAPTAN PAK 45-15MG	1	1	$16,882.68	$16,882.68	1	1.07%
TOTAL	**78**	**12***	**$1,575,321.94**	**$20,196.44**	**6.5**	**100%**

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

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[3] Jynarque® (Tolvaptan) Prescribing Information. Otsuka Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/204441s008lbl.pdf. Last revised 10/2020. Last accessed 08/11/2025.
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Appendix N

Fiscal Year 2025 Annual Review of Breast Cancer Medications and 30-Day Notice to Prior Authorize Datroway® (Datopotamab Deruxtecan-dlnk) and Itovebi™ (Inavolisib)

Oklahoma Health Care Authority
September 2025

Current Prior Authorization Criteria

Utilization data for Keytruda® (pembrolizumab) and approval criteria for indications other than breast cancer can be found in the December 2024 Drug Utilization Review (DUR) Board packet. This medication 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 2025 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.

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 regimen; or
    b. For HER-2 low [immunohistochemistry (IHC) 1+ or IHC 2+/in situ hybridization (ISH)-] disease, must meet the following:
        i. Member received prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.

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

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.

Keytruda® (Pembrolizumab) 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 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.

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

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

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 2025

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 2024							
FFS	124	629	$9,754,064.58	$15,507.26	$551.70	28,039	17,680
Aetna	14	33	$551,736.15	$16,719.28	$699.29	1,887	789
Humana	11	22	$341,245.02	$15,511.14	$545.12	1,467	626
OCH	9	16	$263,056.55	$16,441.03	$584.57	932	450
2024 Total	**131**	**700**	**$10,910,102.30**	**$15,585.86**	**$558.20**	**32,325**	**19,545**
Fiscal Year 2025							
FFS	70	413	$6,947,526.55	$16,822.10	$598.15	19,915	11,615
Aetna	33	156	$2,632,975.92	$16,878.05	$622.16	8,040	4,232
Humana	28	124	$2,009,334.32	$16,204.31	$581.57	7,259	3,455
OCH	26	130	$2,419,177.76	$18,609.06	$652.42	9,531	3,708
2025 Total	**138**	**823**	**$14,009,014.55**	**$17,021.89**	**$608.82**	**44,745**	**23,010**
% Change	**5.30%**	**17.60%**	**28.40%**	**9.20%**	**9.10%**	**38.40%**	**17.70%**
Change	**7**	**123**	**$3,098,912.25**	**$1,436.03**	**$50.62**	**12,420**	**3,465**

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

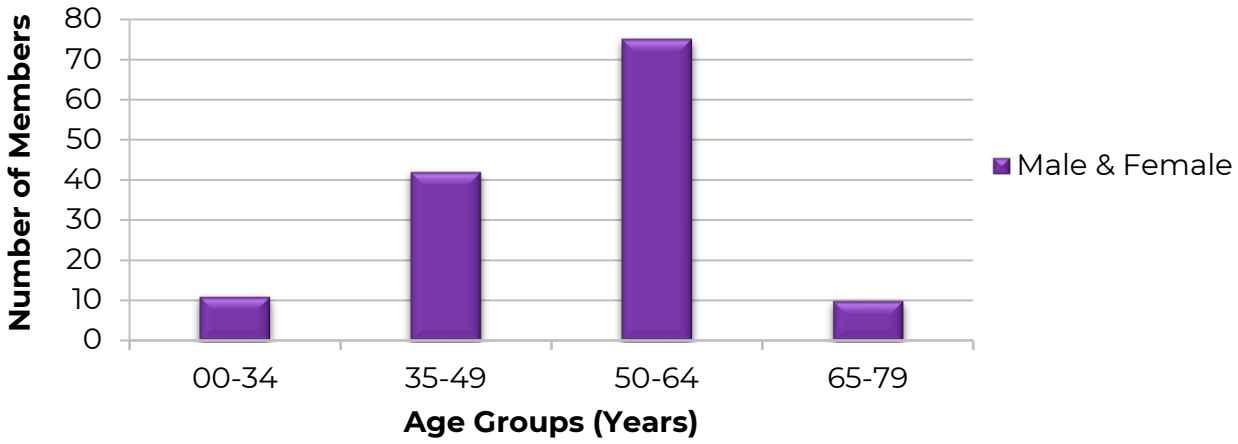
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	134	1,322	$6,748,240.37	$5,104.57	9.87
Aetna	4	13	$42,677.34	$3,282.87	3.25
Humana	2	4	$19,880.76	$4,970.19	2
OCH	11	31	$143,544.47	$4,630.47	2.82
2024 Total	**136**	**1,370**	**$6,954,342.94**	**$5,076.16**	**10.07**
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**
% Change	**0.00%**	**0.36%**	**-9.16%**	**-9.49%**	**0.40%**
Change	**0**	**5**	**-$636,713.24**	**-$481.52**	**0.04**

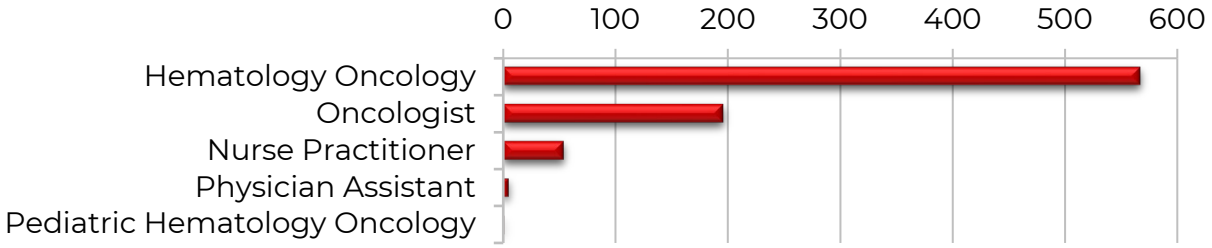
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective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

- Aggregate drug rebates collected during fiscal year 2024 for breast cancer medications totaled $7,029,442.28.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2024 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2025 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)

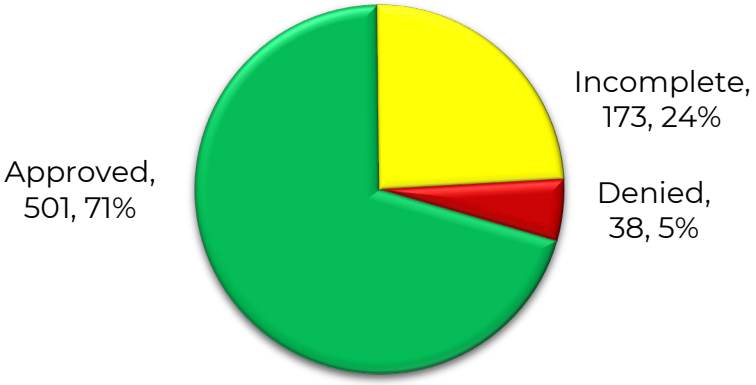


Prior Authorization of Breast Cancer Medications

There were 712 prior authorization requests submitted for breast cancer medications during fiscal year 2025. The following chart shows the status of the submitted petitions for fiscal year 2025.

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

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	308	67%	130	28%	20	4%	**458**
Aetna	44	56%	34	43%	1	1%	**79**
Humana	82	93%	0	0%	6	7%	**88**
OCH	67	77%	9	10%	11	13%	**87**
Total	**501**	**71%**	**173**	**24%**	**38**	**5%**	**712**

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

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

Anticipated Patent Expiration(s):

- 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): February 2034
- Kisqali® (ribociclib): April 2036
- Kisqali® Femara® Co-Pack (ribociclib/letrozole): April 2036
- Ibrance® (palbociclib tablet): August 2036
- Orserdu® (elacestrant): January 2038
- Itovebi™ (inavolisib): April 2038
- Tukysa® (tucatinib): April 2038

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

- **October 2024:** The FDA approved Itovebi™ (inavolisib), in combination with palbociclib and fulvestrant, for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally

advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.

- **January 2025:** The FDA approved Datroway® (datopotamab deruxtecan-dlnk) for the treatment of adult patients with unresectable or metastatic, HR-positive, HER2-negative immunohistochemistry (IHC) 0, IHC 1+, or IHC 2+/in situ hybridization (ISH)-negative breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.
- **January 2025:** The FDA approved Enhertu® (fam-trastuzumab deruxtecan-nxki) for a new indication for the treatment of HR-positive, HER2-low (IHC 1+ or IHC 2+/ISH-negative) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on 1 or more endocrine therapies in the metastatic setting.
- **April 2025:** The FDA approved Ibrance® (palbociclib) for a new indication, in combination with inavolisib and fulvestrant, for the treatment of adult patients with endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.
- **June 2025:** The FDA granted accelerated approval to Datroway® for a new indication for the treatment of adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy.

News:

- **October 2024:** Gilead, the manufacturer of Trodelvy® (sacituzumab govitecan-hziy), announced plans to voluntarily withdraw the previous accelerated approval for Trodelvy® for the treatment of adults with locally advanced or metastatic urothelial cancer who have received a platinum-containing chemotherapy and either a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. The required confirmatory trial for this indication did not meet the primary endpoint of overall survival (OS) in the intent-to-treat (ITT) population. In November 2024, the FDA announced that the withdrawal of this indication has been completed.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) guidelines for central nervous system cancers allow for the use of neratinib in combination with ado-trastuzumab emtansine in patients with breast cancer and brain metastases.

Datroway® (Datopotamab Deruxtecan-dlnk) Product Summary[10]

Therapeutic Class: Trop-2-directed antibody and topoisomerase inhibitor conjugate

Indication(s):

- Treatment of adult patients with unresectable or metastatic, HR-positive, HER2-negative (IHC 0, IHC 1+, or IHC 2+/ISH-negative) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease
- Treatment of adult patients with locally advanced or metastatic EGFR-mutated NSCLC who have received prior EGFR-directed therapy and platinum-based chemotherapy
    - This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

How Supplied: 100mg lyophilized powder in a single-dose vial (SDV)

Dosing and Administration:

- The recommended dose is 6mg/kg (up to a maximum of 540mg for patients ≥90kg) as an intravenous (IV) infusion every 3 weeks.
- Datroway® should be continued until disease progression or unacceptable toxicity.

