OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
February 12, 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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After registering, you will receive a confirmation email containing information about joining the webinar.

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – February 12, 2025

DATE: February 5, 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 February 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/Academic Detailing (AD) Program Update – Appendix B

Narrow Therapeutic Index (NTI) List – Appendix C

Action Item – Vote to Prior Authorize Jubbonti® (Denosumab-bbdz) and Update the Approval Criteria for the Osteoporosis Medications – Appendix D

Action Item – Vote to Prior Authorize Aqneursa™ (Levacetylleucine), Lenmeldy™ (Atidarsagene Autotemcel), and Miplyffa™ (Arimoclomol) and Update the Approval Criteria for the Lysosomal Storage Disease Medications – Appendix E

Action Item – Vote to Prior Authorize Yorvipath® (Palopegteriparatide) and Update the Approval Criteria for the Parathyroid Medications – Appendix F

Action Item – Vote to Prior Authorize Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), Fabhalta® (Iptacopan), Piasky® (Crovalimab-akkz), and Voydeya™ (Danicopan) and Update the Approval Criteria for the Complement Inhibitors and Miscellaneous Immunomodulatory Agents – Appendix G

Action Item – Vote to Prior Authorize Labetalol Hydrochloride 400mg Tablet, Nexiclon™ XR [Clonidine Extended-Release (ER)], and Tryvio™ (Aprocitentan) and Update the Approval Criteria for the Antihypertensive Medications – Appendix H

Action Item – Vote to Prior Authorize Acthar® Gel SelfJect™ (Repository Corticotropin Auto-Injector) and Purified Cortrophin® Gel (Repository Corticotropin Injection) and Update the Approval Criteria for the Adrenocorticotropic Hormone (ACTH) Products – Appendix I

Action Item – Vote to Prior Authorize Diflunisal 500mg Tablet, Dolobid™ (Diflunisal) 250mg and 375mg Tablet, and Indomethacin 50mg Suppository and Update the Approval Criteria for the Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) – Appendix J

Action Item – Vote to Prior Authorize Tryngolza™ (Olezarsen) and Update the Approval Criteria for the Antihyperlipidemics – Appendix K

Action Item – Vote to Prior Authorize Wyost® (Denosumab-bbdz) – Appendix L

Action Item – Vote to Update the Approval Criteria for the Ophthalmic Antibiotic Medications – Appendix M

Action Item – Annual Review of Short-Acting Beta$_2$ Agonists (SABAs) – Appendix N

30-Day Notice to Prior Authorize Kebilidi™ (Eladocagene Exuparvovec-tneq) – Appendix O

Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Symbravo® (Meloxicam/Rizatriptan) – Appendix P

Annual Review of Cholestatic Liver Disease Medications and 30-Day Notice to Prior Authorize Iqirvo® (Elafibranor) and Livdelzi® (Seladelpar) – Appendix Q

Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Pantoprazole in 0.9% Sodium Chloride (NaCl) for Intravenous (IV) Injection – Appendix R

Annual Review of Heart Failure (HF) Medications and 30-Day Notice to Prior Authorize Entresto® Sprinkle (Sacubitril/Valsartan Oral Pellets) – 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 – February 12, 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:

Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Bret Haymore –	participating in person
Dr. Craig Kupiec –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Vineetha Thomas –	participating in person
Dr. Beth Walton –	participating in person
Dr. Jennifer Weakley –	participating in person

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

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

Public Comment for Meeting:

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

Items to be presented by Dr. Haymore, Chairman:

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

Items to be presented by Dr. Haymore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. December 11, 2024 DUR Board Meeting Minutes
   B. December 11, 2024 DUR Board Recommendations Memorandum
   C. January 8, 2025 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Academic Detailing (AD) Program Update – See Appendix B**
   A. Pharmacy Help Desk Activity for December 2024
   B. Medication Coverage Activity for December 2024
   C. Pharmacy Help Desk Activity for January 2025
   D. Medication Coverage Activity for January 2025
   E. AD Program Update

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

5. **Narrow Therapeutic Index (NTI) List – See Appendix C**
   A. Introduction
   B. SoonerCare NTI List
   C. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Jubbonti® (Denosumab-bbdz) and Update the Approval Criteria for the Osteoporosis Medications – See Appendix D**
   A. Market News and Updates
   B. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Aqneursa™ (Levacetylleucine), Lenmeldy™ (Atidarsagene Autotemcel), and Miplyffa™ (Arimoclomol) and Update the Approval Criteria for the Lysosomal Storage Disease Medications – See Appendix E**
   A. Market News and Updates
   B. Product Summaries
   C. Cost Comparison: Niemann-Pick Disease Type C (NPC) Products
   D. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Yorvipath® (Palopegteriparatide) and Update the Approval Criteria for the Parathyroid Medications – See Appendix F**
   A. Market News and Updates
   B. Yorvipath® (Palopegteriparatide) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), Fabhalta® (Iptacopan), Piasky® (Crovalimab-akkz), and Voydeya™ (Danicopan) and Update the Approval Criteria for the Complement Inhibitors and Miscellaneous Immunomodulatory Agents – See Appendix G**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Labetalol Hydrochloride 400mg Tablet, Nexiclon™ XR [Clonidine Extended-Release (ER)], and Tryvio™ (Aprocitentan) and Update the Approval Criteria for the Antihypertensive Medications – See Appendix H**
    A. Market News and Updates
    B. Tryvio™ (Aprocitentan) Product Summary
    C. Cost Comparisons
    D. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Acthar® Gel SelfJect™ (Repository Corticotropin Auto-Injector) and Purified Cortrophin® Gel (Repository Corticotropin Injection) and Update the Approval Criteria for the Adrenocorticotropic Hormone (ACTH) Products – See Appendix I**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

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

12. **Action Item – Vote to Prior Authorize Diflunisal 500mg Tablet, Dolobid™ (Diflunisal) 250mg and 375mg Tablet, and Indomethacin 50mg Suppository and Update the Approval Criteria for the Systemic Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) – See Appendix J**
    A. Market News and Updates
    B. Dolobid™ (Diflunisal) Product Summary
    C. Cost Comparison: Indomethacin Products
    D. College of Pharmacy Recommendations

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

13. **Action Item – Vote to Prior Authorize Tryngolza™ (Olezarsen) and Update the Approval Criteria for the Antihyperlipidemics – See Appendix K**
    A. Market News and Updates
    B. Tryngolza™ (Olezarsen) Product Summary
    C. College of Pharmacy Recommendations

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

14. **Action Item – Vote to Prior Authorize Wyost® (Denosumab-bbdz) – See Appendix L**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

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

15. **Action Item – Vote to Update the Approval Criteria for the Ophthalmic Antibiotic Medications – See Appendix M**
    A. Market News and Updates
    B. College of Pharmacy Recommendations

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

16. **Action Item – Annual Review of Short-Acting Beta$_2$ Agonists (SABAs) – See Appendix N**
    A. Current Prior Authorization Criteria
    B. Utilization of SABAs
    C. Prior Authorization of SABAs
    D. Market News and Updates

E. College of Pharmacy Recommendations
F. Utilization Details of SABAs

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

17. 30-Day Notice to Prior Authorize Kebilidi™ (Eladocagene Exuparvovec-tneq) – See Appendix O

A. Introduction
B. Kebilidi™ (Eladocagene Exuparvovec-tneq) Product Summary
C. College of Pharmacy Recommendations

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

18. Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Symbravo® (Meloxicam/Rizatriptan) – See Appendix P

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

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

19. Annual Review of Cholestatic Liver Disease Medications and 30-Day Notice to Prior Authorize Iqirvo® (Elafibranor) and Livdelzi® (Seladelpar) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Cholestatic Liver Disease Medications
C. Prior Authorization of Cholestatic Liver Disease Medications
D. Market News and Updates
E. Product Summaries
F. Cost Comparison: Primary Biliary Cholangitis (PBC) Medications
G. College of Pharmacy Recommendations
H. Utilization Details of Cholestatic Liver Disease Medications

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

20. Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Pantoprazole in 0.9% Sodium Chloride (NaCl) for Intravenous (IV) Injection – See Appendix R

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

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

21. **Annual Review of Heart Failure (HF) Medications and 30-Day Notice to Prior Authorize Entresto® Sprinkle (Sacubitril/Valsartan Oral Pellets) – See Appendix S**
    A. Current Prior Authorization Criteria
    B. Utilization of HF Medications
    C. Prior Authorization of HF Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of HF Medications

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

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

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

23. **Future Business* (Upcoming Product and Class Reviews)**
    A. Anticonvulsants
    B. Growth Hormone Products and Voxzogo® (Vosoritide)
    C. Multiple Sclerosis Medications
    D. Muscular Dystrophy Medications

    *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 DECEMBER 11, 2024

DUR BOARD MEMBERS:	PRESENT	ABSENT
Kenneth Foster, MHS, PA-C		X
Megan A. Hanner, D.O.		X
Bret Haymore, M.D.	X	
John Muchmore, M.D.; Ph.D.; Chairman	X	
Lee Muñoz, D.Ph.	X	
James Osborne, Pharm.D.	X	
Edna Patatanian, Pharm.D., FASHP; Interim Vice Chairwoman	X	
Vineetha Thomas, Pharm.D., BCOP	X	
Beth Walton, Pharm.D.	X	

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	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
Michaela Metts, Pharm.D., MBA, BCPS; Clinical Pharmacist	X	
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Chinemerem Opara, Pharm.D.; Pharmacy Resident	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist	X	
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Tad Autry Pharm.D., BCPS, BCOP		X
Brooke Daugherty, Pharm. D., 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	
Conner Mulvaney, J.D.; Deputy General Counsel	X	
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	

Michelle Tahah, Pharm.D.; Clinical Pharmacist		X
Toney Welborn, M.D., MPH, MS; Medical Director	X	

OTHERS PRESENT:	
Brielle Dozier, Artia Solutions	Phil Lohec, Viatris
Matt John, Otsuka	Tina Hartmann, Arcutis
Gary Parenteau, Dexcom	Erik Schindler, Sanofi
Paul Ford, Johnson & Johnson	Matt Grewe, Leo Pharmaceuticals
Alison Davis, Galderma	John Suelzer, Leo Pharmaceuticals
Dana Mennen, Apellis	Mike Sullivan, Amgen
Janelle Raymond, Intra Bio	Craig Kupiec, Integris
Kimberly Burlison, Orchard Therapeutics	Julia Compton, Novartis
Michele Rayes, HypoPARAthyroidism Association	Patty Keating, HypoPARAthyroidism Association
Ron Abraham, Cencora	Sheleatha Taylor-Bristow
Vincent Lawler, Sanofi	Kristen Winters, Centene
Lindsey Walter	Tracey Maravilla, Ascendis Pharma
Heather Menken	Cherokee Menken
Drew Sligar, Novartis	JJ Roth, Mirum Pharma
Ronnie DePue, Axsome	Dan O'Donnell, Axsome
Patty Laster, BeiGene	Dana Bates, BeiGene
Chrystal Mayes, Sanofi	Jody White, Sanofi
Lauren Vermillion, Regeneron	David Prather, Novo Nordisk
Irene Chung, Aetna	Maya Gharfeh, Oklahoma Allergy and Asthma Society
Kathy Huynh, Southside Dermatology	

PRESENT FOR PUBLIC COMMENT:	
Maya Gharfeh, Oklahoma Allergy and Asthma Society	Kathy Huynh, Southside Dermatology
Ronnie DePue, Axsome Therapeutics	Drew Sligar, Novartis
Tracey Maravilla, Ascendis Pharma	

AGENDA ITEM NO. 1: CALL TO ORDER

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:00pm. Roll call by Dr. Wilcox established the presence of a quorum. Following the roll call, Dr. Cothran and Ms. Buettner recognized Dr. Muchmore for his years of service as DUR Board chair.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: PUBLIC COMMENT FORUM

2A: AGENDA ITEM NO. 6 DR. MAYA GHARFEH, MD, MPH
2B: AGENDA ITEM NO. 6 KATHY HUYNH, PA-C
2C: AGENDA ITEM NO. 10 RONNIE DEPUE
2D: AGENDA ITEM NO. 11 DREW SLIGAR
2E: AGENDA ITEM NO. 13 TRACEY MARAVILLA

ACTION: NONE REQUIRED

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

3A: NOVEMBER 13, 2024 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore

Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/ACADEMIC DETAILING (AD) PROGRAM UPDATE
4A: PHARMACY HELPDESK ACTIVITY FOR NOVEMBER 2024
4B: MEDICATION COVERAGE ACTIVITY FOR NOVEMBER 2024
4C: AD PROGRAM UPDATE
Materials included in agenda packet; presented by Dr. Metts, Dr. Snyder
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: SOONERCARE MAINTENANCE DRUG LIST
5A: INTRODUCTION
5B: MAINTENANCE DRUG LIST
5C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE EBGLYSS™ (LEBRIKIZUMAB) AND UPDATE THE APPROVAL CRITERIA FOR THE ATOPIC DERMATITIS MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: EBGLYSS™ (LEBRIKIZUMAB) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE OHTUVAYRE™ (ENSIFENTRINE) AND UPDATE THE APPROVAL CRITERIA FOR THE ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS
7A: MARKET NEWS AND UPDATES
7B: OHTUVAYRE™ (ENSIFENTRINE) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE NEMLUVIO® (NEMOLIZUMAB-ILTO)
8A: MARKET NEWS AND UPDATES
8B: NEMLUVIO® (NEMOLIZUMAB-ILTO) PRODUCT SUMMARY
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. Haymore
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF SKIN CANCER MEDICATIONS
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF SKIN CANCER MEDICATIONS
9C: PRIOR AUTHORIZATION OF SKIN CANCER MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: COLLEGE OF PHARMACY RECOMMENDATIONS

9F: UTILIZATION DETAILS OF SKIN CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Thomas moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: ANNUAL REVIEW OF ANTIDEPRESSANTS
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF ANTIDEPRESSANTS
10C: PRIOR AUTHORIZATION OF ANTIDEPRESSANTS
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF ANTIDEPRESSANTS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BKEMV™ (ECULIZUMAB-AEEB), EPYSQLI® (ECULIZUMAB-AAGH), FABHALTA® (IPTACOPAN), PIASKY® (CROVALIMAB-AKKZ), AND VOYDEYA™ (DANICOPAN)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
11C: PRIOR AUTHORIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 12: ANNUAL REVIEW OF LYSOSOMAL STORAGE DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AQNEURSA™ (LEVACETYLLEUCINE), LENMELDY™ (ATIDARSAGENE AUTOTEMCEL), AND MIPLYFFA™ (ARIMOCLOMOL)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF LYSOSOMAL STORAGE DISEASE MEDICATIONS
12C: PRIOR AUTHORIZATION OF LYSOSOMAL STORAGE DISEASE MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: PRODUCT SUMMARIES
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF LYSOSOMAL STORAGE DISEASE MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 13: ANNUAL REVIEW OF PARATHYROID MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE YORVIPATH® (PALOPEGTERIPARATIDE)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF PARATHYROID MEDICATIONS
13C: PRIOR AUTHORIZATION OF PARATHYROID MEDICATIONS

13D: MARKET NEWS AND UPDATES
13E: YORVIPATH® (PALOPEGTERIPARATIDE) PRODUCT SUMMARY
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF PARATHYROID MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 14: ANNUAL REVIEW OF OSTEOPOROSIS MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE JUBBONTI® (DENOSUMAB-BBDZ)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF OSTEOPOROSIS MEDICATIONS
14C: PRIOR AUTHORIZATION OF OSTEOPOROSIS MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: JUBBONTI® (DENOSUMAB-BBDZ) PRODUCT SUMMARY
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF OSTEOPOROSIS MEDICATIONS
Materials included in agenda packet; presented by Dr. Metts
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 15: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Metts
ACTION: NONE REQUIRED

AGENDA ITEM NO. 16: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
16A: ANTIHYPERLIPIDEMICS
16B: ANTIHYPERTENSIVE MEDICATIONS
16C: MISCELLANEOUS CANCER MEDICATIONS
16D: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: NOMINATION OF DUR BOARD OFFICERS
17A: NOMINATION AND APPROVAL OF DUR BOARD CHAIR AND VICE CHAIR
Dr. Haymore was nominated for DUR Board Chair by Dr. Patatanian; seconded by Dr. Muñoz
ACTION: MOTION CARRIED
Dr. Patatanian was nominated for DUR Board Vice Chair by Dr. Muñoz; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 18: ADJOURNMENT
The meeting was adjourned at 6:11pm.

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

Memorandum

Date: December 13, 2024

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 December 11, 2024

Recommendation 1: Update on Medication Coverage Authorization Unit/Academic Detailing (AD) Program Update

NO ACTION REQUIRED.

Recommendation 2: SoonerCare Maintenance Drug List

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Ebglyss™ (Lebrikizumab) and Update the Approval Criteria for the Atopic Dermatitis Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Ebglyss™ (lebrikizumab-lbkz) with the following criteria (shown in red):

Ebglyss™ (Lebrikizumab-lbkz) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and
2. Member must be 12 years of age or older and weigh ≥40kg; and
3. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following

topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
5. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) and Dupixent® (dupilumab) must be provided; and
6. Must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
7. Requests for concurrent use of Ebglyss™ with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Ebglyss™ has not been studied in combination with other biologic therapies); and
8. Initial approvals will be for a quantity limit override for the initial dosing for the duration of 16 weeks; and
9. Reauthorization may be granted for the maintenance dosing of 250mg every 4 weeks for a duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

The College of Pharmacy also recommends updating the Adbry® (tralokinumab-ldrm), Cibinqo® (abrocitinib), Dupixent® (dupilumab), and Rinvoq® (upadacitinib) approval criteria based on the recent FDA approvals and age expansion for Adbry®, as well as net costs and to be consistent with clinical practice (changes shown in red):

Adbry® (Tralokinumab-ldrm Injection) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and
2. Member must be:
   a. 12 ~~18~~ years of age or older for use of the prefilled syringe; ~~and~~ or
   b. 18 years of age or older for use of the autoinjector; and
3. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):

a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and

4. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
5. Adbry® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Requests for concurrent use of Adbry® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Adbry® has not been studied in combination with other biologic therapies); and
7. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Cibinqo® (Abrocitinib) and Rinvoq® (Upadacitinib) Approval Criteria [Atopic Dermatitis (AD) Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe AD not adequately controlled with other systemic drug products, including biologics, or when those therapies are not advisable; and
2. For Cibinqo®, member must be 12 years of age or older; and
3. For Rinvoq®, member must be 12 years of age or older; and
4. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
5. Member must have a documented 16-week trial with Adbry® (tralokinumab-ldrm), ~~or~~ Dupixent® (dupilumab), or Ebglyss™ (lebrikizumab-lbkz) that resulted in inadequate response (or have a contraindication or documented intolerance); and
6. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and

7. Requested medication must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
8. For Cibinqo®, prescriber must verify the member will not use antiplatelet therapies (e.g., clopidogrel, prasugrel, ticagrelor) concurrently with Cibinqo®, except for low-dose aspirin, during the first 3 months of treatment; and
9. Cibinqo® and Rinvoq® will not be approved for use in combination with other Janus kinas (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressant medications; and
10. For Rinvoq®, a patient-specific, clinically significant reason why the member cannot use Cibinqo® must be provided; and
11. Initial approvals will be for the duration of 3 months. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
12. For Rinvoq®, the maximum approvable dose for AD is 30mg once daily.

Dupixent® (Dupilumab Injection) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies; and
2. Member must be 6 months of age or older; and
3. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Member's body surface area (BSA) of atopic dermatitis involvement must be provided and the member must have a documented BSA involvement of ≥10% (can apply to member's current BSA or a historical value prior to treatment); and
5. A patient-specific, clinically significant reason the member cannot use Adbry® (tralokinumab-ldrm) must be provided; and
6. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
7. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require

patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
8. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Recommendation 4: Vote to Prior Authorize Ohtuvayre™ (Ensifentrine) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications

MOTION CARRIED by unanimous approval.

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

Ohtuvayre™ (Ensifentrine) Approval Criteria:
1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. Member must be 18 years of age or older; and
3. Member has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; and
4. Member is inadequately controlled on dual or triple combination long-acting bronchodilator therapy (must have ≥3 claims for long-acting bronchodilators in the previous 6 months); and
5. Member must not be taking Daliresp® (roflumilast) concurrently with Ohtuvayre™; and
6. A quantity limit of 60 ampules (150mL) per 30 days will apply.

Next, the College of Pharmacy recommends the following changes to the Dupixent® (dupilumab) criteria based on the new FDA approval, age expansion, and to be consistent with clinical practice (changes shown in red):

Dupixent® (Dupilumab injection) Approval Criteria [Chronic Obstructive Pulmonary Disease (COPD) Diagnosis]:
1. An FDA approved indication for add-on maintenance treatment of members with inadequately controlled COPD; and
2. Member must be 18 years of age or older; and
3. Member has moderate to severe disease [i.e., GOLD 2 or GOLD 3 airflow obstruction as demonstrated by forced expiratory volume in 1 second (FEV_1) ≥30% and <80% predicted] and is symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥2]; and
4. Member must have a blood eosinophil count of ≥300 cells/mcL (can apply to either a recent level or a historical level prior to treatment); and

5. Member must have experienced ≥2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or ≥1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months; and
6. Member is inadequately controlled on triple therapy combination [long-acting beta$_2$ agonist/long-acting muscarinic agonist/inhaled corticosteroid (LABA/LAMA/ICS)] used compliantly within the last 3-6 consecutive months, unless contraindicated; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
8. Dupixent® must be prescribed by a pulmonologist or pulmonary specialist or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. Quantities approved must not exceed FDA recommended dosing requirements.