Cost: The Wholesale Acquisition Cost (WAC) of Datroway® is $4,891.07 per SDV. For a member weighing 80kg, this would result in an estimated cost of $24,455.35 per dose or $440,196.30 per year based on recommended dosing.

Itovebi™ (Inavolisib) Product Summary[11]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment, in combination with palbociclib and fulvestrant, of adults with endocrine-resistant, PIK3CA-mutated, HR-positive, HER2-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy

How Supplied: 3mg and 9mg oral tablets

Dosing and Administration:

- The recommended dose is 9mg orally once daily, with or without food, until disease progression or unacceptable toxicity.
- Itovebi™ should be administered in combination with palbociclib and fulvestrant.

Cost: The WAC of Itovebi™ is $816.68 per 9mg tablet. This would result in an estimated cost of $22,867.04 per 28 days or $297,271.52 per year based on recommended dosing.

Cost Comparison: Trastuzumab Products

Product	Cost Per 10mg	Cost Per 21 Days*	Cost Per Year
Herzuma® (trastuzumab-pkrb) 150mg vial	$77.49	$3,487.05	$62,766.90
Herceptin® (trastuzumab) 150mg vial	$76.18	$3,428.10	$61,705.80
Hercessi™ (trastuzumab-strf) 150mg vial	$76.18	$3,428.10	$61,705.80
Ogivri® (trastuzumab-dkst) 150mg vial	$44.59	$2,006.55	$36,117.90
Kanjinti® (trastuzumab-anns) 150mg vial	$43.28	$1,947.60	$35,056.80
Trazimera® (trastuzumab-qyyp) 150mg vial	$28.62	$1,287.90	$23,182.20
Ontruzant® (trastuzumab-dttb) 150mg vial	$21.99	$989.55	$17,811.90

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 Datroway® (datopotamab deruxtecan-dlnk) and Itovebi™ (inavolisib) with the following criteria (shown in red):

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.

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.

The College of Pharmacy also recommends updating the approval criteria for Enhertu® (fam-trastuzumab deruxtecan-nxki) and Ibrance® (palbociclib) based on recent FDA approvals with the following changes (shown in red):

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.

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.

Next, the College of Pharmacy recommends updating the Trodelvy® (sacituzumab govitecan-hziy) approval criteria based on the withdrawal of the accelerated approval for metastatic urothelial cancer with the following changes (shown in red):

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

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

Additionally, the College of Pharmacy recommends updating the Kadcyla® (ado-trastuzumab emtansine) and Nerlynx® (neratinib) approval criteria based on NCCN recommendations (changes and new criteria noted in red):

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.

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.

Lastly, the College of Pharmacy recommends updating the approval criteria for the trastuzumab products based on 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 Kanjinti®, Ontruzant®, and Trazimera®. Authorization of non-preferred trastuzumab products (Herceptin®, Herceptin Hylecta™, Hercessi™, Herzuma®, or Ogivri®~~, or Ontruzant®~~) 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®~~, or Ontruzant®~~) 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®~~, or Ontruzant®~~) 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.

Utilization Details of Breast Cancer Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ABEMACICLIB PRODUCTS						
VERZENIO TAB 100MG	127	20	$1,991,093.39	$15,677.90	6.35	14.21%
VERZENIO TAB 150MG	124	28	$1,941,454.85	$15,656.89	4.43	13.86%
VERZENIO TAB 50MG	19	4	$290,275.09	$15,277.64	4.75	2.07%
VERZENIO TAB 200MG	1	1	$16,341.49	$16,341.49	1	0.12%
SUBTOTAL	**271**	**53**	**$4,239,164.82**	**$15,642.67**	**5.11**	**30.26%**
RIBOCICLIB PRODUCTS						
KISQALI TAB 600DOSE	136	26	$2,444,679.42	$17,975.58	5.23	17.45%
KISQALI TAB 400DOSE	68	15	$1,003,561.91	$14,758.26	4.53	7.16%
KISQALI TAB 200DOSE	4	1	$28,326.12	$7,081.53	4	0.20%
SUBTOTAL	**208**	**42**	**$3,476,567.45**	**$16,714.27**	**4.95**	**24.82%**
PALBOCICLIB PRODUCTS						
IBRANCE TAB 125MG	88	15	$1,422,303.49	$16,162.54	5.87	10.15%
IBRANCE TAB 100MG	48	7	$779,604.65	$16,241.76	6.86	5.57%
IBRANCE CAP 75MG	29	3	$398,462.47	$13,740.09	9.67	2.84%
IBRANCE TAB 75MG	26	5	$420,598.90	$16,176.88	5.2	3.00%
IBRANCE CAP 125MG	15	3	$244,191.49	$16,279.43	5	1.74%
IBRANCE CAP 100MG	1	1	$15,993.80	$15,993.80	1	0.11%
SUBTOTAL	**207**	**34**	**$3,281,154.80**	**$15,850.99**	**6.09**	**23.42%**
TUCATINIB PRODUCTS						
TUKYSA TAB 150MG	45	12	$1,120,599.05	$24,902.20	3.75	8.00%
TUKYSA TAB 50MG	3	1	$98,483.73	$32,827.91	3	0.70%
SUBTOTAL	**48**	**13**	**$1,219,082.78**	**$25,397.56**	**3.69**	**8.70%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NERATINIB PRODUCTS						
NERLYNX TAB 40MG	25	4	$549,187.75	$21,967.51	6.25	3.92%
SUBTOTAL	**25**	**4**	**$549,187.75**	**$21,967.51**	**6.25**	**3.92%**
TALAZOPARIB PRODUCTS						
TALZENNA CAP 0.5MG	15	3	$274,369.54	$18,291.30	5	1.96%
TALZENNA CAP 0.35MG	5	1	$93,860.54	$18,772.11	5	0.67%
TALZENNA CAP 0.25MG	1	1	$18,952.41	$18,952.41	1	0.14%
TALZENNA CAP 1MG	1	1	$18,948.41	$18,948.41	1	0.14%
SUBTOTAL	**22**	**6**	**$406,130.90**	**$18,460.50**	**3.67**	**2.90%**
ELACESTRANT PRODUCTS						
ORSERDU TAB 345MG	13	5	$310,253.16	$23,865.63	2.6	2.21%
ORSERDU TAB 86MG	5	1	$123,977.75	$24,795.55	5	0.88%
SUBTOTAL	**18**	**6**	**$434,230.91**	**$24,123.94**	**3**	**3.10%**
CAPIVASERTIB PRODUCTS						
TRUQAP PAK 200MG	6	2	$141,703.42	$23,617.24	3	1.01%
TRUQAP TAB 200MG	5	2	$115,340.71	$23,068.14	2.5	0.82%
TRUQAP PAK 160MG	5	2	$72,040.79	$14,408.16	2.5	0.51%
SUBTOTAL	**16**	**6**	**$329,084.92**	**$20,567.81**	**2.67**	**2.35%**
LAPATINIB PRODUCTS						
LAPATINIB TAB 250MG	7	2	$50,600.13	$7,228.59	3.5	0.36%
SUBTOTAL	**7**	**2**	**$50,600.13**	**$7,228.59**	**3.5**	**0.36%**
ALPELISIB PRODUCTS						
PIQRAY 300MG TAB DOSE	1	1	$23,810.09	$23,810.09	1	0.17%
SUBTOTAL	**1**	**1**	**$23,810.09**	**$23,810.09**	**1**	**0.17%**
TOTAL	**823**	**138***	**$14,009,014.55**	**$17,021.89**	**5.96**	**100%**

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

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS*	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PERTUZUMAB J9306 (PERJETA)	324	57	$2,320,076.82	$7,160.73	5.68
FAM-TRASTUZ DER-NXKI J9358 (ENHERTU)	222	35	$1,686,092.35	$7,595.01	6.34
TRASTUZ-QYYP Q5116 (TRAZIMERA)	205	37	$189,406.63	$923.93	5.54
TRASTUZ-ANNS Q5117 (KANJINTI)	201	35	$238,040.31	$1,184.28	5.74
SACITUZ GOV-HZIY J9317 (TRODELVY)	111	10	$589,168.80	$5,307.83	11.1
ADO-TRASTUZ EMT J9354 (KADCYLA)	93	11	$630,828.85	$6,783.11	8.45
ERIBULIN MESYLATE J9179 (HALAVEN)	90	7	$197,099.86	$2,190.00	12.86
TRASTUZ-DTTB Q5112 (ONTRUZANT)	49	6	$81,225.51	$1,657.66	8.17
TRASTUZ-PKRB Q5113 (HERZUMA)	27	6	$75,342.72	$2,790.47	4.5
PERTUZ/TRASTUZ/HYAL-ZZXF J9316 (PHESGO)	22	5	$169,389.60	$7,699.53	4.4
TRASTUZUMAB J9355 (HERCEPTIN)	14	2	$64,643.15	$4,617.37	7

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
IXABEPILONE J9207 (IXEMPRA)	13	2	$61,927.32	$4,763.64	6.5
TRASTUZ-DKST Q5114 (OGIVRI)	4	2	$14,387.78	$3,596.95	2
TOTAL	**1,375**	**136**	**$6,317,629.70**	**$4,594.64**	**10.11**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
DER = deruxtecan; EMT = emtansine; GOV = govitecan; HYAL = hyaluronidase; PERTUZ = pertuzumab; SACITUZ = sacituzumab; TRASTUZ = trastuzumab
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

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Appendix O

30-Day Notice to Prior Authorize Encelto™ (Revakinagene Taroretcel-lwey)

Oklahoma Health Care Authority
September 2025

Introduction[1,2,3,4,5,6,7]

Macular telangiectasia (MacTel) type 2 is a rare, slowly progressive neurodegenerative eye disease of the macula. It typically affects both eyes, although the degree to which each eye is affected can be different. MacTel type 2 causes photoreceptors in the macula to die or lose their ability to function, leading to gradual central vision loss, affecting a person's ability to complete tasks that require sharp central vision. In the early stages of the disease there are no symptoms, but as the disease progresses, symptoms include blurry or distorted vision, blind spots in vision, difficulty reading, identifying details, or missing parts of words or numbers. MacTel type 2 does not cause blindness or peripheral vision loss. There are 2 other types of MacTel, but MacTel type 2 is the most common. MacTel type 2 can be classified as nonproliferative and proliferative disease. The nonproliferative phase is characterized by exudative telangiectasia, leakage of abnormal retinal blood vessels, and foveal atrophy. Evidence suggests that neurodegeneration in the early nonproliferative phase of the disease is caused by the loss of Müller glial cells, which produce trophic factors that are involved in several functions of the retina including photoreceptor survival. In the later proliferative stage of the disease, abnormal blood vessels can grow under the retina leading to neovascular MacTel type 2, which can result in significant vision loss.