Dupixent® (Dupilumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma or Oral Corticosteroid-Dependent Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with moderate-to-severe eosinophilic phenotype asthma or oral corticosteroid-dependent asthma; and
2. Member must be 6 years of age or older; and
3. Member must meet 1 of the following:
    a. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); ~~and~~ or
    b. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
4. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
7. Dupixent® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an

allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
8. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
9. Quantities approved must not exceed FDA recommended dosing requirements.

Dupixent® (Dupilumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in adult members with inadequately controlled CRSwNP; and
2. Member must be 12 ~~18~~ years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
   a. Member has required prior sino-nasal surgery; or
   b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Dupixent® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
10. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and
11. 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. Additionally, compliance will be evaluated for continued approval; and
12. A quantity limit of 2 syringes every 28 days will apply.

Dupixent® (Dupilumab injection) Approval Criteria [Eosinophilic Esophagitis (EoE) Diagnosis]:

1. An FDA approved diagnosis of eosinophilic esophagitis (EoE) defined as:
   a. The presence of clinical symptoms of EoE ~~2 or more episodes of dysphagia~~ ≥2 times per week (i.e., dysphagia, emesis, epigastric pain); and
   b. Intraepithelial eosinophilia [≥15 eosinophils per high-power field (eos/hpf) in the esophagus] ~~Member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf)~~; and
2. Member must be 1 ~~12~~ years of age or older and weigh ≥15 ~~40~~kg; and
3. Dupixent® must be prescribed by a gastroenterologist, allergist, or immunologist, or the member must have been evaluated by a gastroenterologist, allergist, or immunologist within the last 12 months (or be an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and
4. ~~Member must have 2 or more episodes of dysphagia per week; and~~
5. ~~Member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf); and~~
6. Member must have documented trials for a minimum of 8 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
   a. One high-dose proton pump inhibitor; and
   b. One swallowed respiratory corticosteroid (e.g., budesonide); and
7. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
9. A quantity limit of 8mL (4 syringes) every 28 days will apply.

Dupixent® (Dupilumab) Approval Criteria [Prurigo Nodularis (PN) Diagnosis]:

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have a Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist for PN within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and

6. Prescriber must verify that all other causes of pruritus have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); 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. Additionally, compliance will be evaluated for continued approval.

Next, the College of Pharmacy recommends the following changes to the Fasenra® (benralizumab) criteria based on the new FDA approval, age expansion, and to be consistent with the FDA approved label and clinical practice and recommends the following changes to the approval criteria for Nucala (mepolizumab) based on net costs and to be consistent with clinical practice (changes shown in red):

Fasenra® (Benralizumab injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) Diagnosis]:

1. An FDA approved indication for the treatment of EGPA; and
2. Member must be 18 years of age or older; and
3. Member meets 1 of the following:
    a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] with in the past 12 months; or
    b. Member must have refractory disease within the last 6 months following induction of standard treatment regimen administered compliantly for at least 3 months; and
4. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
5. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent equal to or greater than 7.5mg/day) for a minimum of 4 weeks duration; and
6. Fasenra® must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist for EGPA within the last 12 months (or an advanced care practitioner

with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
7. For authorization of Fasenra® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra®; and
9. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 28 days will apply.
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant, and prescriber must verify the member is responding to Fasenra® as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dose regimen from baseline.

Fasenra® (Benralizumab injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 ~~12~~ years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. For authorization of Fasenra® in a health care facility ~~prefilled syringe~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous

administration, monitoring for any allergic reactions, and storage of Fasenra®; and
9. Fasenra must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. For members who require weight-based dosing, the member's recent weight, taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate dose according to package labeling; and
11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
12. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 56 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Granulomatosis with Polyangiitis (EGPA) Diagnosis]:

1. An FDA approved diagnosis of EGPA; and
2. Member must be 18 years of age or older; and
3. Member meets 1 of the following:
    a. Member must have a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] within the past 12 months; or
    b. Member must have refractory disease within the last 6 months following induction of a standard treatment regimen administered compliantly for at least 3 months; and
4. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
5. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥7.5mg/day) for a minimum of 4 weeks duration; and
6. Nucala must be prescribed by an allergist, pulmonologist, pulmonary specialist, or rheumatologist or the member must have been evaluated by an allergist, pulmonologist, pulmonary specialist, or rheumatologist for EGPA within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
7. For authorization of Nucala in a health care facility ~~vial~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous

administration, monitoring for any allergic reactions, and storage of Nucala; and

9. A patient-specific, clinically significant reason why the member cannot use Fasenra® (benralizumab injection) must be provided; and
10. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by a Birmingham Vasculitis Activity Score (BVAS) of 0 (zero), fewer EGPA relapses from baseline, or a decrease in daily OCS dosing from baseline.

Nucala (Mepolizumab Injection) Approval Criteria [Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment in adult members with inadequately controlled CRSwNP; and
2. Member must be 18 years of age or older; and
3. Member must have a documented trial with an intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance); and
4. Member must meet 1 of the following:
   a. Member has required prior sino-nasal surgery; or
   b. Member has previously been treated with systemic corticosteroids in the past 2 years (or has a contraindication or documented intolerance); and
5. Nucala must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
6. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
7. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
8. Member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
9. For authorization of Nucala in a health care facility ~~vial~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
10. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous

administration, monitoring for any allergic reactions, and storage of Nucala; and

11. Requests for concurrent use of Nucala with other biologic medications will be reviewed on a case-by-case basis and will require patient specific information to support the concurrent use; and
12. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
13. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. For authorization of Nucala in a health care facility ~~vial~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and

10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

Nucala (Mepolizumab Injection) Approval Criteria [Hypereosinophilic Syndrome (HES) Diagnosis]:

1. An FDA approved diagnosis of HES for ≥6 months without an identifiable non-hematologic secondary cause; and
2. Member must be 12 years of age or older; and
3. Member must have a past history of at least 2 confirmed HES flares [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of cytotoxic or immunosuppressive therapy, or hospitalization] within the past 12 months; and
4. Member must have a baseline blood eosinophil count of ≥1,000 cells/mcL in the last 4 weeks prior to initiating Nucala; and
5. Diagnosis of FIP1L1-PDGFRα kinase-positive HES will not be approved; and
6. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥10mg/day) for a minimum of 4 weeks duration or member is unable to tolerate corticosteroid therapy due to significant side effects from corticosteroid therapy; and
7. Nucala must be prescribed by a hematologist or a specialist with expertise in treatment of HES (or an advanced care practitioner with a supervising physician who is a hematologist or a specialist with expertise in treatment of HES); and
8. For authorization of Nucala in a health care facility ~~vial~~, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
9. For authorization of Nucala prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
10. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
11. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval. For continued approval, member must be compliant and prescriber must verify the member is responding to Nucala as demonstrated by fewer HES flares from baseline or a decrease in daily OCS dosing from baseline.

Additionally, the College of Pharmacy recommends the following changes to the Xolair® (omalizumab) criteria based on the new FDA approval and to be consistent with clinical practice and recommends the following changes to

the Tezspire® (tezepelumab-ekko) approval criteria to be consistent with clinical practice (changes shown in red):

Xolair® (Omalizumab) Approval Criteria [Immunoglobulin E (IgE)-Mediated Food Allergy Diagnosis]:

1. An FDA approved diagnosis of IgE-mediated food allergy for the reduction of allergic reactions; and
2. Member must be 1 year of age or older; and
3. Member must have a diagnosis of peanut, milk, egg, wheat, cashew, hazelnut, or walnut allergy confirmed by a positive skin test, positive in vitro test for food-specific IgE, or positive clinician-supervised oral food challenge (documentation of allergy testing results must be submitted); and
4. Prescriber must confirm member will use Xolair® with an allergen-avoidant diet; and
5. Member must have a pretreatment serum IgE level between 30 and 1,850 IU/mL; and
6. Member's weight must be between 10kg and 150kg; and
7. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
9. For authorization of Xolair® in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
10. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
11. Xolair® must be prescribed by an allergist or immunologist or the member must have been evaluated by an allergist or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
12. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to therapy. Additionally, compliance will be evaluated for continued approval.

Xolair® (Omalizumab Injection) Approval Criteria [Asthma Diagnosis]:

1. Diagnosis of severe persistent asthma [as per National Asthma Education and Prevention Program (NAEPP) guidelines]; and
2. Member must be between 6 and 75 years of age; and
3. Member must have a positive skin test to at least 1 perennial aeroallergen (positive perennial aeroallergens must be listed on the prior authorization request); and
4. Member must have a pretreatment serum IgE level between 30 and 1,300 IU/mL (depending on member age); and
5. Member's weight must be between 20kg and 150kg; and
6. Member must have failed a medium-to-high-dose ICS used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
7. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
8. For authorization of Xolair® ~~vial~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or ~~and~~
9. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
10. Xolair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
11. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past 12 months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and
12. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval.

Xolair® (Omalizumab Injection) Approval Criteria [Chronic Idiopathic Urticaria (CIU) Diagnosis]:

1. An FDA approved diagnosis of CIU; and
2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and

4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. For authorization of Xolair® ~~vial~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or ~~and~~
7. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
8. Prescriber must be an allergist, immunologist, or dermatologist (or an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist); and
9. A trial of a second-generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
10. Initial dosing will only be approved for 150mg every 4 weeks. If the member has inadequate results at this dose, then the dose may be increased to 300mg every 4 weeks; and
11. Initial approvals will be for the duration of 3 months at which time compliance will be evaluated for continued approval.

Xolair® (Omalizumab Injection) Approval Criteria [Nasal Polyps Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of nasal polyps in adult members with inadequate response to nasal corticosteroids; and
2. Member must be 18 years of age or older; and
3. Member must have a trial of intranasal corticosteroids for at minimum the past 4 weeks; and
4. Prescriber must verify member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
5. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
6. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and
7. Member must have a pretreatment serum IgE level between 30 and 1,500 IU/mL; and
8. Member's weight must be between 31kg and 150kg; and
9. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and

10. For authorization of Xolair® ~~vial~~ in a health care facility, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or ~~and~~
11. For authorization of Xolair® prefilled autoinjector or prefilled syringe for self-administration, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
12. Xolair® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
13. 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. Additionally, compliance will be evaluated for continued approval.

Tezspire® (Tezepelumab-ekko) Approval Criteria:

1. An FDA approved diagnosis of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or that resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. For authorization of Tezspire® in a health care facility ~~vial or pre-filled syringe~~, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; or ~~and~~
7. For authorization of Tezspire® pre-filled pen for self-administration, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire®; and

8. Tezspire® must be prescribed by a pulmonologist or pulmonary specialist, or the member must have been evaluated by a pulmonologist or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

Finally, the College of Pharmacy recommends the following changes to the Asthma and COPD Maintenance Medications Product Based Prior Authorization (PBPA) category (changes noted in red in the following PBPA Tier charts and criteria):

1. Creation of Tier-1 approval criteria based on the member's age; and
2. Removing the prior authorization of Wixela Inhub® (fluticasone/ salmeterol inhalation powder) based on net costs; and
3. Moving Alvesco® (ciclesonide) and fluticasone propionate (generic Flovent®) from Tier-1 to Tier-2 based on net costs; and
4. Moving QVAR® RediHaler® (beclomethasone dipropionate) from Tier-2 to Tier-1 based on net costs; and
5. Removal of ArmonAir® Digihaler® (fluticasone propionate) and AirDuo® Digihaler® (fluticasone propionate/salmeterol) due to product discontinuations; and
6. The prior authorization of formoterol fumarate nebulizer solution kit and placement into Tier-2 of the long-acting beta$_2$ agonists (LABA) and long-acting muscarinic antagonists (LAMA) category.

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
beclomethasone dipropionate (QVAR® RediHaler®)	~~**beclomethasone dipropionate (QVAR® RediHaler®)**~~
budesonide (Pulmicort Flexhaler®)	budesonide/formoterol (Symbicort Aerosphere®)
budesonide/formoterol (Symbicort®)β – **Brand Preferred**	**ciclesonide (Alvesco®)**
~~**ciclesonide (Alvesco®)**~~	**fluticasone propionate (Flovent®)**
fluticasone furoate (Arnuity® Ellipta®)	fluticasone furoate/vilanterol (Breo® Ellipta®) – **Brand Preferred**
~~**fluticasone propionate (Flovent®)**~~	~~**fluticasone propionate (ArmonAir® Digihaler®)**~~
fluticasone propionate/salmeterol (Advair®)α	~~**fluticasone propionate/salmeterol (AirDuo® Digihaler®)**~~
mometasone furoate (Asmanex®)	fluticasone propionate/salmeterol (AirDuo RespiClick®)
mometasone furoate/formoterol (Dulera®)◊	mometasone furoate/formoterol 50mcg/5mcg (Dulera®)

~~Tier-1 products indicated for the member's age are covered with no prior authorization required.~~

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria apply to each Tier-2 product.
β Does not include Breyna®; authorization of Breyna® requires a reason why the member cannot use the brand formulation (Symbicort®).
~~α Does not include Wixela Inhub®; authorization of Wixela Inhub® requires a reason why the member cannot use the brand formulation (Advair®) or other generic formulations of fluticasone propionate/salmeterol.~~
◊ Includes all strengths other than Dulera® 50mcg/5mcg.

Inhaled Corticosteroids (ICS) and Combination Products Tier-1 Approval Criteria:

1. Tier-1 products indicated for the member's age are covered with no prior authorization required; or
2. Tier-1 products will be approved for members younger than the FDA approved age range if prescribed by a pulmonologist, immunologist, or an allergist (or a mid-level practitioner supervised by a pulmonologist, immunologist, or an allergist).

~~AirDuo® Digihaler® (Fluticasone Propionate/Salmeterol Inhalation Powder) Approval Criteria:~~

~~1. An FDA approved diagnosis of asthma; and~~
~~2. Member must be 12 years of age or older; and~~
~~3. A patient-specific, clinically significant reason why the member requires AirDuo® Digihaler® over AirDuo RespiClick® and all preferred Tier-1 inhaled corticosteroid (ICS) and long-acting beta$_2$-agonist (ICS/LABA) products (Advair®, Dulera®, and Symbicort®) must be provided; and~~
~~4. Failure of Advair®, Dulera®, and Symbicort® or a reason why Advair®, Dulera®, and Symbicort® are not appropriate for the member must be provided; and~~
~~5. Member must have used an ICS for at least 1 month immediately prior; and~~
~~6. Member must be considered uncontrolled by provider [required rescue medication >2 days a week (not for prevention of exercise induced bronchospasms) and/or needed oral systemic corticosteroids]; or~~
~~7. A clinical situation warranting initiation with combination therapy due to severity of asthma; and~~
~~8. Prescriber agrees to closely monitor member adherence; and~~
~~9. Member should be capable and willing to use the Companion Mobile App and to follow the Instructions for Use, and member must ensure the Digihaler® Companion Mobile App is compatible with their specific smartphone; and~~
~~10. Member's phone camera must be functional and able to scan the inhaler QR code and register the AirDuo® Digihaler® inhaler; and~~
~~11. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and member compliance >80% with prescribed maintenance therapy must be provided. In addition, a patient-specific, clinically significant~~

~~reason why the member cannot transition to Tier-1 medications must be provided. Tier structure rules continue to apply.~~

~~ArmonAir® Digihaler® (Fluticasone Propionate Inhalation Powder) Approval Criteria:~~

~~1. An FDA approved diagnosis of asthma; and~~
~~2. Member must be 12 years of age or older; and~~
~~3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) and other preferred monotherapy inhaled corticosteroids (ICS) are not appropriate for the member must be provided; and~~
~~4. The prescriber agrees to closely monitor member adherence; and~~
~~5. The member should be capable and willing to use the Companion Mobile App and to follow the Instructions for Use, and member must ensure the Digihaler® Companion Mobile App is compatible with their specific smartphone; and~~
~~6. The member's phone camera must be functional and able to scan the inhaler QR code and register the ArmonAir® Digihaler® inhaler; and~~
~~7. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and member compliance >80% with prescribed maintenance therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier-1 medications must be provided. Tier structure rules continue to apply.~~

Alvesco® (Ciclesonide) and Fluticasone Propionate (Generic Flovent®) ~~QVAR® RediHaler® (Beclomethasone Dipropionate)~~ Approval Criteria:

1. An FDA approved diagnosis of asthma; and
~~2. Member must be at the age indicated for the requested product:~~
~~a. QVAR® RediHaler®: Member must be 4 years of age or older; and~~
3. A trial of all available Tier-1 inhaled corticosteroids appropriate to the members' age or a patient-specific, clinically significant reason why they are not appropriate for the member must be provided.

~~Wixela Inhub® (Fluticasone/Salmeterol Inhalation Powder) Approval Criteria:~~

~~1. A patient-specific, clinically significant reason why the member cannot use the brand formulation (Advair® Diskus®), or other generic formulations (fluticasone/salmeterol) must be provided (brand formulation and other generics are preferred and do not require prior authorization).~~

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
Long-Acting Beta$_2$ Agonists* (LABA)	
salmeterol inhalation powder (Serevent®)	arformoterol nebulizer solution (Brovana®)

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
	formoterol nebulizer solution (Perforomist®)
	formoterol nebulizer solution kit
	olodaterol inhalation spray (Striverdi® Respimat®)
Long-Acting Muscarinic Antagonists (LAMA)	
aclidinium inhalation powder (Tudorza® PressAir®)	revefenacin inhalation solution (Yupelri®)
tiotropium inhalation powder (Spiriva® HandiHaler®) **– Brand Preferred**	
tiotropium soft mist inhaler (Spiriva® Respimat®)	
umeclidinium inhalation powder (Incruse® Ellipta®)	

*Tier-1 combination products that contain a long-acting beta$_2$ agonist (LABA) qualify for the LABA trial requirement.
Tier-1 medications do not require prior authorization.
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).

Recommendation 5: Vote to Prior Authorize Nemluvio® (Nemolizumab-ilto)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Nemluvio® (nemolizumab-ilto) with the following criteria (shown in red):

Nemluvio® (Nemolizumab-ilto) Approval Criteria [Prurigo Nodularis (PN) Diagnosis]:

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have severe pruritus as defined by a Peak Pruritus Numeric Rating Scale (PP-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist for PN within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Prescriber must verify that all other causes of pruritus have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):

a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and

8. A patient-specific, clinically significant reason why the member cannot use Dupixent® (dupilumab) must be provided; and
9. Requests for concurrent use of Nemluvio® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Nemluvio® has not been studied in combination with other biologic therapies); and
10. The member's recent weight must be provided, and approval quantities will be based on the FDA approved dosing regimen; and
11. Initial approvals will be for the duration of 16 weeks. Reauthorization (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Recommendation 6: Annual Review of Skin Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Keytruda® (pembrolizumab) and Opdivo® (nivolumab) based on recent FDA approvals (new criteria and changes shown in red):

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

1. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo (nivolumab)]; and
2. Disease progression following prior systemic therapy; and
   a. Member is not a candidate for curative surgery or radiation; and
   b. Used in 1 of the following settings:
      i. In combination with lenvatinib for advanced endometrial cancer that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); or
      ii. As a single agent for advanced endometrial cancer that is MSI-H or dMMR; or
3. Primary advanced (newly diagnosed stage III/IVA or stage IVB) or recurrent endometrial cancer; and
   a. Used in combination with carboplatin and paclitaxel followed by single-agent maintenance pembrolizumab.

Keytruda® (Pembrolizumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic malignant pleural mesothelioma; and
2. Used as first-line therapy in adult members; and
3. Used in combination with pemetrexed and platinum chemotherapy.

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

1. Diagnosis of NSCLC; and
2. For first-line therapy for recurrent, advanced, or metastatic disease, meeting the following:
    a. Used in combination with Yervoy® (ipilimumab) and 2 cycles of platinum-doublet chemotherapy; and
    b. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
    c. Expresses programmed death ligand 1 (PD-L1) ≥1%; or
3. For first-line therapy for resectable disease (>4cm or node positive), meeting the following:
    a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy for up to 3 treatment cycles; or
4. For resectable disease (tumors ≥4cm or node positive), meeting the following:
    a. Used in the neoadjuvant setting in combination with platinum-doublet chemotherapy, followed by single-agent nivolumab as adjuvant treatment after surgery; and
    b. No known EGFR mutations or ALK rearrangements; or
5. For second-line therapy for metastatic disease, meeting the following:
    a. Tumor histology is 1 of the following:
        i. Adenocarcinoma; or
        ii. Squamous cell; or
        iii. Large cell; and
    b. Disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin); and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
    d. Used as a single agent; and
    e. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Urothelial Bladder Cancer Diagnosis]:

1. Diagnosis of urothelial carcinoma; and
    a. Member has undergone radical resection; and
    b. Disease is at high risk of recurrence; or
2. Diagnosis of metastatic or unresectable locally advanced disease; and
    a. Used as second-line or greater therapy; and
    b. Previous failure of a platinum-containing regimen; and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; or
3. Diagnosis of metastatic or unresectable urothelial carcinoma; and
    a. Used as first-line therapy; and
    b. In combination with cisplatin and gemcitabine.