The cause of MacTel type 2 is unknown; however, research has shown it may have a genetic component, although a specific gene has not been identified, and patients with diabetes or hypertension are at an increased risk. MacTel type 2 is typically diagnosed by an ophthalmologist as it can be challenging to diagnose due to the potential of symptoms mimicking other conditions [e.g., age-related macular degeneration (AMD)]. MacTel type 2 affects people over 40 years of age; however, it usually becomes noticeable around 50 to 60 years of age with the average age of diagnosis being 57 years of age. The prevalence of MacTel type 2 has been estimated to be about 0.1% in people older than 40 years of age. Previously there were no U.S. Food and Drug Administration (FDA) approved treatment options for MacTel type 2; however, patients who progressed to neovascular MacTel type 2 could be treated with ophthalmic vascular endothelial growth factor (VEGF) inhibitors.

In March 2025, the FDA approved Encelto™ (revakinagene taroretcel-lwey) as the first FDA approved treatment for MacTel type 2. Encelto™ releases recombinant human ciliary neurotrophic factor (rhCNTF) to the retina, which has been shown to reduce photoreceptor cell loss.

Encelto™ (Revakinagene Taroretcel-lwey) Product Summary[8,9,10]

Therapeutic Class: Allogenic encapsulated cell-based gene therapy

Indication(s): Treatment of adults with idiopathic MacTel type 2

How Supplied: Sterile, single-dose implant that contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line)

Dosing and Administration:

- Encelto™ is administered by a single surgical intravitreal procedure performed by a qualified ophthalmologist.
- The recommended dose is 1 Encelto™ implant per affected eye.
- The provider should carefully inspect Encelto™ prior to use and refer to the *Instructions for Use* in the *Prescribing Information* when preparing for and performing surgical placement or removal of Encelto™.
- Encelto™ implant should be removed if vitrectomy with a complete gas fill or silicone oil fill is required or if infectious endophthalmitis occurs.

Efficacy: The safety and efficacy of Encelto™ were studied in 2 identically designed, randomized, multicenter, sham-controlled studies in adult patients.

- <u>Key Inclusion Criteria:</u>
  - At least 1 study eye with a diagnosis of MacTel type 2 with evidence of fluorescein leakage and at least 1 of the other features including the following:
    - Hyperpigmentation that is outside of a 500-micron radius from the center of the fovea
    - Retinal opacification
    - Crystalline deposits
    - Right-angle vessels
    - Inner/outer lamellar cavities
  - 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-ODT)
  - Best corrected visual acuity (BCVA) or 54-letter score or better (20/80 or better Snellen equivalent) measured by Early Treatment Diabetic Retinopathy Study (ETDRS) chart at screening

- Key Exclusion Criteria:
  - Neovascular MacTel type 2
- Intervention: Randomized to receive either Encelto™ intravitreal implant or sham procedure under standard operative procedures
- Primary Outcome: Rate of change in the area EZ loss (IS/OS macular PR loss) over 24 months as measured by SD-OCT
- Primary Outcome Results:
  - Study 1: 0.075mm^2 [95% confidence interval (CI): 0.05, 0.10] in the Encelto™ group vs. 0.166mm^2 (95% CI: 0.14, 0.19) in the sham group; treatment difference: -0.091mm^2 (95% CI: -0.13, -0.06; P<0.0001)
  - Study 2: 0.111mm^2 (95% CI: 0.08, 0.14) in the Encelto™ group vs. 0.160mm^2 (95% CI: 0.13, 0.19) in the sham group; treatment difference: -0.049mm^2 (95% CI: -0.089, -0.008; P=0.0186)

Cost: The Wholesale Acquisition Cost (WAC) of Encelto™ is $250,000 per implant.

Recommendations

The College of Pharmacy recommends the prior authorization of Encelto™ (revakinagene taroretcel-lwey) with the following 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.

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Appendix P

Fiscal Year 2025 Annual Review of Hyperphosphatemia Medications and 30-Day Notice to Prior Authorize Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet

Oklahoma Health Care Authority
September 2025

Current Prior Authorization Criteria

Generic calcium acetate containing products, brand name Fosrenol® (lanthanum carbonate 500mg, 750mg, and 1,000mg chewable tablet and 750mg and 1,000mg oral powder packet), PhosLo® (calcium acetate gel capsule), and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
    a. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use all phosphate binders available without prior authorization must be provided; and
    b. A patient-specific, clinically significant reason why the member cannot use Velphoro® (sucroferric oxyhydroxide) must be provided; or
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in members with CKD not on dialysis; and
    a. Documented lab results verifying IDA; and
    b. Documented intolerance or inadequate response to prior treatment with oral iron; and
3. A quantity limit of 12 tablets per day will apply based on the maximum recommended dose.

Lanthanum Carbonate (Generic Fosrenol®) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with end stage renal disease (ESRD); and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; and

3. Fosrenol® is brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Renagel® (Sevelamer Hydrochloride) Approval Criteria:

1. An FDA approved indication for the control of serum phosphorus in members with chronic kidney disease (CKD) on dialysis; and
2. A patient-specific, clinically significant reason why the member cannot use Renvela® (sevelamer carbonate) 800mg tablets or other phosphate binders available without prior authorization must be provided.

Velphoro® (Sucroferric Oxyhydroxide) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided.

Xphozah® (Tenapanor) Approval Criteria:

1. An FDA approved indication to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis; and
2. Member must be 18 years of age or older; and
3. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use all phosphate binders available without prior authorization must be provided; and
4. Documented trial of inadequate response to at least 1 iron-based phosphate binder [e.g., Auryxia® (ferric citrate), Velphoro® (sucroferric oxyhydroxide)] or a patient-specific clinically significant reason why the member cannot use an iron-based phosphate binder must be provided.

Utilization of Hyperphosphatemia Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

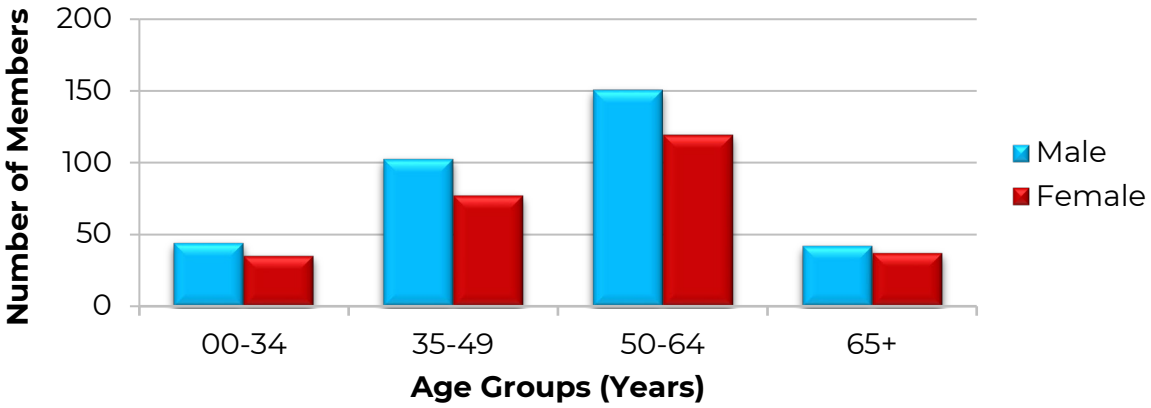
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	545	1,941	$657,034.46	$338.50	$11.73	362,592	56,008
Aetna	25	38	$9,819.67	$258.41	$8.81	5,860	1,115
Humana	23	30	$1,1027.26	$367.58	$12.25	3420	900
OCH	37	63	$15,364.46	$243.88	$8.33	9451	1,845
2024 Total	**579**	**2,072**	**$693,245.85**	**$334.58**	**$11.58**	**381,323**	**59,868**
Fiscal Year 2025							
FFS	438	1,504	$426,368.15	$283.49	$9.87	281,961	43,218
Aetna	54	115	$33,821.84	$294.10	$7.44	21,853	4,546
Humana	87	215	$35,494.40	$165.09	$4.48	37,464	7,919
OCH	71	189	$28,150.78	$148.95	$5.06	31,959	5,560
2025 Total	**606**	**2,023**	**$523,835.17**	**$258.94**	**$8.55**	**373,237**	**61,243**
% Change	**4.70%**	**-2.40%**	**-24.40%**	**-22.60%**	**-6.20%**	**-2.10%**	**2.30%**
Change	**27**	**-49**	**-$169,410.68**	**-$75.64**	**-$3.03**	**-8,086**	**1,375**