Lastly, the College of Pharmacy recommends updating the Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Opdivo® (nivolumab), Yervoy® (ipilimumab), and Zelboraf® (vemurafenib) approval criteria based on National Comprehensive Cancer Network (NCCN) recommendations (changes and new criteria shown in red):

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.

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

1. Diagnosis of recurrent or metastatic cervical cancer; and
    a. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and
    b. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
        i. Disease progression on or after chemotherapy; or
        ii. As first-line therapy in combination with chemotherapy, with or without bevacizumab; or
        iii. As second line or subsequent therapy as a single agent; or
2. Diagnosis of FIGO Stage III-IV cervical cancer; and
    a. Used in combination with concomitant chemotherapy and radiation.

Keytruda® (Pembrolizumab) Approval Criteria [Classical Hodgkin Lymphoma (cHL) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. For adult members:
    a. Diagnosis of relapsed or refractory cHL; and
        i. Used as a single agent; or
        ii. Exception: lymphocyte-predominant Hodgkin lymphoma; or
        iii. Used in Second-line or subsequent systemic therapy in combination with gemcitabine, vinorelbine, and liposomal doxorubicin (GVD) or ifosfamide, carboplatin, and etoposide (ICE); or
3. For pediatric members:
    a. Used as a single agent; and
    b. Diagnosis of refractory cHL; or

c. Relapsed disease after ≥2 therapies; or
d. Decrease in cardiac function is observed.

Keytruda® (Pembrolizumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Member must have 1 of the following:
   a. As a single agent for locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
   b. As a single agent within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
   c. As a single agent frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy or any platinum-containing chemotherapy; and
      i. Cisplatin ineligibility is defined as:
         1. Baseline creatinine clearance of <60mL/min; or
         2. ECOG performance status of 2; or
         3. Class III heart failure; or
         4. Grade 2 or greater peripheral neuropathy; or
         5. Grade 2 or greater hearing loss; or
   d. In combination with enfortumab vedotin-ejfv for locally advanced or metastatic urothelial carcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cervical, Vaginal, or Vulvar Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic cervical, vaginal, or vulvar cancer; and
2. Used as second-line or subsequent therapy; and
3. Used as a single agent; and
4. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab), Yervoy® (ipilimumab)].

Opdivo® (Nivolumab) Approval Criteria [Hodgkin Lymphoma Diagnosis]:

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma; and
   a. Exception: lymphocyte-predominant HL
2. Nivolumab must be used in 1 of the following settings:
   a. As a single-agent; or
   b. In combination with doxorubicin, vinblastine, and dacarbazine (AVD) for primary systemic therapy in stage III-IV disease; or
   c. In combination with brentuximab vedotin as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and

3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

Opdivo® (Nivolumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Must meet 1 of the following criteria:
   a. Disease relapsed within 6 months of initial chemotherapy; or
   b. Disease is progressive on initial chemotherapy; and
2. Used as a single agent ~~or in combination with ipilimumab~~; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

~~**Yervoy® (Ipilimumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:**~~

~~1. Diagnosis of SCLC; and~~
~~2. Must meet 1 of the following criteria:~~
~~a. Disease relapsed within 6 months of initial chemotherapy; or~~
~~b. Disease is progressive on initial chemotherapy; and~~
~~3. Used in combination with nivolumab.~~

Zelboraf® (Vemurafenib) Approval Criteria [Hairy-Cell Leukemia Diagnosis]:

1. Diagnosis of hairy-cell leukemia; and
   a. Used as a single agent; and
      i. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine); or
   b. Used in combination with rituximab or obinutuzumab for patients who are not candidates for purine analogs.

Recommendation 7: Annual Review of Antidepressants

MOTION CARRIED by unanimous approval.

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

1. Moving Aplenzin® (bupropion ER) from Special PA Tier to Tier-1 based on net costs; and
2. Removal of the general Special PA approval criteria and updating with specific criteria for each product for clarity.

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps
escitalopram tabs & soln (Lexapro®)			fluoxetine tabs

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
fluoxetine caps & soln (Prozac®)			fluoxetine DR (Prozac® Weekly™)
fluvoxamine (Luvox®)			fluvoxamine CR (Luvox CR®)
paroxetine (Paxil®)			paroxetine CR (Paxil CR®)
sertraline tabs & soln (Zoloft®)			sertraline 150mg & 200mg caps
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	~~**bupropion ER (Aplenzin®)**~~
bupropion ER (Aplenzin®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
duloxetine (Cymbalta®)		nefazodone (Serzone®)	duloxetine (Drizalma Sprinkle™)
mirtazapine (Remeron®, Remeron SolTab®)		vilazodone (Viibryd®)	duloxetine 40mg (Irenka™)
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)			trazodone 300mg tabs (Desyrel®)
venlafaxine tabs & ER caps (Effexor®, Effexor XR®)			venlafaxine besylate ER 112.5mg tablets
venlafaxine 75mg & 150mg ER tabs (Effexor XR®)			venlafaxine ER 225mg tabs (Effexor XR®)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/ bupropion (Auvelity®)
			esketamine nasal spray (Spravato®)
			gepirone (Exxua™)
			zuranolone (Zurzuvae™)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria applies.
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets

~~**Antidepressants Special Prior Authorization (PA) Approval Criteria:**~~

~~1. Use of any Special PA medication will require a patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 medications; or~~
~~2. A petition may be submitted for consideration whenever a unique patient-specific situation exists; and~~
~~3. Tier structure rules still apply.~~

Forfivo XL® [Bupropion Extended-Release (ER)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products, including using 3 bupropion 150mg XL tablets to achieve the 450mg dose, must be provided.

Luvox CR® (Fluvoxamine CR) and Paxil CR® (Paroxetine CR) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Tier-1 immediate-release products that are available without prior authorization must be provided.

Venlafaxine Extended-Release (ER) 225mg Tablet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products, including using 3 venlafaxine ER 75mg capsules or tablets to achieve the 225mg dose, must be provided.

Recommendation 8: Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), Fabhalta® (Iptacopan), Piasky® (Crovalimab-akkz), and Voydeya™ (Danicopan)

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

Recommendation 9: Annual Review of Lysosomal Storage Disease Medications and 30-Day Notice to Prior Authorize Aqneursa™ (Levacetylleucine), Lenmeldy™ (Atidarsagene Autotemcel), and Miplyffa™ (Arimoclomol)

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

Recommendation 10: Annual Review of Parathyroid Medications and 30-Day Notice to Prior Authorize Yorvipath® (Palopegteriparatide)

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

Recommendation 11: Annual Review of Osteoporosis Medications and 30-Day Notice to Prior Authorize Jubbonti® (Denosumab-bbdz)

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

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

NO ACTION REQUIRED.

Recommendation 13: Future Business

NO ACTION REQUIRED.

Recommendation 14: Nomination of DUR Board Officers

MOTION(S) CARRIED by unanimous approval.

- Dr. Haymore nominated and confirmed as chair.
- Dr. Patatanian nominated and confirmed as vice chair.

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

Memorandum

Date: January 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 Packet Meeting on January 8, 2025

Recommendation 1: Prenatal Vitamin (PNV) Utilization Update

NO ACTION REQUIRED.

Recommendation 2: Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Tryngolza™ (Olezarsen)

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

Recommendation 3: Annual Review of Adrenocorticotropic Hormone (ACTH) Products and 30-Day Notice to Prior Authorize Acthar® SelfJect™ (Corticotropin Auto-Injector) and Purified Cortrophin® Gel (Repository Corticotropin Injection)

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

Recommendation 4: Annual Review of Xgeva® (Denosumab) and 30-Day Notice to Prior Authorize Wyost® (Denosumab-bbdz)

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

Recommendation 5: Annual Review of Systemic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and 30-Day Notice to Prior Authorize Diflunisal 500mg Tablet, Dolobid™ (Diflunisal) 250mg and 375mg Tablet, and Indomethacin 50mg Suppository

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

Recommendation 6: Annual Review of Ophthalmic Antibiotic Medications

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

Recommendation 7: Annual Review of Gastrointestinal (GI) Cancer Medications and 30-Day Notice to Prior Authorize Tevimbra® (Tislelizumab-jsgr), Vyloy® (Zolbetuximab-clzb), and Ziihera® (Zanidatamab)

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

Recommendation 8: Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Fyarro® (Sirolimus Protein-Bound Particles for Injectable Suspension), Niktimvo™ (Axatilimab-csfr), Ojemda™ (Tovorafenib), Tecelra® (Afamitresgene Autoleucel), and Voranigo® (Vorasidenib)

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

Recommendation 9: Annual Review of Non-Malignant Solid Tumor Medications

NO ACTION REQUIRED

Recommendation 10: Annual Review of Antihypertensive Medications and 30-Day Notice to Prior Authorize Labetalol Hydrochloride 400mg Tablet, Nexiclon™ XR [Clonidine Extended-Release (ER)], and Tryvio™ (Aprocitentan)

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

Recommendation 11: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

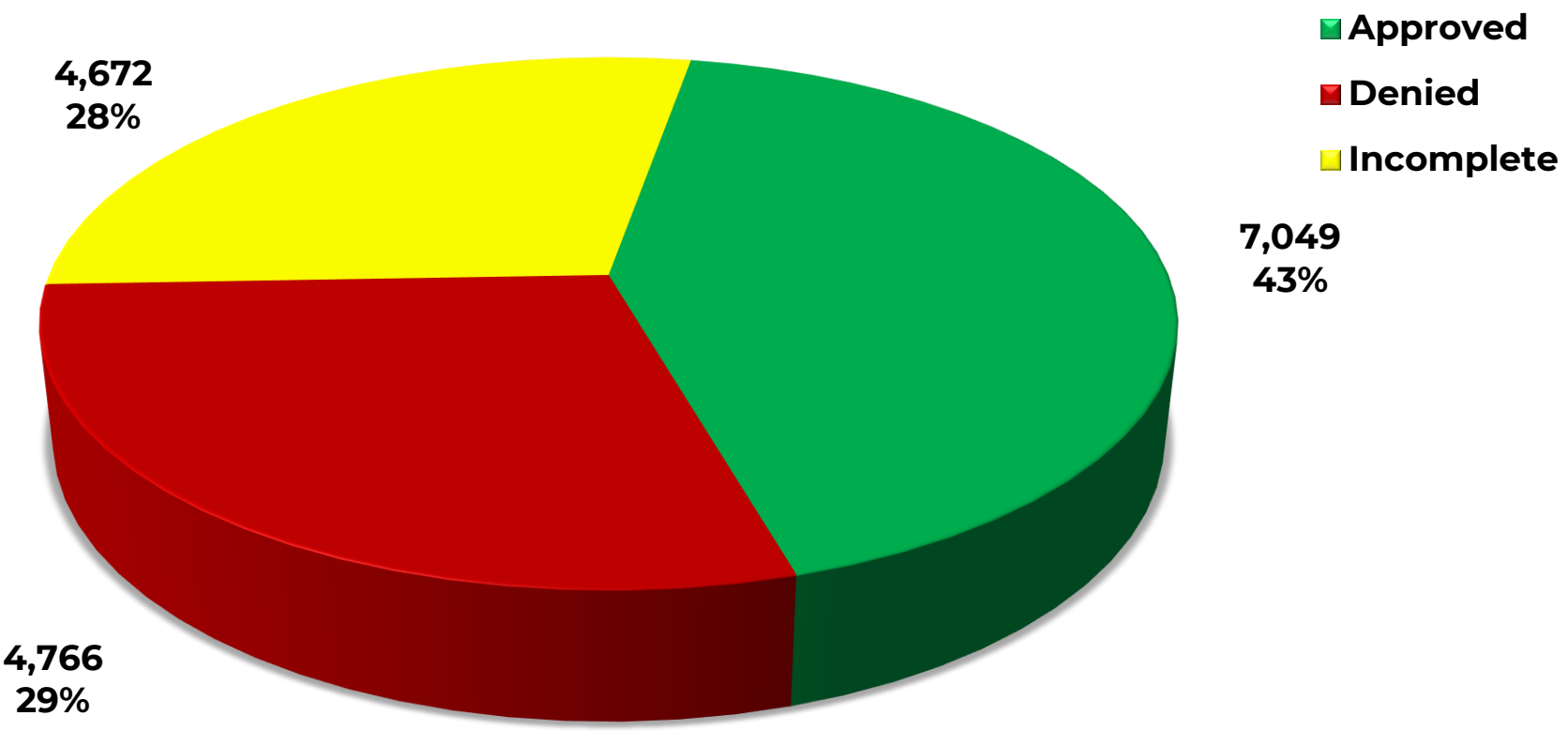
NO ACTION REQUIRED.

Recommendation 12: Future Business

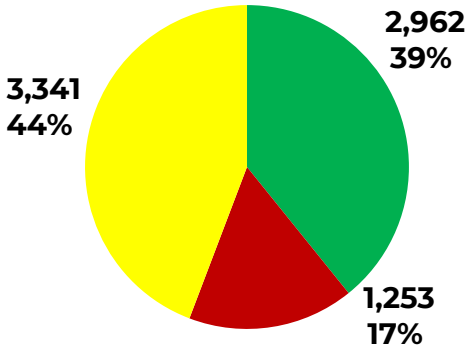
NO ACTION REQUIRED.

Appendix B

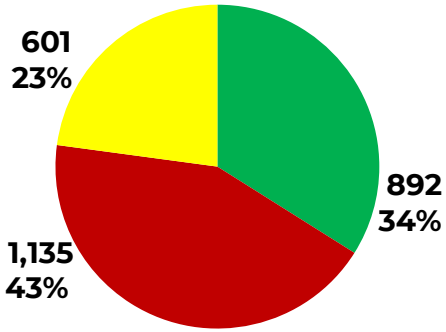
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: DECEMBER 2024



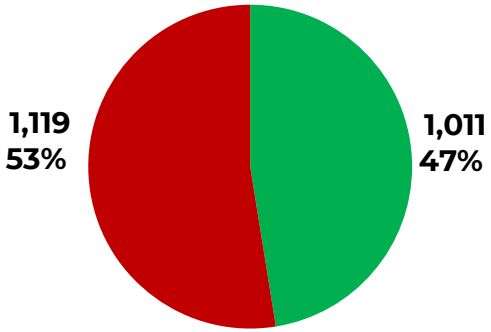
SoonerCare FFS



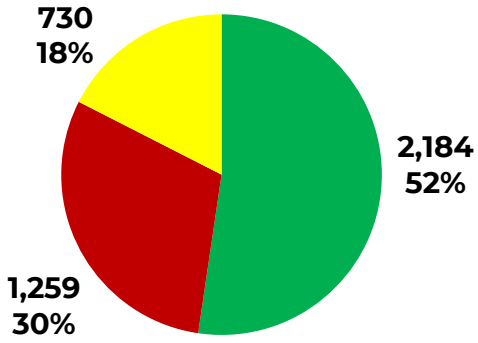
SoonerSelect Aetna



SoonerSelect Humana

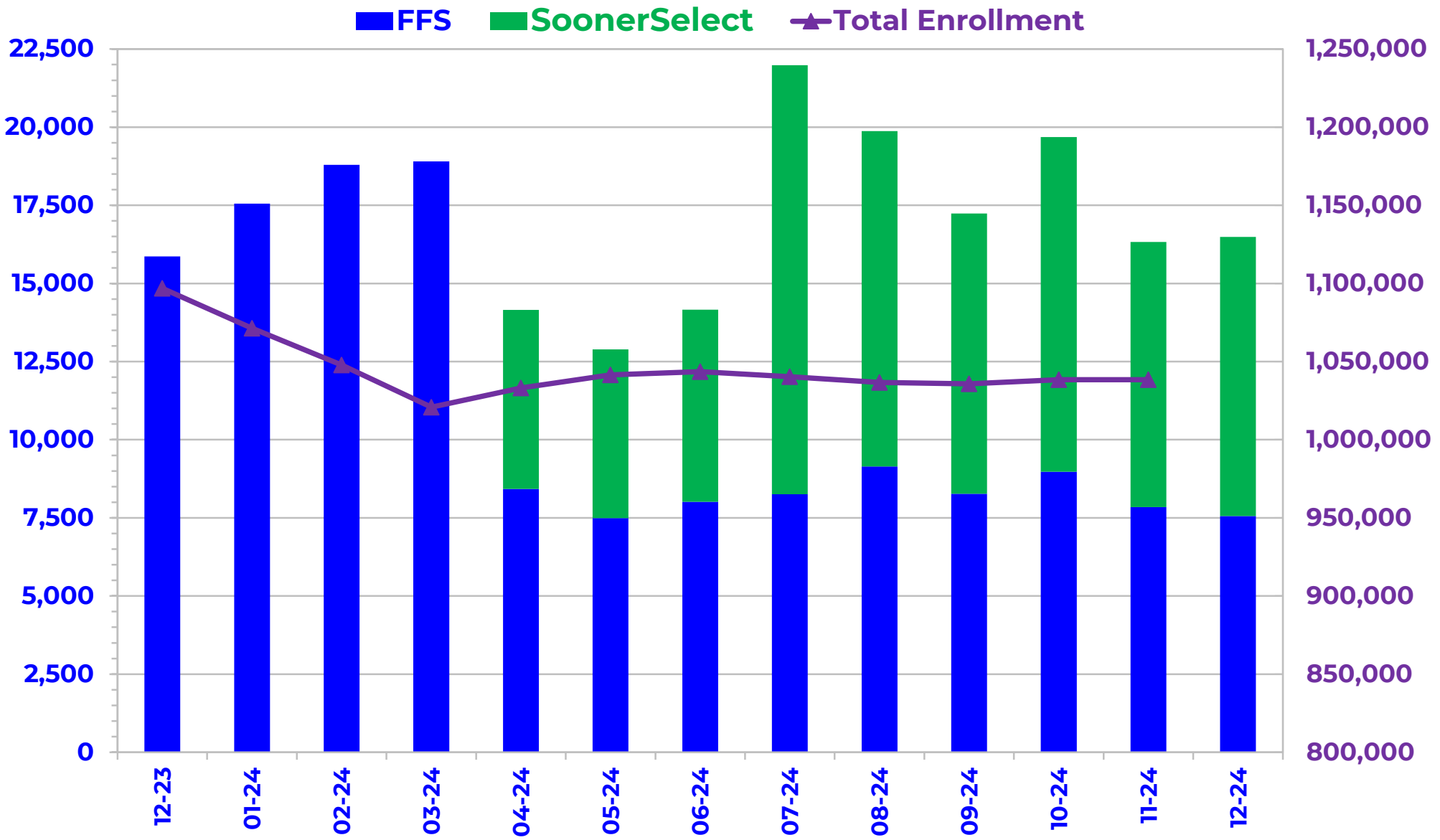


SoonerSelect OK Complete Health



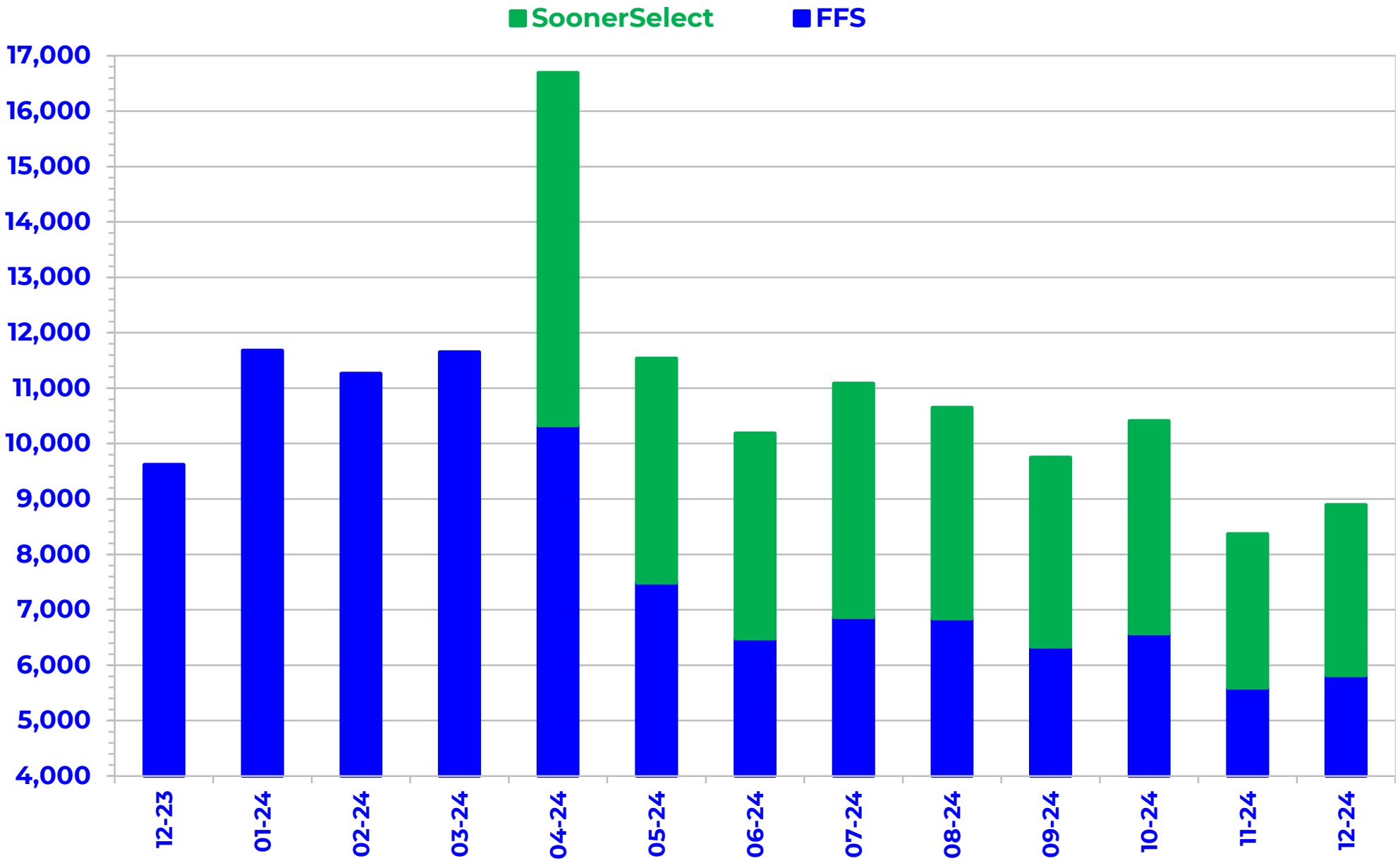
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: DECEMBER 2023 – DECEMBER 2024