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

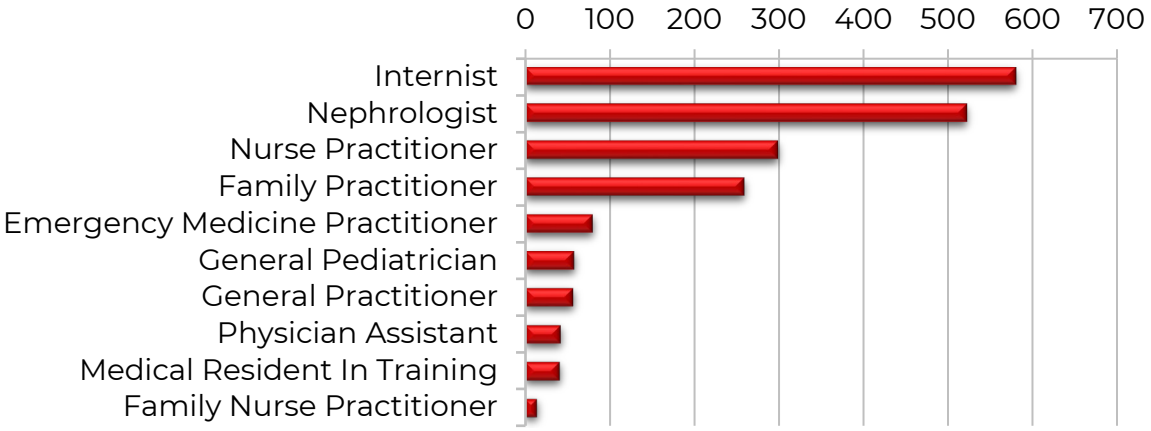
- Aggregate drug rebates collected during fiscal year 2024 for the hyperphosphatemia medications totaled $523,967.92.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. Please note, fiscal year 2024 aggregate drug rebate totals have been included in this report for informational purposes only, as the rebates for fiscal year 2025 are still being collected at this time. The costs included in this report do not reflect net costs.

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

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



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



Prior Authorization of Hyperphosphatemia Medications

There were 148 prior authorization requests submitted for hyperphosphatemia medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	16	15%	71	68%	17	16%	**104**
Aetna	2	29%	2	29%	3	43%	**7**
Humana	4	27%	0	0%	11	73%	**15**
OCH	10	45%	2	9%	10	45%	**22**
Total	**32**	**21%**	**75**	**51%**	**41**	**28%**	**148**

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

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Renvela® (sevelamer carbonate tablet): October 2025
- Auryxia® (ferric citrate): July 2030
- Renvela® (sevelamer carbonate packet for suspension): December 2030
- Xphozah® (tenapanor): April 2034
- Velphoro® (sucroferric oxyhydroxide): May 2035

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

- **June 2025:** The FDA approved the addition of the results of a lactation study in the package labeling for Xphozah® (tenapanor). The *Use in Specific Population* section now mentions that tenapanor and its major metabolite, M1, were not detected in human breast milk. Previously, the package labeling reported that no data were available on the presence of tenapanor in either human or animal milk, although it did state the minimal systemic absorption of tenapanor would not result in a clinically relevant exposure to breastfed infants.

Pipeline:

- **Oxylanthanum Carbonate (OLC):** Unicycive Therapeutics announced the publication of data from a Phase 2 clinical study that evaluated the safety and tolerability of OLC, an investigational drug formulation of Fosrenol® (lanthanum carbonate), in patients with chronic kidney disease (CKD) on dialysis. At baseline, 59% of patients had serum phosphate levels below 5.5mg/dL; this increased to greater than 90% at study completion. The most common treatment-related adverse effects were gastrointestinal (9% diarrhea and 6% vomiting). As compared to the reference-listed drug, OLC tablets are smaller in size, can be swallowed whole without chewing, and contain more active ingredients per tablet. Unicycive Therapeutics anticipates these characteristics of OLC will reduce overall pill burden and increase patient compliance to phosphate binders. Unicycive Therapeutics plans to seek approval with the FDA under the 505(b)(2) pathway.

Cost Comparison: Lanthanum Carbonate Products

Product	Cost Per Unit	Cost Per Day*
Fosrenol® (lanthanum carbonate) 750mg packet	**$12.01**	**$48.04**
Fosrenol® (lanthanum carbonate) 1,000mg packet	**$12.01**	**$36.03**
Fosrenol® (lanthanum carbonate) 750mg chewable tablet	$12.01	$48.04
Fosrenol® (lanthanum carbonate) 1,000mg chewable tablet	$12.01	$36.03
lanthanum carbonate 750mg chewable tablet (generic)	$3.63	$14.52
lanthanum carbonate 1,000mg chewable tablet (generic)	$3.15	$9.45

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 the typical maximum daily dose of 3,000mg.
Unit = packet

Recommendations

The College of Pharmacy recommends the prior authorization of Fosrenol® (lanthanum carbonate) 750mg and 1,000mg Oral Powder Packet based on net costs with the following criteria (shown in red):

Fosrenol® (Lanthanum Carbonate) 750mg and 1,000mg Oral Powder Packet Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the chewable tablet formulation must be provided.

The College of Pharmacy also recommends designating Auryxia® as brand preferred, and updating the approval criteria based on net costs (changes shown in red):

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; ~~and~~ or
   ~~a. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use all phosphate binders available without prior authorization must be provided; and~~
   ~~b. A patient-specific, clinically significant reason why the member cannot use Velphoro® (sucroferric oxyhydroxide) must be provided; or~~
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in members with CKD not on dialysis; and
   a. Documented lab results verifying IDA; and
   b. Documented intolerance or inadequate response to prior treatment with oral iron; and

3. Auryxia® is brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. A quantity limit of 12 tablets per day will apply based on the maximum recommended dose.

Lastly, the College of Pharmacy recommends updating the lanthanum carbonate (generic Fosrenol®) approval criteria and removing the brand preferred status of Fosrenol® (lanthanum carbonate) 1,000mg chewable tablet based on net costs (changes shown in red):

Lanthanum Carbonate (Generic Fosrenol®) 500mg and 750mg Chewable Tablet Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with end stage renal disease (ESRD); and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; and
3. Fosrenol® 500mg and 750mg chewable tablet are brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Generic calcium acetate containing products, brand name Fosrenol® (lanthanum carbonate 500mg~~,~~ and 750mg~~, and 1,000mg~~ chewable tablet ~~and 750mg and 1,000mg oral powder packet~~), lanthanum carbonate (generic Fosrenol®) 1000mg chewable tablet, PhosLo® (calcium acetate gel capsule), and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Utilization Details of Hyperphosphatemia Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NO PA REQUIRED						
SEVELAMER CARBONATE PRODUCTS						
SEVELAMER CARB TAB 800MG	1,313	403	$66,597.42	$50.72	3.26	12.71%
SEVELAMER CARB POW 2.4GM	34	14	$5,419.01	$159.38	2.43	1.03%
SEVELAMER CARB POW 0.8GM	30	14	$2,751.45	$182.88	2.14	0.42%
SUBTOTAL	**1,377**	**431**	**$77,502.79**	**$56.28**	**3.19**	**14.80%**
CALCIUM ACETATE PRODUCTS						
CALC ACETATE CAP 667MG	419	175	$18,236.11	$43.52	2.39	3.48%
CALC ACETATE TAB 667MG	49	20	$3,868.24	$78.94	2.45	0.74%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**468**	**195**	**$22,104.35**	**$47.23**	**2.4**	**4.22%**
LANTHANUM CARBONATE PRODUCTS						
FOSRENOL CHW 500MG	26	8	$76,252.22	$2,932.78	3.25	14.56%
FOSRENOL CHW 750MG	17	5	$34,730.81	$2,042.99	3.4	6.63%
FOSRENOL CHW 1,000MG	15	5	$19,781.39	$1,318.76	3	3.78%
FOSRENOL POW 1,000MG	6	1	$6,552.18	$1,092.03	6	1.25%
FOSRENOL POW 750MG	1	1	$1,088.03	$1,088.03	1	0.21%
SUBTOTAL	**65**	**20**	**$138,404.63**	**$2,129.30**	**3.25**	**26.42%**
NO PA SUBTOTAL	**1,910**	**646**	**$238,011.77**	**$124.61**	**2.96**	**45.44%**
PA REQUIRED						
SUCROFERRIC OXYHYDROXIDE PRODUCTS						
VELPHORO CHW 500MG	78	28	$214,961.06	$2,755.91	2.79	41.04%
SUBTOTAL	**78**	**28**	**$214,961.06**	**$2,755.91**	**2.79**	**41.04%**
TENAPANOR HYDROCHLORIDE PRODUCTS						
XPHOZAH TAB 30MG	13	4	$38,599.33	$2,969.18	3.25	7.37%
XPHOZAH TAB 20MG	5	1	$15,458.05	$3,091.61	5	2.95%
SUBTOTAL	**18**	**5**	**$54,057.38**	**$3,003.19**	**3.6**	**10.32%**
FERRIC CITRATE PRODUCTS						
AURYXIA TAB 210MG	13	8	$13,880.06	$1,067.70	1.63	2.65%
SUBTOTAL	**13**	**8**	**$13,880.06**	**$1,067.70**	**1.63**	**2.65%**
LANTHANUM CARBONATE PRODUCTS						
LANTHANUM CHW 500MG	3	3	$2,570.44	$856.81	1	0.49%
SUBTOTAL	**3**	**3**	**$2,570.44**	**$856.81**	**1**	**0.49%**
SEVELAMER HYDROCHLORIDE PRODUCTS						
SEVELAMER HCL TAB 800MG	1	1	$354.46	$354.46	1	0.07%
SUBTOTAL	**1**	**1**	**$354.46**	**$354.46**	**1**	**0.07%**
PA REQUIRED SUBTOTAL	**113**	**45**	**$285,823.40**	**$2,529.41**	**2.51**	**54.56%**
TOTAL	**2,023**	**606***	**$523,835.17**	**$258.94**	**3.34**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CALC = calcium; CAP = capsule; CARB = carbonate; CHW = chewable; HCL = hydrochloride; PA = prior authorization; POW = powder; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 08/2025. Last accessed 08/25/2025.
[2] Xphozah® (Tenapanor) Prescribing Information. Keryx Biopharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/213931s005lbl.pdf. Last revised 06/16/2025. Last accessed 08/25/2025.
[3] Unicycive Therapeutics, Inc. Unicycive Therapeutics Announces the Publication of Oxylanthanum Carbonate Pivotal Trial Data in Clinical Journal of the American Society of Nephrology. Available online at: https://ir.unicycive.com/news/detail/107/unicycive-therapeutics-announces-the-publication-of. Issued 07/24/2025. Last accessed 08/25/2025.

Appendix Q

Fiscal Year 2025 Annual Review of Cystic Fibrosis (CF) Medications and 30-Day Notice to Prior Authorize Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor)

Oklahoma Health Care Authority
September 2025

Current Prior Authorization Criteria

Bronchitol® (Mannitol Inhalation Powder) Approval Criteria:

1. An FDA approved diagnosis of cystic fibrosis (CF) in members 18 years of age or older; and
    a. Bronchitol® will not require a prior authorization and claims will pay at the point of sale if the adult member has a reported diagnosis of CF within the past 12 months of claims history; and
    b. If the member does not have a reported diagnosis, a manual prior authorization will be required for coverage consideration; and
2. A quantity limit of 560 capsules per 28 days will apply.

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
2. Documentation must be submitted with results of *CFTR* genetic testing; and
3. Member must be 1 month of age or older; and
4. Members using Kalydeco® must be supervised by a pulmonary disease specialist; and
5. Prescriber must verify the member has been counseled on proper administration of Kalydeco® including taking with a fat-containing food; and
6. 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
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 Kalydeco®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
9. 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
10. 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
11. 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
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; and
14. 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
2. 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
3. Orkambi® will not be approved for members with CF other than those homozygous for the *F508del* mutation; and
4. Member must be 12 months of age or older; and
5. Members using Orkambi® must be supervised by a pulmonary specialist; and
6. Prescriber must verify the member has been counseled on proper administration of Orkambi® including taking with a fat-containing food; and
7. 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
8. Prescriber must verify that pediatric members will receive baseline and follow-up ophthalmological examinations as recommended in the package labeling; and
9. Members must not be taking any of the following medications concomitantly with Orkambi®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
10. 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
11. 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
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; and
14. 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
2. 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
3. Member must be 6 years of age or older; and
4. Members using Symdeko® must be supervised by a pulmonary specialist; and
5. 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
6. Prescriber must verify that member has been counseled on proper administration of Symdeko® including taking with a fat-containing food; and
7. 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
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 Symdeko®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's wort; and
10. A quantity limit of 2 tablets per day or 56 tablets per 28 days will apply; 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 must be provided for members who switched from Orkambi® to Symdeko®; and
13. 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 *in vitro* data; and
2. 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
3. Member must be 2 years of age or older; and
4. Members using Trikafta® must be supervised by a pulmonary specialist; and
5. 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
6. Prescriber must verify that member has been counseled on proper administration of Trikafta® including taking with a fat-containing food; and
7. Prescriber must verify that ALT, AST, and bilirubin will be assessed prior to initiating Trikafta®, every 3 months during the first year of treatment, and annually thereafter; and
8. Prescriber must verify that the member does not have severe hepatic impairment; 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 Trikafta®: 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 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

12. 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
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® or Symdeko® to Trikafta®; and
15. Subsequent approvals will be for the duration of 1 year.

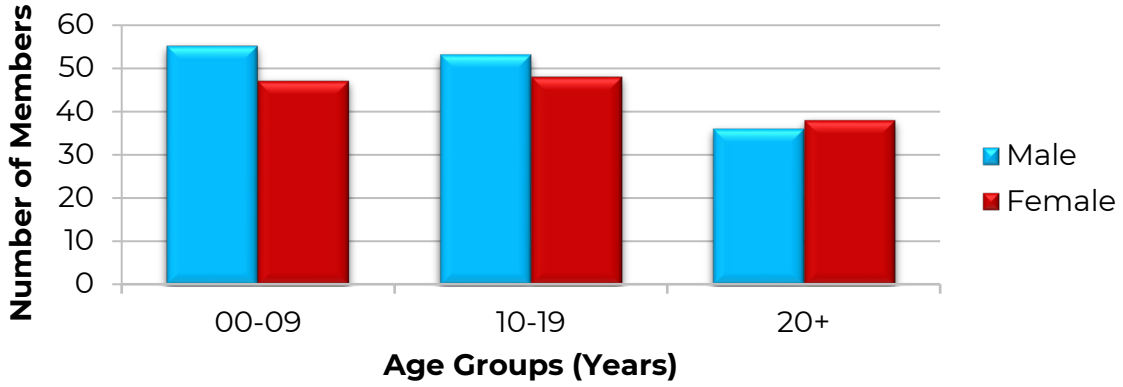
Utilization of CF Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

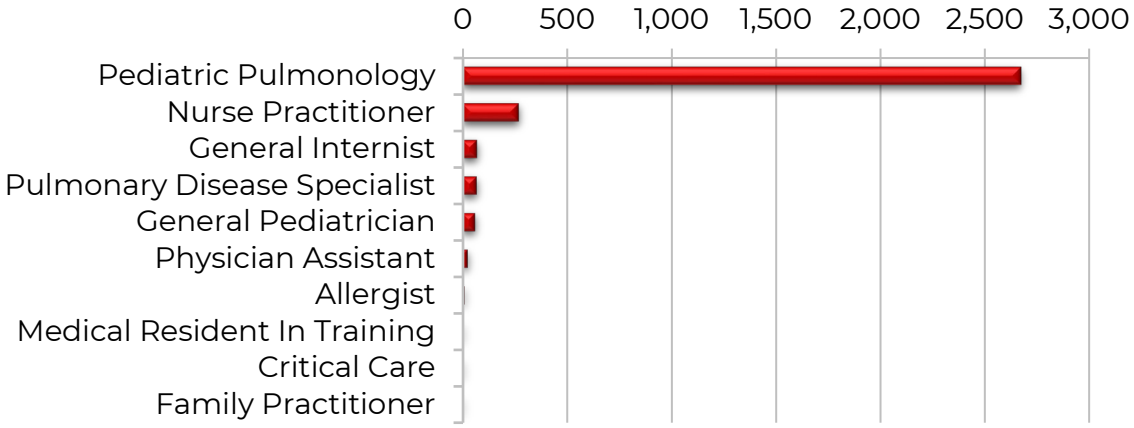
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	301	3,229	$44,784,251.20	$13,869.39	$425.90	336,345	105,152
Aetna	24	98	$1,519,566.71	$15,505.78	$525.07	8,666	2,894
Humana	42	162	$2,454,638.37	$15,152.09	$518.73	14,388	4,732
OCH	36	125	$1,908,786.58	$15,270.29	$514.91	11,274	3,707
2024 Total	**307**	**3,614**	**$50,667,242.86**	**$14,019.71**	**$434.97**	**370,673**	**116,485**
Fiscal Year 2025							
FFS	191	1,710	$24,420,274.81	$14,280.86	$428.61	185,820	56,976
Aetna	30	315	$5,202,563.93	$16,516.08	$561.23	27,500	9,270
Humana	51	685	$10,519,938.34	$15,357.57	$509.49	60,756	20,648
OCH	45	496	$7,551,828.66	$15,225.46	$507.21	47,446	14,889
2025 Total	**277**	**3,206**	**$47,694,605.74**	**$14,876.67**	**$468.59**	**321,522**	**101,783**
% Change	**-9.80%**	**-11.30%**	**-5.90%**	**6.10%**	**7.70%**	**-13.30%**	**-12.60%**
Change	**-30**	**-408**	**-$2,972,637.12**	**$856.96**	**$33.62**	**-49,151**	**-14,702**

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

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



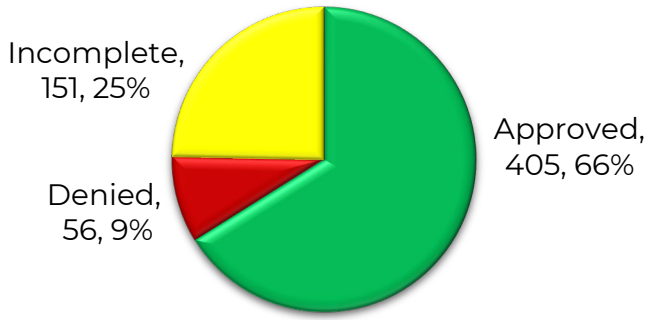
Top Prescriber Specialties of CF Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of CF Medications

There were 612 prior authorization requests submitted for CF medications during fiscal year 2025. The following chart shows the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	268	63%	137	32%	19	4%	**424**
Aetna	29	81%	1	3%	6	17%	**36**
Humana	40	82%	0	0%	9	18%	**49**
OCH	68	66%	13	13%	22	21%	**103**
Total	**405**	**66%**	**151**	**25%**	**56**	**9%**	**612**

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

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

Anticipated Patent Expiration(s):

- 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):

- **December 2024:** The FDA approved Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor) for the treatment of CF in patients 6 years of age and older who have at least 1 *F508del* mutation or another mutation in the CF transmembrane conductance regulator (*CFTR*) gene that is responsive to Alyftrek®.
- **December 2024:** The FDA approved a label expansion for Trikafta® (elexacaftor/tezacaftor/ivacaftor) to include patients with a mutation that is responsive to Trikafta® based on clinical and/or *in vitro* data, allowing 94 additional non-*F508del CFTR* mutations to be added to the Trikafta® label. This label expansion allows approximately 300 additional CF patients to be eligible for CFTR modulator therapy. Additionally, the safety information on liver injury and liver failure has been updated from *Warnings and Precautions* to a *Boxed Warning*.

News:

- **June 2025:** Vertex Pharmaceuticals presented data for multiple studies demonstrating positive clinical and quality of life benefits of treatment with CFTR modulators at the European Cystic Fibrosis Society's conference. Data from a pooled analysis across CFTR modulators showed that a reduction in sweat chloride (SwCl) was associated with

improved outcomes for patients with CF. For all clinical outcomes in the study, SwCl levels below 60mmol/L were associated with greater benefit including better and more stable lung function, fewer pulmonary exacerbations, better nutritional status, and better quality of life. Results from a post hoc analysis from the Phase 3 randomized, controlled and open-label trials of Alyftrek® suggest treatment with Alyftrek® is associated with improved health-related quality of life outcomes in adolescents and adults, and with improved CF symptoms and general functioning in children 6-11 years of age compared to patients treated with Trikafta®.