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: DECEMBER 2023 – DECEMBER 2024



SoonerCare FFS Prior Authorization Activity

12/1/2024 Through 12/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals - Misc.	3	1	1	1	360
Amebicides	1	1	0	0	24
Amphetamines	557	356	7	194	354
Analgesics - Anti-Inflammatory	206	89	34	83	316
Analgesics - Nonnarcotic	10	0	2	8	0
Analgesics - Opioid	316	132	23	161	129
Androgens - Anabolic	58	18	12	28	313
Anorectal and Related Products	3	0	3	0	0
Anthelmintics	19	9	1	9	14
Anti-Infective Agents - Misc.	26	7	3	16	179
Anti-Obesity Agents	91	12	59	20	53
Antianginal Agents	2	1	0	1	360
Antianxiety Agents	14	1	3	10	1
Antiasthmatic and Bronchodilator Agents	401	84	80	237	318
Antibiotics	38	15	5	18	264
Anticoagulants	7	1	2	4	57
Anticonvulsants	208	104	17	87	320
Antidepressants	184	39	37	108	258
Antidiabetics	1,162	317	252	593	355
Antidiarrheal/Probiotic Agents	1	0	0	1	0
Antidotes and Specific Antagonists	2	1	0	1	360
Antiemetics	17	4	2	11	159
Antifungals	1	0	0	1	0
Antihistamines	15	2	6	7	352
Antihyperlipidemics	55	16	11	28	201
Antihypertensives	11	6	1	4	359
Antimalarials	2	2	0	0	357
Antimyasthenic/Cholinergic Agents	2	0	0	2	0
Antineoplastics and Adjunctive Therapies	185	124	3	58	181
Antiparkinson and Related Therapy Agents	4	0	2	2	0
Antipsychotics/Antimanic Agents	290	106	37	147	338
Antivirals	26	7	10	9	33
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	228	136	17	75	357
Beta Blockers	7	2	0	5	356
Calcium Channel Blockers	15	6	2	7	359
Cardiovascular Agents - Misc.	64	29	9	26	338
Chemicals	3	1	2	0	360
Contraceptives	44	18	6	20	328
Corticosteroids	14	2	4	8	54

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Cough/Cold/Allergy	1	0	1	0	0
Dermatologicals	362	101	98	163	233
Diagnostic Products	34	15	1	18	111
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	7	6	0	1	359
Diuretics	11	6	1	4	300
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	0	1	0
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	137	61	17	59	228
Estrogens	9	5	1	3	248
Gastrointestinal Agents - Misc.	249	55	61	133	238
Genitourinary Agents - Misc.	4	1	1	2	360
Gout Agents	4	1	0	3	358
Hematological Agents - Misc.	17	13	0	4	356
Hematopoietic Agents	47	16	12	19	135
Hypnotics/Sedatives/Sleep Disorder Agents	53	6	10	37	240
Laxatives	15	4	2	9	239
Medical Devices and Supplies	166	33	43	90	223
Migraine Products	284	57	113	114	247
Minerals and Electrolytes	7	2	0	5	183
Miscellaneous Therapeutic Classes	53	25	5	23	284
Multivitamins	6	4	0	2	360
Musculoskeletal Therapy Agents	30	7	8	15	225
Nasal Agents - Systemic and Topical	18	4	3	11	353
Neuromuscular Agents	98	44	39	15	331
Ophthalmic Agents	41	11	5	25	208
Other*	30	8	1	21	235
Otic Agents	19	0	5	14	0
Passive Immunizing and Treatment Agents	6	0	0	6	0
Pharmaceutical Adjuvants	1	1	0	0	85
Progestins	4	0	1	3	0
Psychotherapeutic and Neurological Agents - Misc.	226	73	50	103	216
Respiratory Agents - Misc.	15	9	0	6	301
Stimulants - Misc.	241	103	25	113	305
Thyroid Agents	5	3	1	1	360
Ulcer Drugs/Antispasmodics/Anticholinergics	55	15	10	30	310
Urinary Antispasmodics	72	17	16	39	327
Vaginal and Related Products	7	1	2	4	91
Vitamins	34	7	19	8	214
Total	**6,662**	**2,363**	**1,204**	**3,095**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	10	7	0	3	285
Compound	11	5	1	5	17
Diabetic Supplies	2	2	0	0	88
Dosage Change	146	137	0	9	13
High Dose	2	1	0	1	360
Lost/Broken Rx	39	37	0	2	18
MAT Override	8	4	2	2	82
NDC vs Age	138	78	21	39	260
NDC vs Sex	12	9	1	2	298
Nursing Home Issue	39	37	0	2	14
Opioid MME Limit	48	19	2	27	132
Opioid Quantity	26	15	1	10	160
Other	36	28	6	2	20
Quantity vs Days Supply	324	195	12	117	289
STBS/STBSM	9	3	2	4	31
Step Therapy Exception	4	3	1	0	152
Stolen	3	2	0	1	9
Temporary Unlock	1	1	0	0	2
Third Brand Request	36	16	0	20	37
Overrides Total	**894**	**599**	**49**	**246**	
Total Regular PAs + Overrides	**7,556**	**2,962**	**1,253**	**3,341**	

Denial Reasons	
Unable to verify required trials.	2,879
Does not meet established criteria.	1,288
Lack required information to process request.	489
Other PA Activity	
Duplicate Requests	787
Letters	31,124
No Process	2
Helpdesk Initiated Prior Authorizations	342
PAs Missing Information	464
Pharmacotherapy	93
Changes to Existing PAs	559

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

SoonerSelect Aetna Prior Authorization Activity

12/1/2024 Through 12/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	1	1	0	0	182
Amphetamines	231	164	29	38	364
Analgesics - Anti-Inflammatory	84	48	16	20	336
Analgesics - Nonnarcotic	3	0	3	0	0
Analgesics - Opioid	132	61	50	21	135
Androgens - Anabolic	34	7	27	0	365
Anorexiants Non-Amphetamine	1	0	0	1	0
Anthelmintics	12	7	5	0	30
Antianxiety Agents	21	8	1	12	365
Antiasthmatic and Bronchodilator Agents	160	22	80	58	269
Antibiotics	11	3	4	4	304
Anticoagulants	4	3	0	1	182
Anticonvulsants	39	12	16	11	314
Antidepressants	149	33	51	65	307
Antidiabetics	423	135	230	58	336
Antidotes and Specific Antagonists	1	1	0	0	365
Antiemetics	3	0	0	3	0
Antifungals	4	1	2	1	84
Antihistamines	11	3	8	0	365
Antihyperlipidemics	20	2	9	9	365
Antihypertensives	26	2	2	22	365
Anti-Infective Agents - Misc.	20	10	7	3	111
Antineoplastics And Adjunctive Therapies	23	8	0	15	234
Anti-Obesity Agents	54	2	49	3	292
Antiparkinson and Related Therapy Agents	7	0	2	5	0
Antipsychotics/Antimanic Agents	139	42	65	32	365
Antivirals	4	1	2	1	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	58	33	20	5	354
Beta Blockers	19	0	1	18	0
Calcium Channel Blockers	16	3	3	10	365
Cardiovascular Agents - Misc.	22	8	13	1	365
Contraceptives	18	3	11	4	365
Corticosteroids	4	0	2	2	0
Dermatologicals	196	68	100	28	207
Diagnostic Products	50	29	8	13	365
Digestive Aids	1	0	0	1	0
Diuretics	10	0	0	10	0
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	1	0	0	365
Endocrine and Metabolic Agents - Misc.	19	12	4	3	219
Estrogens	6	4	1	1	319
Gastrointestinal Agents - Misc.	71	23	44	4	233
Gout Agents	4	0	2	2	0
Hematological Agents - Misc.	3	2	0	1	227
Hematopoietic Agents	11	6	4	1	314
Hypnotics/Sedatives/Sleep Disorder Agents	17	2	8	7	228
Laxatives	10	2	7	1	197
Medical Devices and Supplies	56	18	25	13	365
Migraine Products	128	28	90	10	175
Minerals and Electrolytes	2	0	0	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
Miscellaneous Therapeutic Classes	6	2	3	1	365
Multivitamins	4	4	0	0	365
Musculoskeletal Therapy Agents	42	1	15	26	90
Nasal Agents - Systemic and Topical	11	0	4	7	0
Neuromuscular Agents	5	0	2	3	0
Ophthalmic Agents	17	0	9	8	0
*Other	10	3	4	3	365
Otic Agents	14	2	12	0	30
Passive Immunizing and Treatment Agents	1	1	0	0	365
Progestins	1	1	0	0	365
Psychotherapeutic and Neurological Agents - Misc.	30	8	19	3	166
Respiratory Agents - Misc.	1	1	0	0	182
Stimulants - Misc.	67	43	20	4	354
Thyroid Agents	5	1	1	3	365
Ulcer Drugs/Antispasmodics/Anticholinergics	35	4	10	21	277
Urinary Antispasmodics	13	2	9	2	273
Vitamins	27	1	26	0	84
****Total**	**2,628**	**892**	**1,135**	**601**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Other	602	1	0	601	365
Quantity Level Limit	26	26	0	0	262
Step Therapy Met	3	3	0	0	142
Overrides Total	**631**	**30**	**0**	**601**	

Denial Reason	
Benefit	86
Experimental/Investigational	140
Lack Required Infomation to Process Request	70
Medical Necessity	839
Other PA Activity	
Duplicate Requests	7
Letters	3,234
No Process	201
Changes to existing PAs	0
Helpdesk initiated PA	1
PAs missing info	6

*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

12/1/2024 Through 12/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	2	0	2	0	0
Amphetamines	2	1	1	0	365
Analgesics - Anti-Inflammatory	44	30	14	0	365
Analgesics - Nonnarcotic	1	0	1	0	0
Analgesics - Opioid	73	33	40	0	264
Androgens - Anabolic	50	8	42	0	272
Anthelmintics	3	2	1	0	365
Antiasthmatic and Bronchodilator Agents	123	30	93	0	202
Antibiotics	2	0	2	0	0
Anticonvulsants	11	6	5	0	319
Antidepressants	33	14	19	0	316
Antidiabetics	175	77	98	0	278
Antiemetics	1	1	0	0	365
Antihyperlipidemics	8	4	4	0	166
Anti-Infective Agents - Misc.	6	5	1	0	328
Antineoplastics and Adjunctive Therapies	27	22	5	0	268
Anti-Obesity Agents	43	2	41	0	243
Antivirals	3	0	3	0	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	9	4	5	0	284
Calcium Channel Blockers	1	0	1	0	0
Cardiovascular Agents - Misc.	9	6	3	0	353
Contraceptives	9	5	4	0	267
Dermatologicals	85	44	41	0	265
Diagnostic Products	9	8	1	0	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	0	2	0	0
Endocrine and Metabolic Agents - Misc.	24	13	11	0	339
Estrogens	1	1	0	0	365
Gastrointestinal Agents - Misc.	67	31	36	0	165
Gout Agents	1	0	1	0	0
Hematological Agents - Misc.	1	1	0	0	90
Hematopoietic Agents	10	6	4	0	227
Histamine H3-Receptor Antagonist/Inverse Agonists	1	1	0	0	365
Hypnotics/Sedatives/Sleep Disorder Agents	10	1	9	0	84
Laxatives	2	0	2	0	0
Migraine Products	77	35	42	0	175
Miscellaneous Therapeutic Classes	6	5	1	0	304
Multivitamins	1	1	0	0	365
Musculoskeletal Therapy Agents	20	6	14	0	324
Nasal Agents - Systemic and Topical	6	0	6	0	0
Neuromuscular Agents	13	9	4	0	274
Ophthalmic Agents	22	6	16	0	456
*Other	10	7	3	0	231
Passive Immunizing and Treatment Agents	2	1	1	0	183
Psychotherapeutic and Neurological Agents - Misc.	25	13	12	0	209
Respiratory Agents - Misc.	2	1	1	0	365
Stimulants - Misc.	10	6	4	0	365
Thyroid Agents	6	4	2	0	365
Ulcer Drugs/Antispasmodics/Anticholinergics	6	0	6	0	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
Urinary Antispasmodics	22	5	17	0	150
Vitamins	41	4	37	0	145
Total	**1,117**	**459**	**658**	**0**	

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Ingredient Duplication	95	55	40	0	302
MAT Override	8	7	1	0	456
NDC vs Age	323	227	96	0	265
Opioid MME Limit	4	2	2	0	184
Opioid Quantity	4	3	1	0	456
Quantity vs Days Supply	178	127	51	0	279
STBS/STBSM	84	15	69	0	66
Step Therapy Exception	241	96	145	0	158
Other	76	20	56	0	103
Overrides Total	**1,013**	**552**	**461**	**0**	
Total Regular PAs + Overrides	**2,130**	**1,011**	**1,119**	**0**	

Denial Reasons	
Benefit	385
Medical Necessity	734

*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

12/1/2024 Through 12/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	142	103	12	27	128
Analgesics - Anti-Inflammatory	87	49	26	12	365
Analgesics - Nonnarcotic	9	2	5	2	6
Analgesics - Opioid	260	81	140	39	172
Androgens - Anabolic	66	8	44	14	355
Anorectal and Related Products	3	0	3	0	0
Anorexiants Non-Amphetamine	2	0	2	0	0
Antacids	1	1	0	0	365
Anthelmintics	11	6	3	2	365
Antianginal Agents	5	3	0	2	10
Antianxiety Agents	82	55	12	15	75
Antiasthmatic and Bronchodilator Agents	239	97	101	41	135
Antibiotics	14	3	8	3	365
Anticoagulants	4	3	1	0	132
Anticonvulsants	280	211	15	54	92
Antidepressants	345	222	63	60	142
Antidiabetics	701	381	209	111	195
Antiemetics	8	7	0	1	25
Antifungals	6	0	3	3	0
Antihistamines	12	2	7	3	365
Antihyperlipidemics	39	26	8	5	88
Antihypertensives	82	59	4	19	47
Anti-Infective Agents - Misc.	11	3	5	3	368
Antineoplastics and Adjunctive Therapies	11	9	1	1	323
Anti-Obesity Agents	48	3	40	5	142
Antiparkinson and Related Therapy Agents	8	5	3	0	21
Antipsychotics/Antimanic Agents	209	125	46	38	161
Antivirals	8	2	4	2	56
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	49	23	20	6	261
Beta Blockers	63	46	1	16	32
Calcium Channel Blockers	31	24	2	5	115
Cardiovascular Agents - Misc.	31	17	12	2	330
Contraceptives	13	4	6	3	191
Corticosteroids	13	4	6	3	133
Cough/Cold/Allergy	1	0	0	1	0
Dermatologicals	204	74	101	29	258
Diagnostic Products	23	11	9	3	322
Dietary Products/Dietary Management Products	2	1	1	0	19
Digestive Aids	2	2	0	0	364
Diuretics	28	21	0	7	20
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	32	15	12	5	265
Estrogens	4	1	3	0	21
Gastrointestinal Agents - Misc.	59	23	31	5	197
Genitourinary Agents - Misc.	9	8	1	0	131
Gout Agents	1	0	1	0	0
Hematological Agents - Misc.	6	5	0	1	165
Hematopoietic Agents	10	4	3	3	365

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

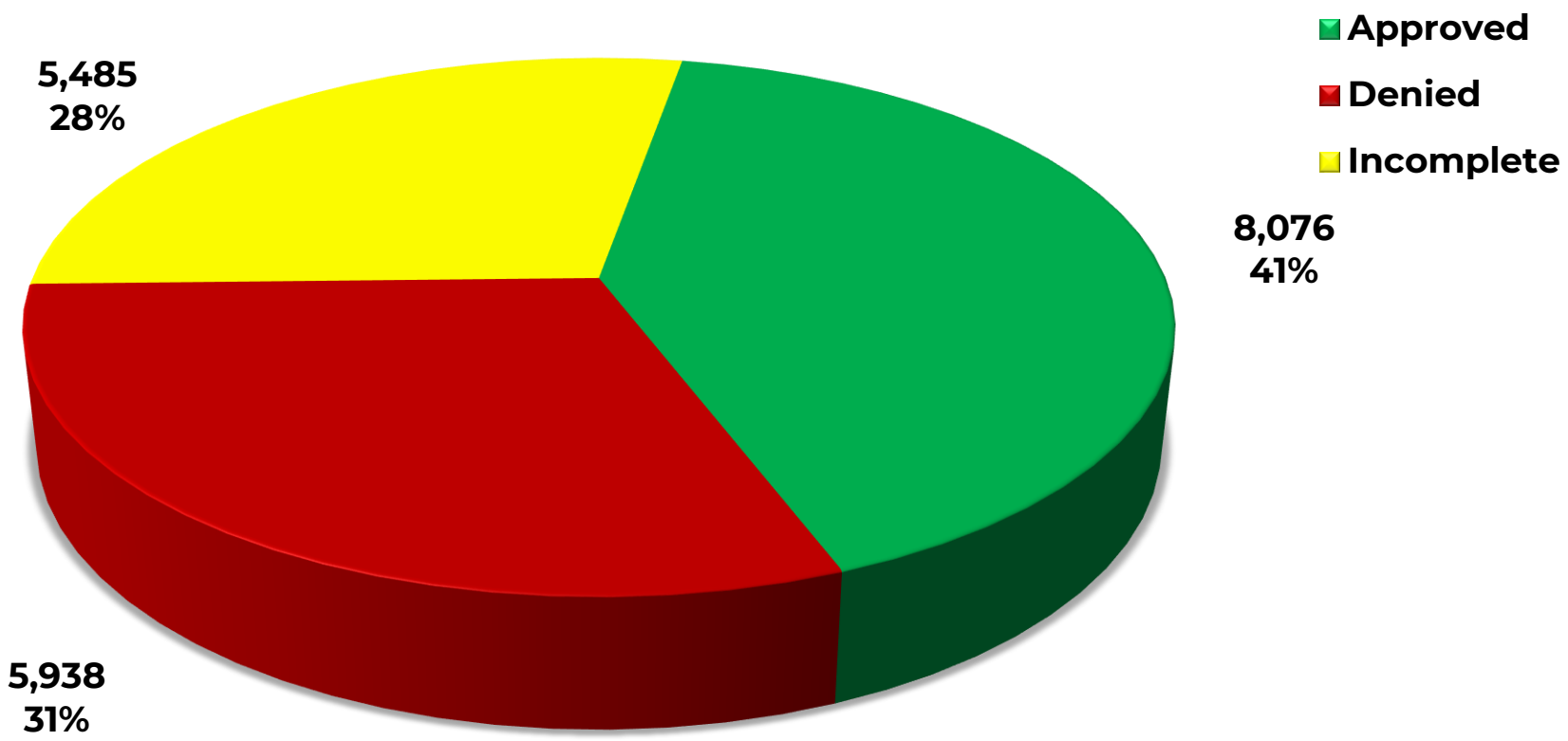
	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	31	11	15	5	245
Laxatives	8	0	4	4	0
Medical Devices and Supplies	96	54	32	10	325
Migraine Products	135	46	68	21	338
Minerals and Electrolytes	1	0	1	0	0
Miscellaneous Therapeutic Classes	6	1	4	1	365
Multivitamins	7	5	2	0	297
Musculoskeletal Therapy Agents	17	2	11	4	365
Nasal Agents - Systemic and Topical	6	1	3	2	369
Neuromuscular Agents	7	1	3	3	365
Nutrients	1	1	0	0	365
Ophthalmic Agents	41	10	13	18	211
*Other	55	11	15	29	234
Otic Agents	49	20	21	8	218
Psychotherapeutic and Neurological Agents - Misc.	42	12	25	5	249
Respiratory Agents - Misc.	13	5	3	5	291
Stimulants - Misc.	210	150	30	30	260
Thyroid Agents	43	27	3	13	58
Ulcer Drugs/Antispasmodics/Anticholinergics	93	64	17	12	69
Urinary Antispasmodics	37	14	14	9	146
****Total**	**4,173**	**2,184**	**1,259**	**730**	