Pipeline:

- **Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor):** Alyftrek® is currently being studied in a Phase 3 trial for patients 2 to 5 years of age with CF. The Phase 3 trial has completed enrollment. Currently Alyftrek® is only FDA approved in patients 6 years of age or older.
- **ARCT-032:** ARCT-032 is an investigational mRNA replacement therapy designed to deliver a new copy of the CFTR mRNA into the airways via inhalation. ARCT-032 is currently in Phase 2 with interim data expected in September 2025. A Phase 3 trial is anticipated to be initiated in 2026.
- **SP-101:** SP-101 is an investigational inhaled recombinant adeno-associated virus (AAV) gene therapy that is combined with doxorubicin being studied in adults with CF who are ineligible for or cannot tolerate CFTR modulator therapy. Spirovant Sciences announced that the first patient has been dosed in the Phase 1/2 trial, and they are continuing to enroll patients. SP-101 has been granted Orphan Drug and Rare Pediatric Disease designations by the FDA.
- **Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor):** Trikafta® is currently being studied in a Phase 3 trial in patients 12 years of age or older who have a partial function *CFTR* mutation. This trial will evaluate the efficacy of Trikafta® in patients who have 2 *CFTR* mutations not currently approved for Trikafta®. The trial has completed enrollment.

Alyftrek® (Vanzacaftor/Tezacaftor/Deutivacaftor) Product Summary[12,13]

Therapeutic Class: Combination CFTR potentiator (deutivacaftor) and CFTR correctors (vanzacaftor and tezacaftor)

Indication(s): Treatment of CF in patients 6 years of age and older who have at least 1 *F508del* mutation or another responsive mutation in the *CFTR* gene

- If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least 1 indicated mutation.

How Supplied: Alyftrek® is supplied as fixed dose combination tablets in the following strengths:

- Vanzacaftor/tezacaftor/deutivacaftor 4/20/50mg
- Vanzacaftor/tezacaftor/deutivacaftor 10/50/125mg

Dosing and Administration:

Age	Weight	Once Daily Dose
6 to <12 years	<40kg	3 tablets of vanzacaftor/tezacaftor/ deutivacaftor 4/20/50mg
	≥40kg	2 tablets of vanzacaftor/tezacaftor/ deutivacaftor 10/50/125mg
≥12 years	Any weight	

- Prior to initiating Alyftrek®, liver function tests [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and bilirubin] should be obtained in all patients and should be monitored every month during the first 6 months of treatment, then every 3 months during the next 12 months, then at least annually thereafter.
- Alyftek® should not be used in patients with severe hepatic impairment or in patients with moderate hepatic impairment unless the benefit outweighs the risk. If used, no dose adjustment is recommended. Liver function tests should be closely monitored.
- See the full *Prescribing Information* for dosage modifications for concomitant use with strong or moderate CYP3A inhibitors and a list of *CFTR* gene mutations responsive to Alyftrek®.

Efficacy: Alyftrek® was studied in 2 randomized, double-blind, active-controlled trials, SKYLINE 102 and SKYLINE 103, comparing Alyftrek® to elexacaftor, tezacaftor, and ivacaftor (ELX/TEZ/IVA) for 971 patients who were 12 years of age or older with CF.

- Key Inclusion Criteria:
  - SKYLINE 102:
    - Heterozygous for *F508del* and a minimal function mutation
    - Forced expiratory volume in 1 second (FEV_1) ≥40% and ≤90% of predicted mean for age, sex, and height for participants currently receiving ELX/TEZ/IVA
    - FEV_1 ≥40% and ≤80% for participants not currently receiving ELX/TEZ/IVA
  - SKYLINE 103:
    - ≥1 of the following genotypes: homozygous for the *F508del* mutation, heterozygous for the *F508del* mutation and either a gating or a residual function mutation, or at least 1 mutation responsive to ELX/TEZ/IVA with no *F508del* mutation
    - FEV_1 ≥40% and ≤90% of predicted mean for age, sex, and height for participants currently receiving CFTR modulator therapy

        - FEV_1 ≥40% and ≤80% for participants not currently receiving therapy with a CFTR modulator
- Key Exclusion criteria:
    - History of intolerance to ELX/TEZ/IVA
- Intervention(s): Patients were randomized 1:1 to receive Alyftrek® or ELX/TEZ/IVA for 52 weeks.
    - To establish a reliable on-treatment baseline, all study participants received ELX/TEZ/IVA during a 4-week run-in period, and the baseline values for all endpoints were measured at the end of the ELX/TEZ/IVA run-in.
- Endpoint(s):
    - Primary: Non-inferiority in mean absolute change in percent predicted FEV_1 ($ppFEV_1$) from baseline through week 24
        - Both trials included a prespecified non-inferiority margin of -3.0%.
    - Key Secondary Endpoint: Mean absolute change from baseline in SwCl through week 24
- Results:
    - Primary Endpoint:
        - SKYLINE 102: Absolute change in $ppFEV_1$ was 0.5% for those on Alyftrek® vs. 0.3% for those on ELX/TEZ/IVA [treatment difference: 0.2%; 95% confidence interval (CI): -0.7, 1.1; P<0.001]
        - SKYLINE 103: Absolute change in $ppFEV_1$ was 0.2% for those on Alyftrek® vs. 0.0% for those on ELX/TEZ/IVA (treatment difference: 0.2%; 95% CI: -0.5, 0.9; P<0.001)
    - Secondary Endpoint:
        - SKYLINE 102: Absolute change in SwCl was -7.5mmol/L for those on Alyftrek® vs. 0.9mmol/L for those on ELX/TEZ/IVA (treatment difference: -8.4mmol/L; 95% CI: -10.5, -6.3; P<0.0001)
        - SKYLINE 103: Absolute change in SwCl was -5.1mmol/L for those on Alyftrek® vs. -2.3mmol/L for those on ELX/TEZ/IVA (treatment difference: -2.8mmol/L; 95% CI: -4.7, -0.9; P=0.0034)

Cost Comparison:

Product	Cost per Tablet	Cost Per 28 Days	Cost Per Year
Alyftrek® (vanz/teza/deut) 10/50/125mg	**$507.22**	**$28,404.32***	**$369,256.16**
Trikafta® (elx/teza/iva and iva) 100/50/75mg	$338.15	$28,404.60⁺	$369,259.80

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
deut = deutivacaftor; elx = elexacaftor; iva = ivacaftor; teza = tezacaftor; vanz = vanzacaftor
*Cost per 28 days based on the maximum FDA approved dosing of 2 tablets once daily.
⁺Cost per 28 days is based on the maximum FDA approved dosing of 2 tablets in the morning and 1 tablet of ivacaftor in the evening.

Recommendations

The College of Pharmacy recommends the prior authorization of Alyftrek® (vanzacaftor/tezacaftor/deutivacaftor) with the following criteria (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 *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.

Additionally, the College of Pharmacy recommends updating the Trikafta® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) approval criteria based on the new FDA approved label expansion, clinical practice and to be consistent with the other CFTR modulator therapies (changes shown in red):

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 ALT, AST, and bilirubin will be assessed prior to initiating Trikafta, every 3 months during the first year of treatment, and annually thereafter; and~~
7. 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
8. Prescriber must verify that the member does not have severe hepatic impairment; 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 Trikafta®: rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort; and
11. 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
12. 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
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) or Symdeko® (tezacaftor/ivacaftor and ivacaftor); and
15. Subsequent approvals will be for the duration of 1 year.

Finally, the College of Pharmacy recommends updating the Kalydeco® (ivacaftor) approval criteria to be consistent with the FDA approved label, clinical practice, and the other CFTR modulator therapies and recommends updating the Orkambi® (lumacaftor/ivacaftor) and Symdeko® (tezacaftor/ivacaftor and ivacaftor) approval criteria to be consistent with clinical practice and the other CFTR modulator therapies (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 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.