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

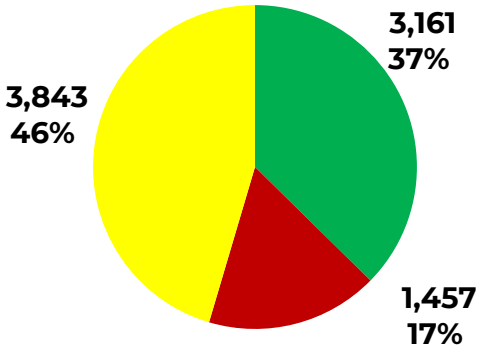
Denial Reasons	
Benefit	69
Medical Necessity	1,190

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

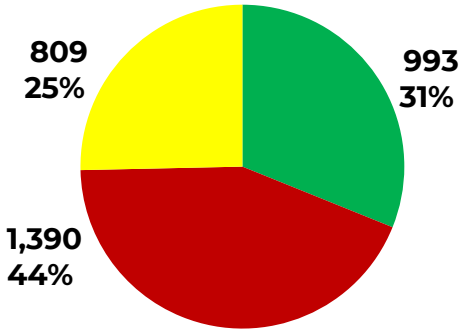
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JANUARY 2025



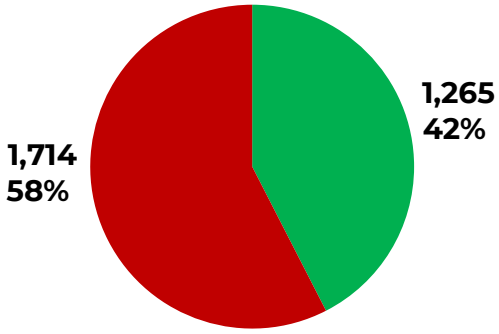
SoonerCare FFS



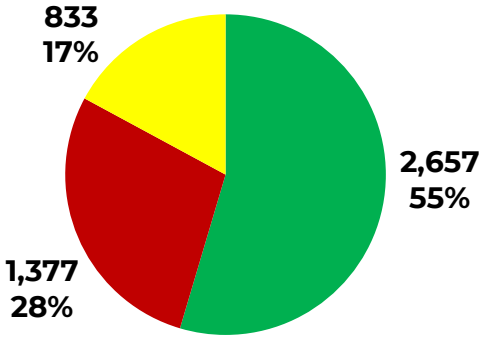
SoonerSelect Aetna



SoonerSelect Humana

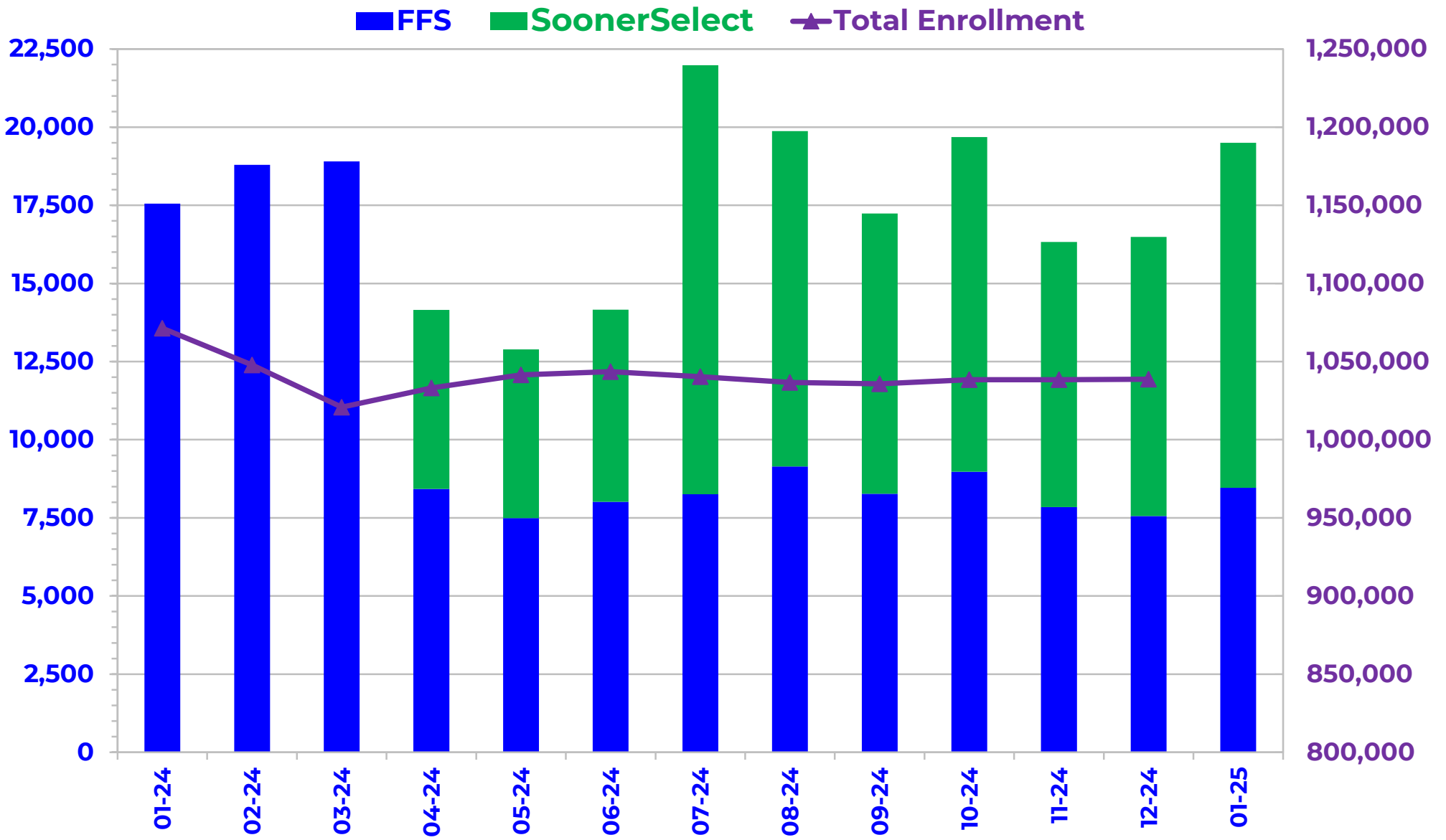


SoonerSelect OK Complete Health



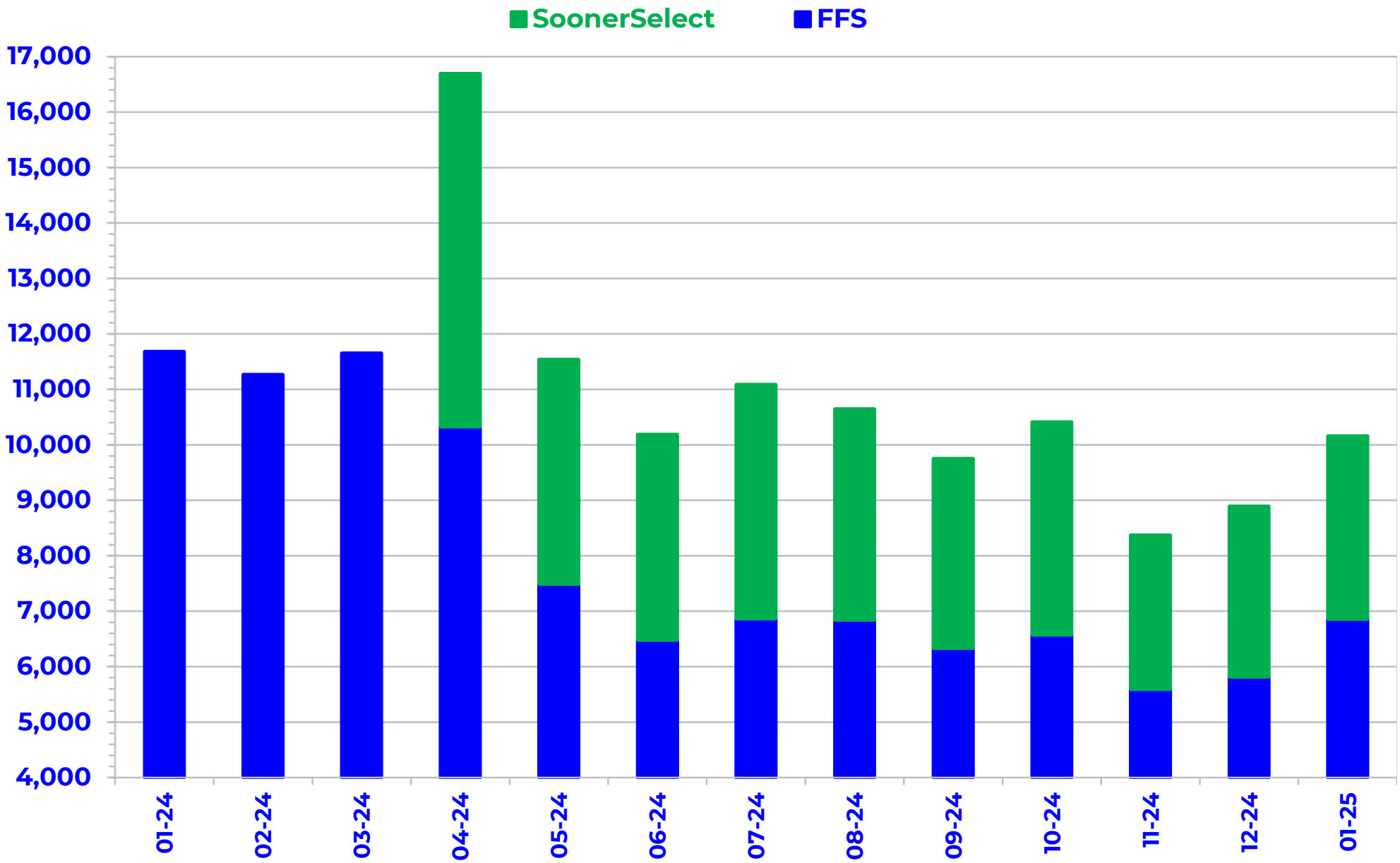
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JANUARY 2024 – JANUARY 2025



**Humana call volume includes calls through the Pharmacy Help Desk. Member services calls regarding pharmacy benefit are not included.*

SoonerCare FFS Prior Authorization Activity

1/1/2025 Through 1/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	650	422	12	216	356
Analgesics - Anti-Inflammatory	173	63	25	85	312
Analgesics - Nonnarcotic	6	1	2	3	174
Analgesics - Opioid	325	121	25	179	137
Androgens - Anabolic	66	18	18	30	333
Anorectal and Related Products	2	0	1	1	0
Anorexiants Non-Amphetamine	3	0	3	0	0
Anthelmintics	5	2	1	2	21
Anti-Infective Agents - Misc.	31	11	5	15	257
Anti-Obesity Agents	86	6	67	13	80
Antianginal Agents	2	2	0	0	359
Antianxiety Agents	14	3	1	10	240
Antiasthmatic and Bronchodilator Agents	462	97	104	261	331
Antibiotics	25	9	5	11	250
Anticoagulants	13	1	3	9	359
Anticonvulsants	202	81	15	106	324
Antidepressants	209	41	40	128	279
Antidiabetics	1,278	339	303	636	351
Antidiarrheal/Probiotic Agents	2	0	2	0	0
Antidotes and Specific Antagonists	6	0	1	5	0
Antiemetics	18	2	3	13	10
Antifungals	6	2	1	3	45
Antihistamines	21	6	5	10	358
Antihyperlipidemics	45	7	15	23	227
Antihypertensives	12	1	0	11	329
Antimalarials	6	2	0	4	130
Antimyasthenic/Cholinergic Agents	2	0	1	1	0
Antineoplastics and Adjunctive Therapies	201	135	13	53	169
Antiparkinson and Related Therapy Agents	4	1	3	0	358
Antipsychotics/Antimanic Agents	329	99	37	193	362
Antivirals	17	7	3	7	34
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	208	127	16	65	351
Beta Blockers	15	6	0	9	329
Calcium Channel Blockers	12	4	2	6	359
Cardiovascular Agents - Misc.	108	55	12	41	331
Chemicals	2	0	0	2	0
Contraceptives	36	21	4	11	356
Corticosteroids	22	4	2	16	271
Cough/Cold/Allergy	3	1	1	1	360
Dermatologicals	496	129	140	227	232
Diagnostic Products	56	26	4	26	163
Dietary Products/Dietary Management Products	4	1	2	1	360
Digestive Aids	12	10	0	2	314
Diuretics	16	9	2	5	322
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	4	2	0	2	359
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	164	71	33	60	214
Estrogens	11	4	2	5	272

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents - Misc.	289	74	75	140	259
Genitourinary Agents - Misc.	6	3	1	2	248
Gout Agents	9	2	2	5	249
Hematological Agents - Misc.	19	14	0	5	337
Hematopoietic Agents	46	18	6	22	104
Hypnotics/Sedatives/Sleep Disorder Agents	55	11	10	34	216
Laxatives	21	6	1	14	268
Medical Devices and Supplies	289	47	68	174	259
Migraine Products	346	57	124	165	282
Minerals and Electrolytes	5	1	1	3	360
Miscellaneous Therapeutic Classes	47	17	6	24	348
Multivitamins	6	4	0	2	314
Musculoskeletal Therapy Agents	44	8	10	26	276
Nasal Agents - Systemic and Topical	9	1	2	6	360
Neuromuscular Agents	68	30	23	15	337
Nutrients	1	0	0	1	0
Ophthalmic Agents	53	13	12	28	315
Other*	54	19	3	32	188
Otic Agents	32	0	4	28	0
Passive Immunizing and Treatment Agents	2	0	1	1	0
Pharmaceutical Adjuvants	1	1	0	0	360
Progestins	7	3	0	4	360
Psychotherapeutic and Neurological Agents - Misc.	251	82	48	121	227
Respiratory Agents - Misc.	30	16	3	11	320
Stimulants - Misc.	261	86	26	149	322
Thyroid Agents	8	3	1	4	279
Ulcer Drugs/Antispasmodics/Anticholinergics	47	10	7	30	207
Urinary Antispasmodics	33	3	6	24	361
Vaccines	2	1	1	0	360
Vaginal and Related Products	1	0	1	0	0
Vasopressors	2	0	1	1	0
Vitamins	37	0	28	9	0
Total	**7,471**	**2,479**	**1,405**	**3,587**	

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	15	4	0	11	298
Compound	15	13	0	2	13
Dosage Change	171	162	0	9	15
High Dose	1	1	0	0	360
Ingredient Duplication	2	1	0	1	20
Lost/Broken Rx	43	39	4	0	19
MAT Override	17	11	1	5	79
NDC vs Age	160	108	21	31	267
NDC vs Sex	15	12	1	2	329
Nursing Home Issue	64	46	1	17	15
Opioid MME Limit	49	14	4	31	132
Opioid Quantity	21	12	1	8	173
Other	31	25	2	4	17

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Quantity vs Days Supply	316	195	13	108	275
STBS/STBSM	20	10	1	9	46
Step Therapy Exception	10	5	1	4	256
Stolen	6	4	2	0	23
Third Brand Request	34	20	0	14	17
Overrides Total	**990**	**682**	**52**	**256**	
Total Regular PAs + Overrides	**8,461**	**3,161**	**1,457**	**3,843**	

Denial Reasons	
Unable to verify required trials.	3,358
Does not meet established criteria.	1,491
Lack required information to process request.	553
Other PA Activity	
Duplicate Requests	638
Letters	34,888
No Process	4
Helpdesk Initiated Prior Authorizations	392
PAs Missing Information	346
Pharmacotherapy	83
Changes to Existing PAs	527

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

SoonerSelect Aetna Prior Authorization Activity

1/1/2025 Through 1/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	4	1	3	0	180
Amphetamines	222	161	19	42	358
Analgesics - Anti-Inflammatory	96	47	25	21	330
Analgesics - Nonnarcotic	9	0	7	2	0
Analgesics - Opioid	158	75	54	29	168
Androgens - Anabolic	64	16	43	4	365
Anthelmintics	9	3	4	2	24
Antianginal Agents	1	0	0	1	0
Antianxiety Agents	36	11	11	14	344
Antiasthmatic and Bronchodilator Agents	136	19	77	38	326
Antibiotics	23	1	3	19	31
Anticoagulants	8	0	3	5	0
Anticonvulsants	66	17	20	28	322
Antidepressants	204	49	62	90	332
Antidiabetics	516	121	287	100	314
Antiemetics	6	0	3	3	0
Antifungals	1	1	0	0	181
Antihistamines	15	4	10	1	365
Antihyperlipidemics	36	2	13	21	273
Antihypertensives	26	4	3	19	365
Anti-Infective Agents - Misc.	12	4	4	4	116
Antineoplastics and Adjunctive Therapies	28	9	1	18	288
Anti-Obesity Agents	88	4	79	4	112
Antiparkinson and Related Therapy Agents	4	0	1	3	0
Antipsychotics/Antimanic Agents	146	50	61	33	365
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	96	71	21	4	358
Beta Blockers	24	1	0	23	365
Calcium Channel Blockers	16	0	5	11	0
Cardiovascular Agents - Misc.	24	7	14	2	325
Contraceptives	10	1	7	2	365
Corticosteroids	5	0	1	4	0
Dermatologicals	306	90	153	60	200
Diagnostic Products	50	23	15	12	359
Digestive Aids	4	4	0	0	365
Diuretics	12	0	0	12	0
Endocrine and Metabolic Agents - Misc.	21	12	8	1	162
Estrogens	5	2	3	0	275
Gastrointestinal Agents - Misc.	81	31	43	6	269
Genitourinary Agents - Misc.	1	0	1	0	0
Gout Agents	3	1	0	2	365
Hematological Agents - Misc.	9	6	2	1	333
Hematopoietic Agents	5	2	2	1	273
Hypnotics/Sedatives/Sleep Disorder Agents	38	4	18	16	226
Laxatives	9	1	6	2	30
Medical Devices and Supplies	79	25	40	14	328
Migraine Products	143	30	100	13	202
Minerals and Electrolytes	10	0	0	10	0
Miscellaneous Therapeutic Classes	5	2	0	3	365

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Multivitamins	4	2	1	1	365
Musculoskeletal Therapy Agents	44	0	13	31	0
Nasal Agents - Systemic and Topical	16	0	10	6	0
Neuromuscular Agents	6	2	0	4	197
Ophthalmic Agents	11	3	7	1	242
*Other	23	3	13	7	303
Otic Agents	22	4	17	1	28
Psychotherapeutic and Neurological Agents - Misc.	23	11	7	5	201
Respiratory Agents - Misc.	2	2	0	0	273
Stimulants - Misc.	69	36	22	11	355
Thyroid Agents	6	1	1	4	181
Ulcer Drugs/Antispasmodics/Anticholinergics	61	7	18	36	365
Urinary Antispasmodics	16	4	11	1	365
Vaccines	1	1	0	0	181
Vaginal and Related Products	1	0	1	0	0
Vitamins	43	5	37	1	336
****Total**	**3,218**	**993**	**1,390**	**809**	

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	1	1	0	0	90
Other	816	5	0	809	365
Quantity Level Limit	18	18	0	0	275
Overrides Total	**835**	**24**	**0**	**809**	

Denial Reason	
Benefit	130
Experimental/Investigational	137
Lack Required Infomation to Process Request	100
Medical Necessity	1,023
Other PA Activity	
Duplicate Requests	14
Letters	3,858
No Process	276
Changes to existing PAs	0
Helpdesk initiated PA	1
PAs missing info	9

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

SoonerSelect Humana Prior Authorization Activity

1/1/2025 Through 1/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amphetamines	1	1	0	0	365
Analgesics - Anti-Inflammatory	49	38	11	0	357
Analgesics - Nonnarcotic	5	2	3	0	243
Analgesics - Opioid	90	43	47	0	248
Androgens - Anabolic	60	25	35	0	278
Anthelmintics	1	1	0	0	365
Antiasthmatic and Bronchodilator Agents	120	30	90	0	174
Antibiotics	5	0	5	0	0
Anticonvulsants	7	3	4	0	402
Antidepressants	53	27	26	0	279
Antidiabetics	203	74	129	0	242
Antiemetics	2	0	2	0	0
Antifungals	1	0	1	0	0
Antihistamines	1	0	1	0	0
Antihyperlipidemics	18	8	10	0	140
Anti-Infective Agents - Misc.	6	3	3	0	243
Antineoplastics and Adjunctive Therapies	35	31	4	0	230
Anti-Obesity Agents	68	7	61	0	148
Antipsychotics/Antimanic Agents	1	0	1	0	0
Antivirals	7	2	5	0	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	9	4	5	0	243
Cardiovascular Agents - Misc.	31	17	14	0	431
Chemicals	1	0	1	0	0
Contraceptives	16	8	8	0	282
Corticosteroids	4	2	2	0	119
Dermatologicals	116	68	48	0	202
Diagnostic Products	59	56	3	0	334
Digestive Aids	2	1	1	0	183
Diuretics	2	0	2	0	0
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	3	0	3	0	0
Endocrine and Metabolic Agents - Misc.	19	13	6	0	347
Estrogens	2	1	1	0	183
Gastrointestinal Agents - Misc.	54	26	28	0	212
Gout Agents	3	0	3	0	0
Hematological Agents - Misc.	3	3	0	0	365
Hematopoietic Agents	15	8	7	0	277
Hypnotics/Sedatives/Sleep Disorder Agents	13	1	12	0	365
Laxatives	4	1	3	0	122
Migraine Products	111	65	46	0	228
Minerals and Electrolytes	3	1	2	0	182
Miscellaneous Therapeutic Classes	7	2	5	0	469
Multivitamins	2	2	0	0	365
Musculoskeletal Therapy Agents	26	16	10	0	333
Nasal Agents - Systemic and Topical	6	1	5	0	61
Neuromuscular Agents	19	11	8	0	175
Ophthalmic Agents	26	15	11	0	293
*Other	13	8	5	0	350
Otic Agents	1	0	1	0	0
Psychotherapeutic and Neurological Agents - Misc.	23	13	10	0	239