Utilization Details of CF Medications: Fiscal Year 2025

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	943	118	$24,995,541.36	$26,506.41	7.99	52.41%
TRIKAFTA TAB 50-25-37.5/75MG	237	29	$6,292,690.59	$26,551.44	8.17	13.19%
TRIKAFTA GRA 100-50-75/75MG	226	29	$5,874,730.06	$25,994.38	7.79	12.32%
TRIKAFTA GRA 80-40-60/59.5MG	79	12	$2,098,035.39	$26,557.41	6.58	4.40%
SUBTOTAL	**1,485**	**188**	**$39,260,997.40**	**$26,438.38**	**7.9**	**82.32%**
DORNASE ALFA PRODUCTS						
PULMOZYME SOL 1MG/ML	1,241	173	$5,161,511.37	$4,159.16	7.17	10.82%
SUBTOTAL	**1,241**	**173**	**$5,161,511.37**	**$4,159.16**	**7.17**	**10.82%**
TOBRAMYCIN NEBULIZED PRODUCTS						
TOBRAMYCIN NEB 300MG/5ML	318	102	$151,609.44	$476.76	3.12	0.32%
TOBRAMYCIN NEB 300MG/4ML	20	9	$71,919.85	$3,595.99	2.22	0.15%
KITABIS PAK NEB 300MG/5ML	4	1	$18,045.64	$4,511.41	4	0.04%
BETHKIS NEB 300MG/4ML	1	1	$6,193.16	$6,193.16	1	0.01%
SUBTOTAL	**343**	**113**	**$247,768.09**	**$722.36**	**3.04**	**0.52%**
VANZACAFTOR/TEZACAFTOR/DEUTIVACAFTOR COMBINATION PRODUCTS						
ALYFTREK TAB 10-50-125MG	34	11	$966,127.92	$28,415.53	3.09	2.03%
ALYFTREK TAB 4-20-50MG	13	3	$369,403.19	$28,415.63	4.33	0.77%
SUBTOTAL	**47**	**14**	**$1,335,531.11**	**$28,415.56**	**3.36**	**2.80%**
AZTREONAM NEBULIZED PRODUCTS						
CAYSTON INH 75MG	36	10	$435,886.96	$12,107.97	3.6	0.91%
SUBTOTAL	**36**	**10**	**$435,886.96**	**$12,107.97**	**3.6**	**0.91%**
TEZACAFTOR/IVACAFTOR AND IVACAFTOR COMBINATION PRODUCTS						
SYMDEKO TAB 100-150/150MG	23	3	$572,593.51	$24,895.37	7.67	1.20%
SUBTOTAL	**23**	**3**	**$572,593.51**	**$24,895.37**	**7.67**	**1.20%**
LUMACAFTOR/IVACAFTOR COMBINATION PRODUCTS						
ORKAMBI GRA 100-125MG	18	5	$418,507.02	$23,250.39	3.6	0.88%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**18**	**5**	**$418,507.02**	**$23,250.39**	**3.6**	**0.88%**
TOBRAMYCIN POWDER PRODUCTS						
TOBI PODHALER CAP 28MG	9	3	$102,496.64	$11,388.52	3	0.21%
SUBTOTAL	**9**	**3**	**$102,496.64**	**$11,388.52**	**3**	**0.21%**
IVACAFTOR PRODUCTS						
KALYDECO TAB 150MG	2	1	$53,114.82	$26,557.41	2	0.11%
KALYDECO GRA 75MG	2	1	$106,198.82	$53,099.41	2	0.22%
SUBTOTAL	**4**	**2**	**$159,313.64**	**$39,828.41**	**2**	**0.33%**
TOTAL	**3,206**	**277***	**$47,694,605.74**	**$14,876.67**	**11.57**	**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 2025 = 07/01/2024 to 06/30/2025

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[3] Vertex Pharmaceuticals. Vertex Announces U.S. FDA Approval for Trikafta® (Elexacaftor/Tezacaftor/Ivacaftor and Ivacaftor) to Include Additional Non-*F508del* Trikafta®-Responsive Variants. Available online at: https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-us-fda-approval-trikafta. Issued 12/20/2024. Last accessed 08/12/2025.
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Appendix R

Fiscal Year 2025 Annual Review of Amyloidosis Medications and 30-Day Notice to Prior Authorize Attruby™ (Acoramidis)

Oklahoma Health Care Authority
September 2025

Current Prior Authorization Criteria

Amvuttra® (Vutrisiran) 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. Amvuttra® will not be approved for concomitant use with Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), Vyndamax® (tafamidis), or Wainua®; and
9. Authorization for Amvuttra® will 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.

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), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine) or Wainua®;; 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.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of the polyneuropathy of 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. Tegsedi® 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 agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. 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 Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua® (eplontersen); and
11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® 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
13. A quantity limit of 4 syringes per 28 days will apply.

Vyndamax® (Tafamidis) and Vyndaqel® (Tafamidis Meglumine) 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® or Vyndaqel® 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® or Vyndaqel® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Tegsedi® (inotersen), 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 or 4 Vyndaqel® capsules 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), Onpattro® (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); 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 2025

Fiscal Year 2025 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**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: There were no paid pharmacy claims for amyloidosis medications during fiscal year 2024 to allow for a fiscal year comparison.
Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Fiscal Year 2025 Utilization: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	2	4	$123,380.25	$33,077.06	2
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**2**	**4**	**$123,380.25**	**$33,077.06**	**2**
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**
% Change	**0.00%**	**20.00%**	**66.23%**	**54.73%**	**20.00%**
Change	**0**	**1**	**$241,928.00**	**$39,984.59**	**0.5**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

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

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

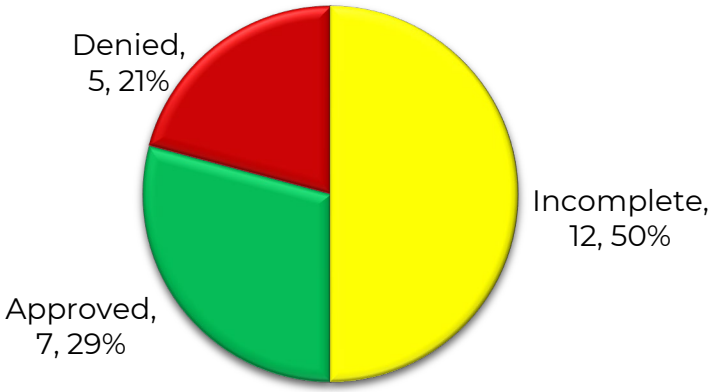
Top Prescriber Specialties of Amyloidosis Medications by Number of Claims: Pharmacy Claims (All Plans)

- The only prescriber specialty listed on paid pharmacy claims for amyloidosis medications during fiscal year 2025 was neurologist.

Prior Authorization of Amyloidosis Medications

There were 24 prior authorization requests submitted for the amyloidosis medications during fiscal year 2025. The following chart shows the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	6	29%	12	57%	3	14%	**21**
Aetna	0	0%	0	0%	2	100%	**2**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	1	100%	0	0%	0	0%	**1**
Total	**7**	**29%**	**12**	**50%**	**5**	**21%**	**24**

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

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

Anticipated Patent Expiration(s):

- Tegsedi® (inotersen): April 2031
- Wainua® (eplontersen): August 2034
- Onpattro® (patisiran): August 2035
- Vyndamax® (tafamidis): August 2035
- Amvuttra® (vutrisiran): July 2036
- Attruby™ (acoramidis): August 2039

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

- **November 2024:** The FDA approved Attruby™ (acoramidis), an oral transthyretin stabilizer, for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) death and CV-related hospitalization.
- **May 2025:** Amvuttra® (vutrisiran) received FDA expanded approval for the treatment of the ATTR-CM with wild-type or variant transthyretin genotypes to reduce CV death and CV-related hospitalization. Amvuttra® is currently the only product FDA approved for the treatment of both ATTR-CM and the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN).

Pipeline:

- **ALXN2220:** The FDA granted Fast Track designation to ALXN2220, an investigational product being evaluated in the Phase 3 DepleTTR-CM trial by Neurimmune and Alexion for the treatment of ATTR-CM. ALXN2220 is a human monoclonal antibody designed to induce depletion of cardiac amyloid deposits with the potential to restore cardiac function. Primary completion of the trial is currently estimated to be June 2027.
- **Nexiguran Ziclumeran (Nex-z, NTLA-2001):** Regeneron Pharmaceuticals, in collaboration with Intellia, is evaluating nexiguran ziclumeran, a *TTR* gene knockout therapy using CRISPR/Cas9, in Phase 3 clinical trials for the treatment of ATTR-CM and hATTR-PN.
- **Wainua™ (Eplontersen):** Ionis Pharmaceuticals announced that the FDA granted Fast Track designation to Ionis and AstraZeneca's eplontersen for the treatment of ATTR-CM in adults. Eplontersen is currently marketed as Wainua® and was FDA approved in December 2023 for the treatment hATTR-PN. Eplontersen is currently being evaluated in the global CARDIO-TTRansform study, which currently has an estimated primary completion date of April 2026.

Attruby™ (Acoramidis) Product Summary[9,10]

Therapeutic Class: Transthyretin stabilizer

Indication(s): Treatment of wild-type or variant ATTR-CM in adults to reduce CV death and CV-related hospitalization

How Supplied: 356mg film-coated tablets

Dosing and Administration: 712mg (2 tablets) orally twice daily

Efficacy: Attruby™ was evaluated in a multicenter, international, randomized, double-blind, placebo-controlled study in 611 patients.

- Key Inclusion Criteria:
  - Diagnosis of ATTR-CM with either wild-type or variant transthyretin genotype
  - History of heart failure with New York Heart Association (NYHA) Class I-III symptoms due to ATTR-CM
  - On stable CV medical therapy
- Key Exclusion Criteria:
  - History of acute myocardial infarction, acute coronary syndrome, coronary revascularization or experienced a stroke or transient ischemic attack within the 90 days prior to screening
  - Confirmed diagnosis of primary (light chain) amyloidosis
  - Current treatment with any FDA approved or experimental drug for ATTR-CM
- Intervention(s):
  - Attruby™ 712mg orally twice daily vs. placebo tablet orally twice daily
- Primary Endpoint(s):
  - Composite endpoint of all-cause mortality and cumulative frequency of CV-related hospitalizations (CVH) over 30 months
- Results:
  - A statistically significant reduction in the composite endpoint (P=0.018) was seen in the Attruby™ arm (n=409) vs. the placebo arm (n=202).
  - All-cause mortality was reported in 19% of patients in the Attruby™ arm vs. 26% of patients the placebo arm.
  - The mean number of CVH events was 0.3 vs. 0.6 per year.

Cost Comparison:

Product	Cost Per Tablet	Cost Per Year*
Attruby™ (acoramidis) 356 mg tablet	**$167.49**	**$241,185.60**
Vyndamax® (tafamidis) 61mg tablet	$744.41	$267,987.60
Vyndaqel® (tafamidis meglumine) 20mg tablet	$186.10	$267,987.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per year is based on the FDA recommended dosing of Attruby™ 712mg twice daily, Vyndamax® 61mg once daily, and Vyndaqel® 80mg once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Attruby™ (acoramidis) with the following criteria (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), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (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.

The College of Pharmacy also recommends updating the approval criteria for Amvuttra® (vutrisiran) based on the new FDA approved indication and the FDA approval of Attruby™ (acoramidis) (changes shown in red):

Amvuttra® (Vutrisiran) Approval Criteria:

1. An FDA approved indication ~~for~~ of 1 of the following:
    a. The treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) amyloidosis; ~~and~~ 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; ~~and~~ 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
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), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), 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.