*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
Respiratory Agents - Misc.	3	2	1	0	212
Stimulants - Misc.	9	7	2	0	365
Thyroid Agents	5	1	4	0	183
Ulcer Drugs/Antispasmodics/Anticholinergics	13	1	12	0	365
Urinary Antispasmodics	10	0	10	0	0
Vaginal and Related Products	1	0	1	0	0
Vitamins	49	4	45	0	42
Total	**1,417**	**653**	**764**	**0**	

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Ingredient Duplication	115	54	61	0	174
NDC vs. Age	344	229	115	0	240
Opioid Quantity	21	19	2	0	326
Other	154	65	89	0	161
Quantity vs. Days Supply	180	113	67	0	231
STBS/STBSM	426	15	411	0	16
Step Therapy Exception	322	117	205	0	144
Overrides Total	**1,562**	**612**	**950**	**0**	
Total Regular PAs + Overrides	**2,979**	**1,265**	**1,714**	**0**	

Denial Reasons	
Benefit	803
Medical Necessity	911

*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

1/1/2025 Through 1/31/2025

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Alternative Medicines	1	0	1	0	0
Amphetamines	245	170	34	41	275
Analgesics - Anti-Inflammatory	76	39	27	10	364
Analgesics - Nonnarcotic	8	0	7	1	0
Analgesics - Opioid	294	109	142	43	257
Androgens - Anabolic	52	8	41	3	354
Anorectal and Related Products	2	0	2	0	0
Anthelmintics	5	1	4	0	365
Antianginal Agents	4	3	0	1	351
Antianxiety Agents	93	64	11	18	347
Antiasthmatic and Bronchodilator Agents	219	118	76	25	352
Antibiotics	11	6	2	3	361
Anticonvulsants	391	297	33	61	350
Antidepressants	460	290	69	101	347
Antidiabetics	708	415	198	95	387
Antiemetics	8	4	1	3	353
Antifungals	2	0	2	0	0
Antihistamines	18	10	8	0	364
Antihyperlipidemics	47	26	15	6	319
Antihypertensives	118	81	0	37	348
Anti-Infective Agents - Misc.	10	3	3	4	248
Antineoplastics and Adjunctive Therapies	10	6	3	1	241
Anti-Obesity Agents	63	1	58	4	28
Antiparkinson and Related Therapy Agents	7	5	1	1	358
Antipsychotics/Antimanic Agents	252	142	57	53	355
Antivirals	11	5	6	0	173
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	66	26	36	4	335
Beta Blockers	68	53	0	15	346
Calcium Channel Blockers	28	22	2	4	347
Cardiovascular Agents - Misc.	35	14	18	3	365
Contraceptives	22	8	13	1	365
Corticosteroids	4	2	2	0	271
Cough/Cold/Allergy	10	9	1	0	365
Dermatologicals	264	98	120	46	281
Diagnostic Products	31	16	6	9	362
Digestive Aids	5	5	0	0	365
Diuretics	42	27	3	12	348
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	1	1	0	365
Endocrine and Metabolic Agents - Misc.	35	14	16	5	286
Estrogens	9	0	9	0	0
Gastrointestinal Agents - Misc.	65	30	24	11	261
Genitourinary Agents - Misc.	7	5	0	2	355
Gout Agents	2	0	1	1	0
Hematological Agents - Misc.	4	2	0	2	90
Hematopoietic Agents	11	6	4	1	341
Hemostatics	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	36	15	20	1	289
Laxatives	4	1	2	1	350
Medical Devices and Supplies	102	60	25	17	363
Migraine Products	176	46	112	18	315

*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
Minerals and Electrolytes	2	0	2	0	0
Miscellaneous Therapeutic Classes	5	2	1	2	365
Multivitamins	4	3	1	0	303
Musculoskeletal Therapy Agents	11	4	4	3	350
Nasal Agents - Systemic and Topical	9	2	6	1	365
Neuromuscular Agents	6	2	4	0	272
Ophthalmic Agents	44	10	12	22	351
*Other	63	20	16	27	303
Otic Agents	60	30	24	6	193
Psychotherapeutic and Neurological Agents - Misc.	61	31	18	12	323
Respiratory Agents - Misc.	8	5	1	2	319
Stimulants - Misc.	265	176	40	49	318
Thyroid Agents	44	31	7	6	348
Ulcer Drugs/Antispasmodics/Anticholinergics	113	73	10	30	350
Urinary Antispasmodics	20	5	8	7	351
Vaccines	3	0	3	0	0
Vaginal and Related Products	3	0	3	0	0
Vitamins	2	0	1	1	0
****Total**	**4,867**	**2,657**	**1,377**	**833**	

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

Denial Reasons	
Benefit	81
Medical Necessity	1,296

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

Academic Detailing Program Update

Oklahoma Health Care Authority
February 2025

Background[1,2,3]

The Academic Detailing (AD) program is an educational initiative combining standards of care with the most current peer-reviewed studies and presenting them in an unbiased, independent, evidence-based manner. AD programs link prescribers with an educator, resulting in improved patient health and cost outcomes. Historically, AD programs that focus specifically on prescribing patterns are shown to reduce inappropriate prescribing to a modest, but significant degree, with a median difference of up to 7%. While not specifically designed to be a tool of cost containment, traditionally AD programs save $2 for every dollar spent.

Since July 2015, under the direction of the Oklahoma Health Care Authority (OHCA), Pharmacy Management Consultants (PMC) has operated an AD program to improve implementation of published guidelines and standards of pediatric care. Continued funding for the PMC-AD pediatric program is through a Health Service Initiative (HSI) grant under the Children's Health Insurance Program (CHIP). As such, special care is taken to identify topics with particular relevance to the care of pediatric members. In June 2023, the Oklahoma State Department of Health (OSDH) initiated the PMC-AD adult program with continued funding from OSDH. The adult program addresses safety and harm reduction strategies related to opioid use. Current and previous areas of focus include treatment of acute and chronic conditions, preventive care, and specialized technical training related to the delivery of pharmacy services. In consultation with OHCA, PMC clinical pharmacists, data analysts, and pharmacy graduate students analyze prescription claims data to determine AD topics, identify providers who may benefit from individualized support from an AD pharmacist, and assess outcomes.

For each topic, the PMC-AD pharmacist prepares educational materials in consultation with the National Resource Center for Academic Detailing (NaRCAD) and offers the program to providers. Educational materials include the following:

- Clinical treatment guidelines
- Provider resources
- Patient and parent resources
- Diagnostic and treatment tools
- Topic-specific continuing medical education (CME) course listings

- Drug alerts and statements from the U.S. Food and Drug Administration (FDA)
- National quality measures [e.g., Healthcare Effectiveness Data and Information Set (HEDIS)]
- OHCA Product Based Prior Authorization (PBPA) coverage criteria

To date, AD services have been provided to nearly 1,200 health care providers and/or their administrative staff, and paid claims for all pediatric members have been used to determine the degree to which guidelines and best practice recommendations are followed by providers. Future AD services will be delivered to providers whose SoonerCare members' fee-for-service paid claims demonstrate possible areas of incomplete guideline implementation. As previously reported, changes in prescribing patterns and associated improvements in health care utilization have led to cost savings to OHCA in the amount of $3,413,207 through December 2024. This amount is inclusive of all federal and supplemental rebates for the analysis periods following AD on the treatment of the following for pediatric SoonerCare members:

- Attention-deficit/hyperactivity disorder (ADHD)
- Use of second generation/atypical antipsychotic medications (SGAs)
- Upper respiratory infections (URIs)
- Persistent asthma
- Diabetes
- Prenatal vitamins
- Co-prescribing naloxone with opioid medications

Current Topic: Pediatric Depression[4,5,6,7,8]

The American Academy of Child & Adolescent Psychiatry Committee on Quality Issues (AACAP-CQI) has a 40-year history of providing "Practice Parameters" which are intended to guide the clinical practice of child and adolescent psychiatry. Each iteration of these topically focused guidelines has been increasingly transparent and increasingly rigorous in its methodology. The most recent AACAP-CQI guidelines for Treatment of Children and Adolescents With Major and Persistent Depressive Disorders were published in May 2023. The American Academy of Pediatrics (AAP) periodically publishes similar guidelines that are intended to address mental health care within the broader scope of pediatric care. The AAP Guidelines for Adolescent Depression in Primary Care (GLAD-PC) are published as a two-part series to provide guidance on (1) diagnosis, assessment, and initial management and (2) treatment and ongoing management of depression. The most recent AAP guidelines were published in March 2018.

Both guidelines recognize the established role of selective serotonin reuptake inhibitor (SSRI) medications and psychosocial interventions, including cognitive behavioral therapy (CBT), in the treatment of pediatric depression

and emphasize the importance of choosing a pharmacotherapy option with the highest efficacy and with the lowest risk of adverse drug events. Specifically, both guidelines name fluoxetine as the pharmacotherapy option meeting those stated needs. Recent systematic reviews and meta-analyses continue to uphold fluoxetine as the preferred pediatric treatment among SSRI medication options. Additionally, these publications have highlighted the low strength of evidence that was previously used when identifying an increased risk of suicidality when using SSRIs in the pediatric population. During an analysis of multiple randomized controlled trials of fluoxetine, no statistically significant difference was found in the primary outcome which was a composite rate of suicidal ideation (SI) or suicide attempt (SA). However, a statistically non-significant trend of increased SI/SA was noted during the acute treatment period (i.e., initial 8-12 weeks of use), and providers are advised to closely monitor pediatric patients initiating SSRI treatment.

Multiple SSRI medications, including fluoxetine capsule and liquid formulations, are available without prior authorization (PA) for SoonerCare members of any age. However, the recommendations of fluoxetine as the SSRI of choice have not been reflected in the prescribing patterns of SoonerCare providers. Reinforced messaging from both the AACAP and AAP served as the source material for the most recent AD topic: Pediatric Depression – Assessment and Management.

Data from SoonerCare paid pharmacy claims and member diagnoses were used to identify providers who stood to benefit from receiving AD services. Prescribing and diagnosis data for pediatric members was compared across the following criteria, with Depression-AD offered to SoonerCare providers meeting 4 or more of the following criteria:

1. Increase of ≥50% in the number of members with antidepressant claims from 2022 to 2023
2. Fluoxetine made up <10% of all antidepressant claims in 2022
3. Fluoxetine made up <10% of all antidepressant claims in 2023
4. Having more members with antidepressant claims than their same specialty peers (e.g., general practitioner, physician assistant)
5. Having >100 members in their practice with claims for any antidepressant medication (excluding specialty providers)
6. Having received AD for another pediatric mental health topic

Depression-AD services were delivered by the PMC-AD pharmacist. Providers in co-practice with identified providers and those who had previously received detailing for other topics were also eligible to receive AD services. In total, 75 providers received Depression-AD services. Depression prescribing patterns were shared with providers on request. Depression-AD was delivered through in-person visits, phone calls, and Zoom meetings.

Results: Usage of Fluoxetine

Outcomes for detailed providers were assessed by 3 separate measures. The first measure addressed prescribing patterns. Overall, detailed providers improved their prescribing of fluoxetine. Prescription claims were compared for providers with members having paid claims for antidepressants during the pre-AD calendar year (CY) 2023, and during the post-AD CY 2024. During CY 2023, fluoxetine made up **8.20%** of all antidepressant prescribing for Depression-AD providers, compared to 21.44% for non-Depression-AD providers. During CY 2024, following Depression-AD, fluoxetine made up **10.65%** of all antidepressant prescribing, compared to 21.66% for non-Depression-AD providers. This represents a **2.45%** change which is a noticeable improvement in the treatment of pediatric depression.

The second measure assessed SAs. During CY 2023 there were 3 documented SAs and during CY 2024 there were 0 documented SAs. While the data does not definitively support Depression-AD resulting in a positive impact on the rate of SAs as some SAs are likely undocumented, it can be reasonably inferred that Depression-AD did not have a worsening effect on SAs.

The third measure assessed non-ambulatory health care service utilization. Inpatient hospital claims were compared for members under the outpatient care of Depression-AD providers. Hospitalizations were included if they were associated with depression diagnoses including:

- Depression
- Major depressive disorder
- Depressive episodes, features, or mood
- Suicidal ideation
- Suicidal attempt
- Intentional self-harm
- Adverse effects of antidepressant medication
- Underdosing of antidepressant medication

During CY 2023, 227 members receiving care from detailed providers completed 1,172 hospitalizations associated with depression. During CY 2024, 130 members receiving care from these providers completed 772 hospitalizations associated with depression. As mentioned above, AD is not a cost containment tool. However, lower costs are an anticipated result of fewer hospitalizations. The total annual cost of CY 2023 hospitalizations for depression was $3,226,138. The total annual cost of CY 2024 hospitalizations for depression is estimated to be $1,834,337 based on CY 2024 paid claims to date. Total estimated annual cost savings of $1,391,801 resulted from Depression-AD.

The Depression-AD prescribing and hospitalization outcomes for detailed providers are shown in Figure 1.

Figure 1: Changes in Depression Academic Detailing Outcomes				
AD Providers (N=75)				
	Pre-AD	**Post-AD**	**Change**	**% Change**
Prescribing Patterns*				
Fluoxetine claims (AD)	8.20%	10.65%	**2.45%**	**29.88%**
Fluoxetine claims (non-AD)	21.44%	21.66%	**0.22%**	**1.03%**
Health Care Utilization‡				
IP members (AD)	227	130	**-97**	**-42.73%**
IP claims (AD)	1,172	722	**-450**	**-38.40%**
IP cost (AD)	$3,226,138	$1,834,337	**-$1,391,801**	**-43.14%**

AD = Academic detailing; N = Number of providers; IP = Inpatient
* Positive indicates improvement
‡ Negative indicates improvement

Across all parameters, detailed providers either maintained or improved their care for pediatric members living with depression.

Provider Satisfaction

Provider satisfaction continues to remain very high as measured by post-visit satisfaction surveys. Providers meeting comparison criteria and those in co-practice were given satisfaction surveys in order to determine their acceptance of the program and to predict the likelihood of participation in future AD topics. Participants in the detailing sessions were given an online survey with an anonymous link and survey results are shown in Figure 3. To date, only 15 providers have been excluded from the PMC-AD program due to an unwillingness to participate. Other reasons for exclusion of targeted providers included the following:

- No longer treating the targeted disease or medication class
- Retired, moved out of state, or inactive license
- No longer treating pediatric patients
- No longer treating SoonerCare members

Figure 2: AD Provider Satisfaction	
The information provided was:	**% choosing agree or strongly agree**
Easily understood	96%
Clearly presented	97%
Evidence-based	97%
Based on the information, I intend to:	**% choosing agree or strongly agree**
Make practice changes as a result	85%
Recommend this program to colleagues	87%
Participate in future topics	91%

AD = academic detailing

Academic Meeting Presentation(s)

Since July 2016, the PMC-AD program leaders have been invited to present program outcomes and breakout sessions at the International Conference on Academic Detailing, the Academy of Managed Care Pharmacy (AMCP), and the American Drug Utilization Review Society (ADURS). Additionally, a poster presentation featuring ADHD-AD results was awarded a silver ribbon at the Nexus 2017 meeting of AMCP. The primary PMC-AD pharmacist is also currently 1 of 11 national training facilitators for NaRCAD.

Summary

As a result of AD interventions, the currently available data shows medication costs, PA submissions, inappropriate prescribing, and health care utilization costs have all been improved substantially. Prescription data has been analyzed using rebated and non-rebated data, pre-and post-detailing patterns for individual providers, and federal fiscal year and calendar year comparisons. Each analysis shows improvements following delivery of AD services.

Providers report satisfaction with the program and intend to participate in future topics. The AD program is well received by providers and targeted providers have fulfilled their stated intentions to make practice changes as prompted by the AD sessions. Continued implementation and expansion of the PMC-AD program is expected to increase delivery of evidence-based health care and reduce health care costs to OHCA.

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[1] Soumerai SB, Avorn J. Economic and Policy Analysis of University-Based Drug "Detailing." *Med Care* 1986; 24(4):313-331. doi: 10.1097/00005650-198604000-00003.
[2] Yeh JS, Van Hoof TJ, Fischer MA. Key Features of Academic Detailing: Development of an Expert Consensus Using the Delphi Method. *Am Health Drug Benefits* 2016; 9(1):42-50.
[3] Rome BN, Dancel E, et al. Academic Detailing Interventions and Evidence-Based Prescribing: A Systematic Review. *JAMA Netw Open* 2025; 8(1):e2453684. doi:10.1001/jamanetworkopen.2024.53684.
[4] Walter HJ, Abright AR, et al. Clinical Practice Guideline for the Assessment and Treatment of Children and Adolescents With Major and Persistent Depressive Disorders. *J Am Acad Child Adolesc Psychiatry* 2023; 62(5):479-502. doi: 10.1016/j.jaac.2022.10.001.
[5] Cheung AH, Zuckerbrot, RA. Guidelines for Adolescent Depression in Primary Care (GLAD-PC): Part II. Treatment and Ongoing Management. *Pediatrics* 2018; 141(3): e20174082. doi.org/10.1542/peds.2017-4082.
[6] Trivedi CG. Fluoxetine, Depression, and Suicide: A Revisit to the Black Box Warning. *J Am Acad Child Adolesc Psychiatry* 2020; 59(10):S233. doi: 10.1016/j.jaac.2020.08.349.
[7] Cipriani A, Furukawa TA, et al. Comparative Efficacy and Acceptability of 21 Antidepressant Drugs for the Acute Treatment of Adults with Major Depressive Disorder: A Systematic Review and Network Meta-Analysis. *Lancet* 2018; 391(10128):1357-1366. doi: 10.1016/S0140-6736(17)32802-7.
[8] Cipriani A, Zhou X, et al. Comparative Efficacy and Tolerability of Antidepressants for Major Depressive Disorder in Children and Adolescents: A Network Meta-Analysis. *Lancet* 2016; 388(10047):881-90. doi: 10.1016/S0140-6736(16)30385-3.

Appendix C

Narrow Therapeutic Index (NTI) Drug List

Oklahoma Health Care Authority
February 2025

Introduction[1,2,3]

The U.S. Food and Drug Administration (FDA) defines narrow therapeutic index (NTI) drugs as drugs where small differences in dose or blood concentration may lead to serious therapeutic failures or adverse drug reactions. NTI drugs generally have the following characteristics:

- Little separation between therapeutic and toxic doses
- Sub-therapeutic concentration may lead to serious therapeutic failure
- Drugs that are subject to therapeutic drug monitoring based on pharmacokinetic (PK) or pharmacodynamic (PD) measures
- In clinical practice, doses are often adjusted in very small increments (<20%)

The FDA Office of Generic Drugs assesses brand/generic interchangeability standards for NTI drugs. NTI drugs analyzed for bioequivalence by the FDA include warfarin, lithium, digoxin, theophylline, tacrolimus, phenytoin, levothyroxine, and carbamazepine. Other groups, including Health Canada, also include cyclosporine and sirolimus in their NTI drug classification group.

The Oklahoma Health Care Authority (OHCA) policy and rules state the following regarding brand necessary certification (317:30-5-77):

> "For certain narrow therapeutic index drugs, a prior authorization will not be required. The DUR Board will select and maintain the list of narrow therapeutic index drugs."

The purpose of this report is to provide the Drug Utilization Review (DUR) Board with the current SoonerCare NTI drug list for review, which is to be maintained by the DUR Board. Medications included in the NTI list are set up to bypass brand/generic substitution requirements in the claims processing system. Action by the DUR Board is not required unless the DUR Board recommends changes to the current NTI drug list.

SoonerCare NTI Drug List

- Carbamazepine
- Clozapine
- Cyclosporine
- Desipramine
- Digoxin
- Esketamine
- Levothyroxine
- Lithium
- Nortriptyline
- Phenytoin
- Sirolimus
- Tacrolimus
- Theophylline
- Warfarin

Recommendations

The College of Pharmacy does not recommend any changes to the SoonerCare NTI Drug List at this time.

[1] U.S. Food and Drug Administration (FDA). FY2015 Regulatory Science Research Report: Narrow Therapeutic Index Drugs. Available online at: https://www.fda.gov/industry/generic-drug-user-fee-amendments/fy2015-regulatory-science-research-report-narrow-therapeutic-index-drugs. Last revised 05/09/2017. Last accessed 01/07/2025.
[2] U.S. FDA. Building Confidence in Generic Narrow Therapeutic Index (NTI) Drugs. Available online at: https://www.fda.gov/about-fda/fda-pharmacy-student-experiential-program/building-confidence-generic-narrow-therapeutic-index-nti-drugs. Last revised 04/10/2020. Last accessed 01/07/2025.
[3] Jiang, Wenlei. FDA Drug Topics: Understanding Generic Narrow Therapeutic Index Drugs. *U.S. FDA*. Available online at: https://www.fda.gov/media/162779/download. Issued 11/01/2022. Last accessed 01/07/2025.

Appendix D

Vote to Prior Authorize Jubbonti® (Denosumab-bbdz) and Update the Approval Criteria for the Osteoporosis Medications

Oklahoma Health Care Authority
February 2025

Market News and Updates[1,2]

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

- **January 2024:** The FDA announced the addition of a *Boxed Warning* for Prolia® (denosumab) for an increased risk of severe hypocalcemia in patients with advanced chronic kidney disease (CKD), including those on dialysis. An investigation found that patients with advanced CKD developed severe hypocalcemia 2 to 10 weeks after each Prolia® injection, with the greatest risk during weeks 2 through 5.
- **March 2024:** The FDA approved Jubbonti® (denosumab-bbdz) injection as the first interchangeable biosimilar to Prolia® (denosumab). Jubbonti® was approved for all currently approved indications for Prolia®.

Recommendations

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

1. Updating the Osteoporosis Medications Tier-2 Approval Criteria to clarify the requirement for hypersensitivity or intolerance to Tier-1 bisphosphonates; and
2. The prior authorization and placement of Jubbonti® (denosumab-bbdz) into the Special PA Tier with unique criteria for use of a biosimilar product; and
3. Adding Bonsity® (teriparatide) to the Forteo® (teriparatide) additional Special PA Approval Criteria for clarity; and
4. Designating Forteo® (teriparatide) as brand preferred and preferring Forteo® (teriparatide) and generic teriparatide over Bonsity® (teriparatide) based on net costs.

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
alendronate tabs (Fosamax®)	alendronate + vitamin D tabs (Fosamax® + D)	abaloparatide inj (Tymlos®)

Osteoporosis Medications*		
Tier-1	**Tier-2**	**Special PA¥**
calcium + vitamin D†	risedronate tabs (Actonel®)	alendronate effervescent tabs (Binosto®)
ibandronate tabs (Boniva®)		alendronate soln (Fosamax®)
zoledronic acid inj (Reclast®)		alendronate 40mg tabs (Fosamax®)
		denosumab inj (Prolia®)
		denosumab-bbdz inj (Jubbonti®)
		ibandronate inj (Boniva® IV)
		risedronate 30mg tabs (Actonel®)
		risedronate DR tabs (Atelvia®)
		romosozumab-aqqg (Evenity®)
		teriparatide inj (Forteo®) – **Brand Preferred**
		teriparatide inj (Bonsity®)

*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).
†OTC calcium + vitamin D must be used at recommended doses in conjunction with Tier-1 bisphosphonates for trial to be accepted unless member has a recent laboratory result showing adequate vitamin D or member is unable to tolerate calcium. OTC calcium + vitamin D are only covered for members with osteoporosis who are being treated with a bisphosphonate.
¥Unique criteria applies to medications in the Special PA Tier.
DR = delayed-release; inj = injection; PA = prior authorization; soln = solution; tabs = tablets

Osteoporosis Medications Tier-2 Approval Criteria:

1. A trial of at least 1 Tier-1 bisphosphonate medication, compliantly used for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
2. Hypersensitivity to or intolerable adverse effect(s) with all Tier-1 bisphosphonate medications (including oral and intravenous routes of administration); and
3. Quantity limits apply based on FDA approved maximum doses.

Boniva® [Ibandronate Intravenous (IV) Solution], Jubbonti® (Denosumab-bbdz), and Prolia® (Denosumab) Approval Criteria:

1. A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or
2. Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications (including oral and intravenous routes of administration); and

3. For Jubbonti®, a patient-specific, clinically significant reason why the member cannot use Prolia® (denosumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Bonsity® (Teriparatide) and Forteo® (Teriparatide) ~~and Teriparatide~~
Approval Criteria:

1. Diagnosis of 1 of the following:
   a. Treatment of postmenopausal women with osteoporosis at high risk for fracture; or
   b. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; or
   c. Treatment of men and women with osteoporosis associated with sustained systemic corticosteroid therapy at high risk for fracture; or
   d. Treatment of non-healing fracture (this indication only pertains to Forteo®); and
2. A minimum 12-month trial with a bisphosphonate plus adequate calcium and vitamin D or a patient-specific, clinically significant reason why the member cannot use a bisphosphonate must be provided; and
3. Use of generic teriparatide will require a patient-specific, clinically significant reason why the member cannot use the brand formulation, Forteo® (teriparatide); and
4. Use of Bonsity® (teriparatide) will require a patient-specific, clinically significant reason why the member cannot use Forteo® (teriparatide) or generic teriparatide formulations; and
5. The diagnosis of non-healing fracture may be approved for 6 months; and
6. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the patient's lifetime; and
7. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy.

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[1] U.S. Food and Drug Administration (FDA). FDA Adds Boxed Warning for Increased Risk of Severe Hypocalcemia in Patients with Advanced Chronic Kidney disease Taking Osteoporosis Medicine Prolia® (Denosumab). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-severe-hypocalcemia-patients-advanced-chronic-kidney-disease. Last revised 02/01/2024. Last accessed 01/28/2025.

[2] U.S. FDA. FDA Approves First Interchangeable Biosimilars to Prolia® and Xgeva® to Treat Certain Types of Osteoporosis and Prevent Bone Events in Cancer. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-prolia-and-xgeva-treat-certain-types-osteoporosis-and. Issued 03/05/2024. Last accessed 01/28/2025.

Appendix E

Vote to Prior Authorize Aqneursa™ (Levacetylleucine), Lenmeldy™ (Atidarsagene Autotemcel), and Miplyffa™ (Arimoclomol) and Update the Approval Criteria for the Lysosomal Storage Disease Medications

Oklahoma Health Care Authority
February 2025

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

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

- **March 2024:** The FDA approved Lenmeldy™ (atidarsagene autotemcel), an autologous hematopoietic stem cell (HSC)-based gene therapy, for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD). Lenmeldy™ is the first FDA approved treatment for MLD.
- **July 2024:** The FDA approved Brineura® (cerliponase alfa) for an age expansion to include patients with neuronal ceroid lipofuscinosis type 2 (CLN2) from the time of birth. Brineura® is not recommended in patients younger than 37 weeks post-menstrual age (gestational age at birth plus post-natal age) or those weighing <2.5kg. Previously, Brineura® was only FDA approved for patients 3 years of age or older with late infantile CLN2. Additionally, a *Boxed Warning* has been added for Brineura® regarding the risk of hypersensitivity reactions, including anaphylaxis.
- **September 2024:** The FDA approved Miplyffa™ (arimoclomol), in combination with miglustat, for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older.
- **September 2024:** The FDA approved Aqneursa™ (levacetylleucine) for the treatment of neurological manifestations of NPC in adults and pediatric patients weighing ≥15 kg.

Lenmeldy™ (Atidarsagene Autotemcel) Product Summary[6]

Therapeutic Class: Autologous HSC-based gene therapy

Indication(s): Treatment of children with PSLI, PSEJ, or ESEJ MLD

How Supplied: Single-dose cell suspension for intravenous (IV) infusion contained in 1 to 8 infusion bags which contain 2-11.8 x 10^6 cells/mL (1.8-11.8 x 10^6 CD34+ cells/mL) suspended in cryopreservation solution

Dosing and Administration:

- The dose of Lenmeldy™ is calculated based on body weight and the MLD subtype, with a minimum and maximum recommended dose. The maximum recommended dose is 30 x 10^6 CD34+ cells/kg for all subtypes. The minimum recommended doses are as follows:
  - PSLI: 4.2 x 10^6 CD34+ cells/kg
  - PSEJ: 9 x 10^6 CD34+ cells/kg
  - ESEJ: 6.6 x 10^6 CD34+ cells/kg
- Patients must undergo HSC mobilization followed by apheresis to obtain the CD34+ cells for manufacturing.
- Myeloablative conditioning must be administered before the infusion of Lenmeldy™.
- Lenmeldy™ is administered as an IV infusion via central venous catheter. Up to 8 bags of Lenmeldy™ may be needed to administer the full dose. Each bag should be infused within 30 minutes via gravity or infusion pump. If more than 1 bag is required for the dose, do not administer more than 1 bag per hour.

Efficacy: The efficacy of Lenmeldy™ was assessed in 2 single-arm, open-label studies and a European expanded access program (EAP). In total, efficacy was assessed for 37 patients who received Lenmeldy™, including 20 PSLI patients, 7 PSEJ patients, and 10 ESEJ patients. Efficacy was compared to an external untreated natural history cohort of children with MLD, including 28 patients with late infantile MLD and 21 patients with early juvenile MLD.

- <u>Key Inclusion Criteria:</u>
  - Biochemical and molecular diagnosis of MLD based on:
    - Arylsulfatase A (ARSA) activity below the normal range; and
    - Presence of 2 disease-causing mutations in the *ARSA* gene or, in the case of a novel *ARSA* variant, a 24-hour urine collection was required to show elevated sulfatide levels
- <u>Key Exclusion Criteria:</u>
  - Underwent allogeneic hematopoietic stem cell transplant (HSCT) within the past 6 months
  - Underwent allogeneic HSCT with evidence of residual cells of donor origin
- <u>Intervention(s):</u>
  - Hematopoietic stem cells were collected by bone marrow collection in 29 patients, by apheresis following administration of granulocyte-colony stimulating factor (G-CSF) and plerixafor in 8 patients, or by both methods in 2 patients
  - All patients received busulfan conditioning prior to Lenmeldy™ administration
  - 39 patients received Lenmeldy™, but 2 children with advanced disease were excluded from the efficacy analysis

- Primary Endpoint(s):
  - Severe motor impairment-free survival, defined as the interval from birth to the first occurrence of loss of locomotion and loss of sitting without support or death in PSLI MLD patients
- Results:
  - PSLI Patients:
    - 17 PSLI patients treated with Lenmeldy™ have been followed until at least 5 years of age, at which time 100% of the Lenmeldy™-treated patients remained event-free compared to 0% of the untreated late infantile children from the natural history cohort
    - 14 patients treated with Lenmeldy™ had sufficient follow-up to determine survival at 6 years of age, at which time 100% of the Lenmeldy™-treated patients were alive compared to only 58% of the untreated patients
  - For results for the 7 PSEJ and 10 ESEJ patients, please refer to the Lenmeldy™ package labeling.

Cost: The Wholesale Acquisition Cost (WAC) for Lenmeldy™ is $4.25 million per 1-time treatment.

Aqneursa™ (Levacetylleucine) Product Summary[7,8]

Therapeutic Class: Modified amino acid

Indication(s): Treatment of neurological manifestations of NPC in adults and pediatric patients weighing ≥15kg

How Supplied: Unit-dose packets containing 1g levacetylleucine strawberry flavored granules

Dosing and Administration:

- Administered orally up to 3 times daily based on actual body weight:

Body Weight	Morning Dose	Afternoon Dose	Evening Dose
15kg to <25kg	1g	No dose	1g
25kg to <35kg	1g	1g	1g
35kg or more	2g	1g	1g

- If the 2g dose is needed, 2 packets must be prepared individually.
- The contents of 1 packet should be emptied into a container with 40mL of water, orange juice, or almond milk. Hot liquid should not be used. The medication should be stirred to form a suspension.
- The suspension should be swallowed immediately (within 30 minutes).
- The above steps should be repeated with a second packet if a dose of 2g is needed.
- See the full *Prescribing Information* for additional instructions if administration through a gastrostomy tube (G-tube) is needed.

Efficacy: The efficacy of Aqneursa™ was assessed primarily in a Phase 3, randomized, double-blind, placebo-controlled, 2-period crossover study that enrolled a total of 60 patients with NPC.

- Key Inclusion Criteria:
  - Confirmed genetic diagnosis of NPC
  - Must be 4 years of age or older and weigh ≥15kg
  - Presence of at least mild disease-related neurological symptoms
  - If utilizing miglustat, patient must have been on a stable dose for at least 42 days prior to study entry and had to agree to continue it at a stable dose throughout the duration of the study
- Intervention(s): Patients were randomized 1:1 to 1 of 2 treatment sequences:
  - Sequence 1: Levacetylleucine for 12 weeks followed by immediate crossover to placebo for 12 weeks; or
  - Sequence 2: Placebo for 12 weeks followed by immediate crossover to levacetylleucine for 12 weeks
- Primary Endpoint(s):
  - Estimated mean functional scale for assessment and rating of ataxia (fSARA) score assessed at the end of each 12-week treatment period (on a scale from 0-16 with lower scores indicating better neurological status)
- Results:
  - Estimated mean fSARA score was 5.1 while receiving levacetylleucine and 5.6 while receiving placebo [treatment difference: -0.4; 95% confidence interval (CI): -0.7, -0.2; P<0.001]

Miplyffa™ (Arimoclomol) Product Summary[9,10]

Therapeutic Class: Heat shock protein inducer

Indication(s): Treatment, in combination with miglustat, of neurological manifestations of NPC in adult and pediatric patients 2 years of age and older

How Supplied: 47mg, 62mg, 93mg, and 124mg oral capsules

Dosing and Administration: Miplyffa™ should be administered orally, in combination with miglustat, with the following recommended doses based on actual body weight:

- 8 to 15kg: 47mg 3 times a day
- >15kg to 30kg: 62mg 3 times a day
- >30kg to 55kg: 93mg 3 times a day
- >55kg: 124mg 3 times a day
- See the full *Prescribing Information* for additional administration instructions for patients who have difficulty swallowing capsules or when the use of a feeding tube (nasogastric or gastric tube) is needed.

Efficacy: The efficacy of Miplyffa™ was assessed primarily in a Phase 2/3 randomized, double-blind, placebo-controlled study that enrolled a total of 50 patients with NPC.

- Key Inclusion Criteria:
  - Confirmed diagnosis of NPC
  - Must be 2 to 19 years of age
  - Presence of at least 1 neurological sign of disease
  - If utilizing miglustat, patient must have been on a stable dose for at least 6 months prior to study entry
- Intervention(s): Patients were randomized 2:1 to receive weight-adjusted arimoclomol (31mg to 124mg) or placebo orally 3 times per day
- Primary Endpoint Evaluated by the FDA:
  - Change from baseline in the rescored 4-domain NPC clinical severity scale (R4DNPCCSS) score at month 12 in the subgroup of patients who also received miglustat (on a scale from 0 to 20 with higher scores indicating more severe impairment)
- Results:
  - The least squares mean change in the R4DNPCCSS score was -0.2 points for patients who received arimoclomol plus miglustat compared to an increase of 2 points for patients who received placebo plus miglustat (treatment difference: -2.2; 95% CI: -3.8, -0.6)

Cost Comparison: NPC Products[11]

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Miplyffa™ (arimoclomol) 124mg capsule	**$1,178.00**	**$106,020.00***	**$1,272,240.00**
Aqneursa™ (levacetylleucine) 1g packet	**$480.36**	**$57,643.20⁺**	**$691,718.40**
Zavesca® (miglustat) 100mg capsule	$187.74	$33,793.20Δ	$405,518.40
Yargesa® (miglustat) 100mg capsule (branded generic)	$267.90	$48,222.00Δ	$578,664.00
miglustat 100mg capsule (generic)	$267.90	$48,222.00Δ	$578,664.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = each capsule or packet
*Cost per 30 days based on the FDA approved max dose of 124mg 3 times a day.
⁺Cost per 30 days based on the FDA approved max dose of 4g per day.
ΔCost per 30 days based on a dose of 200mg 3 times a day.

Recommendations

The College of Pharmacy recommends the prior authorization of Aqneursa™ (levacetylleucine), Lenmeldy™ (atidarsagene autotemcel), and Miplyffa™ (arimoclomol) with the following criteria (shown in red):

Lenmeldy™ (Atidarsagene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of metachromatic leukodystrophy (MLD) confirmed by:
    a. Arylsulfatase A (ARSA) enzyme activity below the normal range in peripheral blood mononuclear cells or fibroblasts (results of assay must be submitted); and
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *ARSA* gene of known polymorphisms (results of genetic testing must be submitted); or
        i. If novel *ARSA* variant(s) are identified, a 24-hour urine collection must demonstrate increased urinary excretion of sulfatides (results must be submitted); and
2. Member must have 1 of the following forms of MLD as determined by the prescriber (clinical documentation must be submitted with the request):
    a. Pre-symptomatic late infantile (PSLI) MLD with expected disease onset ≤30 months of age; or
    b. Pre-symptomatic early juvenile (PSEJ) MLD with expected disease onset >30 months and <7 years of age; or
    c. Early symptomatic early juvenile (ESEJ) MLD with disease onset >30 months and <7 years of age; and
3. Member must be younger than 18 years of age; and
4. Must be prescribed by a geneticist, hematologist/oncologist, neurologist, or other specialist with expertise in the treatment of MLD and the administration of Lenmeldy™; and
5. Member must not have a history of prior hematopoietic stem cell transplantation (HSCT); or
    a. If member has had a HSCT, there is no evidence of residual cells of donor origin; and
6. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Lenmeldy™); and
7. Member must have a negative serology test for human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), cytomegalovirus (CMV), and mycoplasma prior to apheresis; and
8. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Lenmeldy™ administration; and
9. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Lenmeldy™; and

10. Prescriber must verify male and female members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and
11. Prescriber must verify the member has been evaluated for and counseled on all warnings and precautions related to Lenmeldy™, including the risk of thrombosis and thromboembolic events, serious infections, and veno-occlusive disease; and
12. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed annually and integration site analysis as warranted for at least 15 years after treatment with Lenmeldy™; and
13. Must be administered at a Lenmeldy™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Lenmeldy™ dose from receipt to storage to administration; and
14. Approvals will be for 1 dose per member per lifetime.

Aqneursa™ (Levacetylleucine) Approval Criteria:

1. An FDA approved diagnosis of Niemann-Pick disease type C (NPC) confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Will not be approved for concomitant use with Miplyffa™ (arimoclomol); and
5. 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
6. Females of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 7 days after the last dose of Aqneursa™; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Miplyffa™ (Arimoclomol) Approval Criteria:

1. An FDA approved diagnosis of Niemann-Pick disease type C (NPC) confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Must be used in combination with Zavesca® (miglustat); and
    a. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. A patient-specific, clinically significant reason why the member cannot use Aqneursa™ (levacetylleucine) must be provided; and
6. Will not be approved for concomitant use with Aqneursa™; and
7. 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
8. Prescriber must verify that females of reproductive potential have been counseled on the potential risks of embryofetal harm when administered during pregnancy; and
9. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Additionally, the College of Pharmacy recommends updating the approval criteria for Brineura® (cerliponase alfa) based on the recent FDA approved age expansion and label updates (changes shown in red):

Brineura® (Cerliponase Alfa) Approval Criteria:

1. An FDA approved diagnosis of ~~late infantile~~ neuronal ceroid lipofuscinosis type 2 (CLN2) also known as tripeptidyl peptidase-1 (TPP-1) deficiency confirmed by:
    a. Enzyme assay demonstrating a deficiency of TPP-1 enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *TPP1* gene (results of genetic testing must be submitted); and
2. Member must be ~~3 years of age or older~~ at least 37 weeks post-menstrual age (i.e., gestational age at birth plus post-natal age) and weigh ≥2.5kg; and

3. Brineura® must be prescribed by a specialist with expertise in the treatment of CLN2 (or an advanced care practitioner with a supervising physician who is a specialist with expertise in treating CLN2); and
4. Brineura® must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration and prepared to manage anaphylaxis; and
5. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
6. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
7. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
8. Prescriber must be willing to perform regular 12-lead electrocardiogram (ECG) evaluation at baseline and at least every 6 months and verify that they are acceptable to the prescriber; and
9. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
10. Initial authorizations will be for the duration of 6 months, at which time compliance will be required for continued approval. After 12 months of utilization, the prescriber must verify the member is responding to the medication as demonstrated by ≤2 point decline in Motor plus Language CLN2 score from baseline. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment; and
11. Approval quantity will be based on package labeling and FDA approved dosing regimen.