Lastly, the College of Pharmacy recommends updating the Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), Vyndamax® (tafamidis), and Wainua® (eplontersen) approval criteria based on the FDA approval of Attruby™ (acoramidis) (changes shown in red):

Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR-PN) 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 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), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), 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.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of the polyneuropathy of 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. Tegsedi® 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 agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. 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 Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby™ (acoramidis), Onpattro® (patisiran), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua® (eplontersen); and
11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® 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
13. A quantity limit of 4 syringes per 28 days will apply.

Vyndamax® (Tafamidis) and Vyndaqel® (Tafamidis Meglumine) 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® or Vyndaqel® 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® or Vyndaqel® will not be approved for concomitant use with Amvuttra® (vutrisiran), Attruby™ (acoramidis), Onpattro® (patisiran), or Tegsedi® (inotersen), 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 or 4 Vyndaqel® capsules 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), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); 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 Details of Amyloidosis Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMVUTTRA SOL 25MG/0.5ML	2	2	$238,724.82	$119,362.41	1	100%
TOTAL	**2**	**2***	**$238,724.82**	**$119,362.41**	**1**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VUTRISIRAN INJ (J0225)	3	1	$362,327.75	$120,775.92	3
PATISIRAN INJ (J0222)	2	1	$2,980.50	$1,490.25	2
TOTAL	**5⁺**	**2***	**$365,308.25**	**$73,061.65**	**2.5**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2025. Last accessed 08/25/2025.
[2] Attruby™ (Acoramidis) Prescribing Information. BridgeBio Pharma. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/216540s000lbl.pdf. Last revised 11/2024. Last accessed 08/25/2025.
[3] Alnylam® Pharmaceuticals. Alnylam Announces FDA Approval of Amvuttra® (Vutrisiran), the First RNAi Therapeutic to Reduce Cardiovascular Death, Hospitalizations and Urgent Heart Failure Visits in Adults with ATTR Amyloidosis with Cardiomyopathy (ATTR-CM). Available online at: https://investors.alnylam.com/press-release?id=28831. Issued 03/20/2025. Last accessed 08/25/2025.
[4] Neurimme. FDA Fast Track Designation of ALXN2220 for Depletion of Cardiac ATTR. Available online at: https://www.neurimmune.com/news/fda-fast-track-designation-for-alxn2220-for-depletion-of-cardiac-attr. Issued 10/14/2024. Last accessed 08/25/2025.
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Appendix S

30-Day Notice to Prior Authorize Photrexa®/Photrexa® Viscous (Riboflavin 5'-Phosphate)

Oklahoma Health Care Authority
September 2025

Introduction[1,2,3,4]

Corneal ectasia is a broad term that includes both naturally occurring and surgically induced thinning and protrusion of the cornea. There are several types of corneal ectasia including keratoconus, pellucid marginal degeneration, keratoglobus, post-keratorefractive ectasia, and wound ectasia after penetrating corneal transplantation.

Keratoconus is a naturally occurring form of corneal ectasia that typically presents in the second or third decade of life. Keratoconus is a bilateral, progressive, noninflammatory eye condition that causes the cornea to thin out and bulge into a cone shape, which changes the way the cornea brings light into the eye. Keratoconus signs and symptoms include blurry and distorted vision, increased sensitivity to light, and eye redness or swelling. In more advanced cases, increased nearsightedness or astigmatism occurs. As a result, patients may need more frequent changes to their eyeglasses prescription and contacts may not fit properly. Eventually, keratoconus can cause the cornea to scar and cause even worse vision loss. The exact cause of keratoconus is unknown, but it may include genetic factors, chromosomal and enzyme abnormalities, and mechanical factors (i.e., eye rubbing).

The prevalence of keratoconus is estimated to be 1 in 375 people. It can be diagnosed through a routine eye exam; however, it is typically treated by an ophthalmologist. The goal of treatment is to prevent the progression of the disease, and depending on the severity of the disease, treatment can include eyeglasses, contact lenses (including specialized contact lens), intracorneal ring segment implants, or corneal transplantation.

Corneal ectasia can also be surgically induced after Laser-Assisted *in Situ* Keratomileusis (LASIK), small incision lenticule extraction (SMILE), photorefractive keratectomy (PRK), and radial keratotomy (RK). Surgically induced corneal ectasia has similar signs, symptoms, and treatments as keratoconus.

In 2016, Photrexa®/Photrexa® Viscous (riboflavin 5'-phosphate) was approved by the U.S. Food and Drug Administration (FDA) for use with the KXL® System in the corneal cross-linking procedure to treat progressive keratoconus and corneal ectasia following refractive surgery. The procedure uses an ultraviolet

light and Photrexa®/Photrexa® Viscous to strengthen the corneal tissue, stopping disease progression.

Photrexa®/Photrexa® Viscous (Riboflavin 5'-phosphate) Product Summary[5]

Therapeutic Class: Photo-enhancers

Indication(s): For use with the KXL® System in corneal cross-linking for the treatment of progressive keratoconus and corneal ectasia following refractive surgery

How Supplied:

- Photrexa® Viscous is supplied in a 3mL glass syringe containing sterile 1.56mg/mL riboflavin 5'-phosphate in 20% dextran ophthalmic solution
- Photrexa® is supplied in a 3mL glass syringe containing sterile 1.46mg/mL riboflavin 5'-phosphate ophthalmic solution

Dosing and Administration:

- See *Prescribing Information* for full dosing and administration.
- For topical ophthalmic use. Do not inject.
- For single use only. Discard syringe(s) after use.
- Photrexa® Viscous and Photrexa® are for use with the KXL® System only.

Efficacy: The safety and efficacy of Photrexa®/Photrexa® Viscous with the KXL® system were studied in 3 prospective, randomized, parallel-group, open-label, sham-controlled trials.

- Key Inclusion Criteria:
  - Study 1: Patients with a diagnosis of progressive keratoconus or corneal ectasia following refractive surgery
  - Study 2: Patients with a diagnosis of progressive keratoconus only
  - Study 3: Patients with a diagnosis of corneal ectasia following refractive surgery only
- Intervention: In each study, 1 eye was designated as the study eye and was randomized to receive 1 of 2 study treatments (Photrexa®/ Photrexa® Viscous with the KXL® system or sham) at the baseline visit. The patients were evaluated at day 1, week 1, and at months 1, 3, 6, and 12. At month 3 or later, patients had the option of receiving treatment in both the sham study eye and non-study eye and were followed for 12 months from the time of receiving treatment.
- Primary Outcome: The maximum corneal curvature (K_{max}) was assessed at baseline and at months 1, 3, and 12.
- Results: The treated eyes showed increasing improvement in K_{max} from month 3 to month 12.
  - Progressive keratoconus patients had an average K_{max} reduction of 1.4 diopters in Study 1 and 1.7 diopters in Study 2 at month 12 in the

treated eyes, while the sham eyes had an average increase of 0.5 diopter in Study 1 and 0.6 diopter in Study 2 at month 12.
    - The treatment differences [95% confidence interval (CI)] between the groups were -1.9 (-3.4, -0.3) diopters in Study 1 and -2.3 (-3.5, -1.0) in Study 2.
- Corneal ectasia patients had an average K_{max} reduction of 1.0 diopter in Study 1 and 0.5 diopter in Study 3 at 12 months in the treated eyes, while the sham eyes had an average increase of 1.0 diopter in Study 1 and 0.5 diopter in Study 3.
    - The treatment difference (95% CI) between the groups were -2.0 (-3.0, -1.1) diopters in Study 1 and -1.1 (-1.9, -0.3) diopters in Study 3.

Cost: The Wholesale Acquisition Cost (WAC) of Photrexa®/Photrexa® Viscous is $4,560 per kit; therefore, to treat both eyes, the cost would be $9,120.

Recommendations

The College of Pharmacy recommends the prior authorization of Photrexa®/Photrexa® Viscous (riboflavin 5'-phosphate) with the following criteria:

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 and administered by an ophthalmologist; 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.

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Appendix T

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

***Additional information, including the full news release, on the following FDA and DEA updates can be found on the FDA website at: https://www.fda.gov/news-events/fda-newsroom/press-announcements.**

FDA NEWS RELEASE

For Immediate Release: August 14, 2025

FDA Approves First Immunotherapy for Recurrent Respiratory Papillomatosis (RRP)

The FDA approved Papzimeos™ (zopapogene imadenovec-drba), a first-of-its-kind non-replicating adenoviral vector-based immunotherapy for the treatment of adult patients with RRP.

RRP is a rare, chronic disease caused by persistent human papillomavirus (HPV) 6 or 11 infection, leading to the growth of benign tumors in the respiratory tract, most commonly the larynx. The disease is associated with significant morbidity, including voice changes, breathing difficulties, and airway obstruction. There are currently no approved medical therapies that eliminate the need for repeated surgical procedures.

With an estimated 1,000 new cases diagnosed annually in the U.S., RRP represents a rare disease with significant unmet medical need. Until today, no therapies have been approved for RRP. Papzimeos™ is administered via subcutaneous (sub-Q) injection and is designed to stimulate an immune response against cells infected with HPV types 6 and 11. The therapy offers a novel mechanism of action distinct from traditional treatments, which have relied primarily on repeated surgical interventions.

The approval is based on results from a single-arm, open-label trial evaluating Papzimeos™ in adult patients with RRP who required 3 or more surgeries per year. Patients received 4 sub-Q injections of Papzimeos™ over 12 weeks following surgical debulking procedures.

In the pivotal portion of the study, 51.4% of patients (18/35) achieved a complete response—defined as no need for surgical intervention in the 12 months following treatment. Follow-up data showed that durable responses were maintained in most patients through 2 years, with a strong correlation between clinical benefit and the induction of HPV 6/11-specific T cells.

The safety profile was favorable, with most treatment-emergent adverse events being mild to moderate. No dose-limiting toxicities were observed, and no treatment-related serious adverse events were reported.

This approval was completed under Priority Review and the product received both Orphan Drug designation and Breakthrough Therapy designation.

Current Drug Shortages Index (as of August 25, 2025):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bacitracin Ophthalmic Ointment	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***

Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Indocyanine Green Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lactated Ringers Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***

Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***