Lastly, the College of Pharmacy recommends updating the approval criteria for Zavesca® (miglustat) based on net cost and to allow use in patients with NPC (changes and new criteria shown in red):

Zavesca® (Miglustat) Approval Criteria [Gaucher Disease Diagnosis]:

1. An FDA approved diagnosis of mild/moderate type 1 Gaucher disease (GD1) confirmed by:
   a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. A patient-specific, clinically significant reason why the member cannot use 1 of the following enzyme replacement therapies must be provided:
   a. Cerezyme® (imiglucerase); or

   b. Elelyso® (taliglucerase alfa); or
   c. Vpriv® (velaglucerase alfa); and
3. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD1; and
5. Prescriber must verify the member will not take Zavesca® concurrently with another therapy for GD1; and
6. A quantity limit of 90 capsules per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Zavesca® (Miglustat) Approval Criteria [Niemann-Pick Disease Type C (NPC) Diagnosis]:

1. A diagnosis of NPC confirmed by molecular genetic testing confirming biallelic pathogenic variants in the *NPC1* or *NPC2* genes (results of genetic testing must be submitted); and
2. Member must have the presence of at least mild disease-related neurological symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPC; and
4. Zavesca® is brand preferred. Requests for generic miglustat (including Yargesa®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. For members younger than 12 years of age, the member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug; and
6. A quantity limit of 180 capsules per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Gene Therapy for Children with Metachromatic Leukodystrophy. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-children-metachromatic-leukodystrophy. Issued 03/18/2024. Last accessed 01/17/2025.
[2] BioMarin Pharmaceutical Inc. U.S. Food and Drug Administration Approves BioMarin's Brineura® (Cerliponase Alfa) for Children Under 3 Years with CLN2 Disease. Available online at: https://investors.biomarin.com/news/news-details/2024/U.S.-Food-and-Drug-Administration-Approves-BioMarins-BRINEURA-cerliponase-alfa-for-Children-Under-3-Years-with-CLN2-Disease/default.aspx. Issued 07/24/2024. Last accessed 01/17/2025.
[3] Brineura® (Cerliponase Alfa) Prescribing Information. BioMarin Pharmaceutical Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761052s014lbl.pdf. Last revised 07/2024. Last accessed 01/17/2025.
[4] U.S. FDA. FDA Approves First Treatment for Niemann-Pick Disease, Type C. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-niemann-pick-disease-type-c. Issued 09/20/2024. Last accessed 01/17/2025.
[5] U.S. FDA. FDA Approves New Drug to Treat Niemann-Pick Disease, Type C. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treat-niemann-pick-disease-type-c. Issued 09/24/2024. Last accessed 01/17/2025.
[6] Lenmeldy™ (Atidarsagene Autotemcel) Prescribing Information. Orchard Therapeutics North America. Available online at: https://www.fda.gov/media/177109/download?attachment. Last revised 03/2024. Last accessed 01/17/2025.
[7] Aqneursa™ (Levacetylleucine) Prescribing Information. IntraBio Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219132s000lbl.pdf. Last revised 09/2024. Last accessed 01/17/2025.
[8] Bremova-Ertl T, Ramaswami U, Brands M, et al. Trial of N-Acetyl-l-Leucine in Niemann-Pick Disease Type C. *N Engl J Med* 2024; 390(5):421-431. doi: 10.1056/NEJMoa2310151.
[9] Miplyffa™ (Arimoclomol) Prescribing Information. Zevra Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/214927s000lbl.pdf. Last revised 09/2024. Last accessed 01/17/2025.
[10] Mengel E, Patterson MC, Da Riol RM, et al. Efficacy and Safety of Arimoclomol in Niemann-Pick Disease Type C: Results from a Double-Blind, Randomised, Placebo-Controlled, Multinational Phase 2/3 Trial of a Novel Treatment. *J Inherit Metab Dis* 2021; 44(6):1463-1480. doi: 10.1002/jimd.12428.
[11] European Medicines Agency (EMA). Zavesca® (Miglustat) Product Information. Janssen Pharmaceutica NV. Available online at: https://www.ema.europa.eu/en/documents/product-information/zavesca-epar-product-information_en.pdf. Last revised 10/29/2024. Last accessed 01/17/2025.

Appendix F

Vote to Prior Authorize Yorvipath® (Palopegteriparatide) and Update the Approval Criteria for the Parathyroid Medications

Oklahoma Health Care Authority
February 2025

Market News and Updates[1,2]

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

- **August 2024:** The FDA approved Yorvipath® (palopegteriparatide) subcutaneous (sub-Q) injection for the treatment of hypoparathyroidism in adults.

News:

- **October 2022:** It was announced that Takeda will be discontinuing the manufacturing of Natpara® globally at the end of 2024. Supply issues concerning protein particle formation specific and unique to Natpara® led to a recall of Natpara® in 2019, and Takeda explored numerous ways to address the issue but determined that there was not a sustainable solution going forward. Takeda intends to supply available doses to patients currently on Natpara® until stock is expired or depleted.

Yorvipath® (Palopegteriparatide) Product Summary[3]

Therapeutic Class: Parathyroid hormone (PTH) analog

Indication(s): Treatment of hypoparathyroidism in adults

- **Limitation(s) of Use:**
  - Not studied for acute post-surgical hypoparathyroidism
  - Titration scheme only evaluated in adults who first achieved an albumin-corrected serum calcium (Ca) of at least 7.8mg/dL using Ca and active vitamin D treatment

How Supplied: Single-patient use prefilled pens with labeled dosing that can administer 14 doses. Each box contains 2 prefilled pens in the following strengths:

- 168mcg/0.56mL, labeled doses of 6, 9, or 12mcg
- 294mcg/0.98mL, labeled doses of 15, 18, or 21mcg
- 420mcg/1.4mL, labeled doses of 24, 27, or 30mcg

Dosing and Administration:

- The recommended starting dose is 18mcg sub-Q once daily that can be titrated in 3mcg increments or decrements up to a maximum recommended dose of 30mcg sub-Q once daily.
- Only 1 injection should be used to achieve the once daily recommended dosage as using 2 injections increases the risks of unintended changes in serum calcium levels.
- The dose for Yorvipath® should be individualized based on serum Ca levels.

Efficacy: The efficacy of Yorvipath® was studied in a randomized, double-blind, placebo-controlled Phase 3 trial in 82 patients with hypoparathyroidism.

- Key Inclusion Criteria:
  - Postsurgical chronic hypoparathyroidism or autoimmune, genetic, or idiopathic hypoparathyroidism for at least 26 weeks
  - Treated with calcitriol ≥0.5mcg/day or alfacalcidol ≥1.0mcg/day in addition to elemental Ca ≥800mg/day for ≥12 weeks before screening, and on stable doses for ≥5 weeks
  - Albumin-adjusted serum Ca ≥7.8mg/dL, 25 (OH) vitamin D level of 20-80ng/mL, and a magnesium level ≥1.3mg/dL prior to randomization
  - 24-hour urinary Ca excretion >125mg/24 hours
- Intervention(s):
  - Randomized 3:1 to Yorvipath® or placebo at a starting dose of 18mcg/day co-administered with conventional therapy
    - Randomization was stratified based on etiology of hypoparathyroidism; and
    - Therapy was titrated based on album-corrected serum Ca levels
- Primary Endpoint(s):
  - Proportion of patients who achieved the following at week 26:
    - Albumin-corrected serum Ca within the normal range; and
    - Independence from conventional therapy; and
    - No increase in the trial drug at week 22; and
    - No missing active vitamin D and Ca at week 22; and
    - Trial drug dose of ≤30mcg once daily during week 26
- Results:
  - Overall response at week 26:
    - Achieved by 69% of patients who received Yorvipath® vs. 4.8% of patients on placebo [response rate difference: 64.2%; 95% confidence interval (CI): 49.5%, 78.8%]

- Independence from active vitamin D:
  - Achieved by 80.3% of patients on Yorvipath® vs. 47.6% of those on placebo (response rate difference: 32.7%; 95% CI: 9.2%, 56.3%)
- Independence from therapeutic dose of Ca:
  - Achieved by 86.9% of those on Yorvipath® vs. 4.8% on placebo (response rate difference: 82.2%; 95% CI: 70%, 94.4%)
- No increase in study drug dose since week 22:
  - Achieved by 93.4% of patients on Yorvipath® vs. 57.1% on placebo (response rate difference: 36.4%; 95% CI: 14.2%, 58.5%)
- Study drug dose </=30mcg/day up to week 26:
  - Achieved by 91.8% of patients on Yorvipath®.

Cost: The Wholesale Acquisition Cost (WAC) of Yorvipath® is $10,962.50 per pen. This results in an estimated cost of $21,925.00 per 28 days and $285,025.10 per year regardless of dose.

Recommendations

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

Yorvipath® (Palopegteriparatide) Approval Criteria

1. An FDA approved diagnosis of hypoparathyroidism; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify the following:
   a. Member has albumin-corrected serum calcium ≥7.8mg/dL and serum 25(OH) vitamin D is within the normal range; and
   b. Serum calcium will be measured within 7-10 days after the first dose and after any dose change in Yorvipath®, active vitamin D, or calcium supplements; and
   c. Member or member's caregiver has been trained by a health care professional on proper storage, preparation, and subcutaneous (sub-Q) administration of Yorvipath®; and
   d. Member must not have acute post-surgical hypoparathyroidism; and
4. Member must be unable to be adequately well-controlled on calcium supplements and active forms of vitamin D alone; and
5. A quantity limit of 2 pre-filled pens [each package contains (2) 14-day pre-filled pens] per 28 days will apply. The maximum covered dose will be 30mcg per day.

Additionally, the College of Pharmacy recommends the removal of SoonerCare coverage and the prior authorization criteria for Natpara®

(parathyroid hormone) based on product discontinuation (changes shown in red):

~~Natpara® (Parathyroid Hormone) Approval Criteria:~~

1. ~~An FDA approved indication for use as an adjunct to calcium and vitamin D to control hypocalcemia in members with hypoparathyroidism; and~~
    a. ~~Natpara is not FDA approved for hypoparathyroidism caused by calcium-sensing receptor mutations; and~~
    b. ~~Natpara is not FDA approved for hypoparathyroidism due to acute post-surgery; and~~
2. ~~Magnesium deficiency must be ruled out; and~~
3. ~~Member must have pretreatment serum calcium above 7.5mg/dL before starting Natpara; and~~
4. ~~Prescriber must verify the member has sufficient 25-hydroxyvitamin D level per standard of care; and~~
5. ~~Member must be unable to be adequately well-controlled on calcium supplements and active forms of vitamin D alone; and~~
6. ~~Health care provider and dispensing pharmacy must be certified through the Natpara REMS Program; and~~
7. ~~A quantity limit of two cartridges (each package contains two 14-day cartridges) per 28 days will apply. The maximum covered dose will be 100mcg per day.~~

[1] U.S. Food and Drug Administration (FDA). FDA Approves New Drug for Hypoparathyroidism, A Rare Disorder. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-new-drug-hypoparathyroidism-rare-disorder. Issued 08/09/2024. Last accessed 01/17/2025.
[2] Takeda. Takeda to Discontinue Manufacturing of Natpar®/Natpara® for Patients with Hypoparathyroidism at the End of 2024. Available online at: https://www.takeda.com/newsroom/statements/2022/discontinue-manufacturing-natpar-natpara/. Issued 10/04/2022. Last accessed 01/17/2025.
[3] Yorvipath® (Palopegteriparatide) Prescribing Information. Ascendis Pharma. Available online at: https://ascendispharma.us/products/pi/yorvipath/yorvipath_pi.pdf. Last revised 08/2024. Last accessed 01/17/2025.

Appendix G

Vote to Prior Authorize Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), Fabhalta® (Iptacopan), Piasky® (Crovalimab-akkz), and Voydeya™ (Danicopan) and Update the Approval Criteria for the Complement Inhibitors and Miscellaneous Immunomodulatory Agents

Oklahoma Health Care Authority
February 2025

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

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

- **December 2023:** The FDA approved Fabhalta® (iptacopan), a complement factor B inhibitor, as the first oral monotherapy for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
- **March 2024:** The FDA approved Voydeya™ (danicopan), complement factor D inhibitor, as add-on therapy to Soliris® (eculizumab) or Ultomiris® (ravulizumab-cwvz) for the treatment of extravascular hemolysis (EVH) in adults with PNH.
- **March 2024:** The FDA approved Ultomiris® (ravulizumab-cwvz) for a new indication for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive. Soliris® (eculizumab) and Ultomiris® are now FDA approved for the same 4 indications of atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG), PNH, and now NMOSD. Ultomiris® has been modified to provide an extended half-life enabling a longer dosing interval of 8 weeks vs. every 2 weeks with Soliris®. The approval of Ultomiris® for NMOSD was based on the results of the CHAMPION-NMOSD Phase 3 clinical trial which compared Ultomiris® to an external placebo arm from the Soliris® PREVENT clinical trial. The primary endpoint, which was the time to first adjudicated on-trial relapse, was met; no patients had a relapse in the Ultomiris® group over the course of 84 patient-years compared to 20 patients who had an adjudicated relapse in the PREVENT placebo group over the course of 46.9 patient-years.
- **May 2024:** The FDA approved Bkemv™ (eculizumab-aeeb) as an interchangeable biosimilar to Soliris® (eculizumab). Bkemv™ was approved for the treatment of patients with PNH or aHUS, 2 of the 4 currently approved indications for Soliris®.

- **June 2024:** The FDA approved a new indication for Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) to treat chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. The approval was based on the results of the ADHERE trial, which was a 2 stage, multicenter trial that included an open-label period, stage A, to identify Vyvgart® Hytrulo responders who then entered a randomized, double-blind, placebo controlled, withdrawal period, stage B. The results of stage A showed 69% (221/322) of patients treated with Vyvgart® Hytrulo were responders, regardless of prior treatment. Additionally, stage B met its primary endpoint demonstrating a 61% reduction in the risk of relapse versus placebo [hazard ratio (HR): 0.39; 95% confidence interval (CI): 0.25, 0.61; P<0.0001].
- **June 2024:** The FDA approved Piasky® (crovalimab-akkz), a complement C5 inhibitor, for the treatment of PNH in adult and pediatric patients 13 years of age and older who weigh at least 40kg.
- **July 2024:** The FDA approved Epysqli® (eculizumab-aagh) as a biosimilar to Soliris® for the treatment of PNH and aHUS. This is the second biosimilar to Soliris® approved.
- **August 2024:** The FDA granted accelerated approval for Fabhalta® for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk of rapid disease progression. Fabhalta® is the first complement inhibitor approved for this indication.
- **October 2024:** The FDA approved a new indication for Bkemv™ to treat generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Bkemv™ is now approved for 3 of the 4 approved indications for Soliris®.
- **November 2024:** The FDA approved a new indication for Epysqli® to treat gMG in adult patients who are anti-AChR antibody positive. Epysqli® is now approved for 3 of the 4 approved indications for Soliris®.

Guidelines:

- **August 2024:** Updated draft guidelines for the management of IgAN and immunoglobulin A vasculitis (IgAV) were published by Kidney Disease Improving Global Outcomes (KDIGO) for public draft review. Some of the key updates included:
    - The definition of a patient at risk of progressive loss of kidney function was changed from the prior definition of proteinuria >0.75-1g/day despite ≥90 days of optimized supportive care. The update defines at risk patients as having proteinuria ≥0.5g/day (or equivalent), while on or off treatment for IgAN, and recommends treatment/additional treatment should be started in all cases.
    - The treatment goal is to reduce the rate of loss of kidney function <1mL/min per year for the rest of a patient's life. Urine protein excretion is the only validated biomarker to help guide clinical

decision making and should be maintained <0.5g/day and multiple therapies may be needed to achieve this goal.
    - The focus of management for most patients should be simultaneous to prevent or reduce IgA immune complex formation and immune complex-mediated glomerular injury [i.e., treatment with Tarpeyo® (budesonide delayed-release capsule)] as well as to manage the consequences of existing IgAN induced nephron loss [i.e., treatment with lifestyle modifications, renin-angiotensin system inhibitors (RASi), and sodium-glucose cotransporter-2 (SGLT-2) inhibitors].

Fabhalta® (Iptacopan) Product Summary[17]

Therapeutic Class: Complement factor B inhibitor

Indication(s):
- Treatment of adults with PNH
- Reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g
    - This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether Fabhalta® slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

How Supplied: 200mg oral capsule

Dosing and Administration:
- 200mg orally twice daily with or without food
- Patients switching from Soliris® (eculizumab) should initiate Fabhalta® no later than 1 week after the last dose of Soliris®.
- Patients switching from Ultomiris® (ravulizumab-cwvz) should initiate Fabhalta® no later than 6 weeks after the last dose of Ultomiris®.

Efficacy:
- The efficacy of Fabhalta® for the treatment of adults with PNH was studied in 2 clinical trials, the Phase 3 APPLY-PNH trial which studied patients with residual anemia already on an anti-C5 treatment and the Phase 3 APPOINT-PNH trial that studied treatment-naïve patients with PNH. The Phase 3 APPLY-PNH trial was a multi-center, randomized, open-label, active comparator-controlled, parallel group study. The Phase 3 APPOINT-PNH trial was a multi-center, single-arm, open-label trial.

- Key Inclusion Criteria:
    - Both trials:
        - ≥18 years of age
        - Diagnosis of PNH confirmed by high-sensitivity flow cytometry with clone size ≥10%
        - Mean hemoglobin (Hb) level <10g/dL
    - APPLY-PNH required the patient to be on a stable dose of an anti-C5 treatment (eculizumab or ravulizumab) for at least 6 months prior to randomization.
    - APPOINT-PNH required lactate dehydrogenase (LDH) to be >1.5 x upper limit of normal (ULN).
- Intervention:
    - APPLY-PNH:
        - Patients were randomized (8:5) to 1 of the following regimens for 24 weeks:
            - Fabhalta® 200mg orally twice daily
            - Continue anti-C5 treatment
    - APPOINT-PNH:
        - All patients received Fabhalta® 200mg orally twice daily for 24 weeks
- Primary Outcomes and Results:
    - APPLY-PNH:
        - Proportion of patients demonstrating:
            - Sustained increase in ≥2g/dL in Hb levels from baseline in the absence of transfusions
                - 82.3% in the Fabhalta® treated group vs. 0% anti-C5 treatment group (difference: 81.5%; 95% CI: 71.6, 91.4; P<0.0001)
            - Sustained Hb levels ≥12g/dL in the absence of transfusions
                - 67.7% in the Fabhalta® treated group vs. 0% anti-C5 treatment group (difference: 66.6%; 95% CI: 54.6, 78.6; P<0.0001)
    - APPOINT-PNH:
        - Proportion of patients achieving an increase in Hb levels from baseline ≥2g/dL in the absence of transfusions
            - 77.5% of patients treated with Fabhalta® achieved this outcome (95% CI: 61.5%, 89.2%)

- The efficacy of Fabhalta® for the treatment of IgAN was studied in a multi-center, randomized, double-blind trial, called APPLAUSE-IgAN.
    - Key Inclusion Criteria:
        - ≥18 years of age
        - Biopsy-proven IgAN

        - eGFR ≥20mL/min/1.73m^2
        - UPCR ≥1g/g
        - Stable dose of maximally tolerated RAS inhibitor therapy with or without a stable dose of a SGLT-2 inhibitor
    - Intervention:
        - Randomized 1:1 to either Fabhalta® 200mg or placebo twice daily
    - Primary Outcomes and Results:
        - Percent reduction in UPCR at 9 months relative to baseline
            - 44% in the Fabhalta® group vs. 9% in the placebo group (difference: 38%; 95% CI: 26%, 49%; P<0.0001)

Piasky® (Crovalimab-akkz) Product Summary[18]

Therapeutic Class: Complement C5 inhibitor

Indication(s): Treatment of PNH in adult and pediatric patients 13 years of age and older who weigh ≥40kg

How Supplied: 340mg/2mL in a single-dose vial for injection

Dosing and Administration:

- One loading dose administered by intravenous (IV) infusion on day 1, followed by 4 additional weekly loading doses administered by subcutaneous (sub-Q) injections on day 2, 8, 15, and 22.
- The maintenance dose should start on day 29 and is administered every 4 weeks by sub-Q injection.
- The recommended dosing is based on actual body weight (see Figure 1 below).

Figure 1: Piasky® Dosage Regimen Based on Body Weight

Body Weight	≥40kg to <100kg	≥100kg
Loading Dose		
Day 1	1,000mg (IV)	1,500 mg (IV)
Day 2, 8, 15, 22	340mg (sub-Q)	340mg (sub-Q)
Maintenance Dose		
Day 29 & every 4 weeks after	680mg (sub-Q)	1,020mg (sub-Q)

IV = intravenous; sub-Q = subcutaneous

Efficacy: The efficacy of Piasky® in patients with PNH was studied in COMMODORE 2, a Phase 3, randomized, active-controlled, open-label, non-inferiority trial.

- Key Inclusion Criteria:
    - Actual body weight ≥40kg at screening
    - LDH level ≥2 x ULN at screening
    - ≥1 or more PNH-related signs or symptoms in the past 3 months

    - Not previously treated with a complement inhibitor
- Intervention:
    - 204 patients were randomized in a 2:1 ratio to receive either Piasky® or Soliris® (eculizumab)
    - Additionally, 6 pediatric patients (aged >12 years and body weight ≥40kg) received Piasky® as a separate non-randomized cohort.
- Primary Outcomes and Results:
    - Percentage of patients who achieved transfusion avoidance from baseline through week 25
        - 65.7% in the Piasky® group vs. 68.1% in the Soliris® group (difference: -2.8%; 95% CI: -15.7, 11.1)
    - Percentage of patients with hemolysis control (as measured by the mean proportion of patients with LDH ≤1.5 x ULN) from week 5 through week 25
        - 79.3% in the Piasky® group vs. 79.0% in the Soliris® group (odds ratio: 1.02; 95% CI: 0.57, 1.82)

Voydeya™ (Danicopan) Product Summary[19]

Therapeutic Class: Complement factor D inhibitor

Indication(s): Add-on therapy to ravulizumab or eculizumab for the treatment of EVH in adults with PNH

- **Limitation(s) of Use**: Voydeya™ has not been shown to be effective as monotherapy and should only be prescribed as an add-on to ravulizumab or eculizumab.

How Supplied: 50mg and 100mg tablets

Dosing and Administration:

- 150mg 3 times a day orally, with or without food.
- Based on clinical response, may increase to 200mg 3 times daily.

Efficacy: The efficacy of Voydeya™ as add-on therapy to ravulizumab or eculizumab was studied in a multiple-region, randomized, double-blind Phase 3 trial, ALXN2040-PNH-301.

- Key Inclusion Criteria:
    - ≥18 years of age
    - Diagnosis of PNH with clinically significant EVH defined as anemia (Hb ≤9.5g/dL) with absolute reticulocyte count ≥120 x 10^9/L with or without transfusion support
    - On a stable dose of ravulizumab or eculizumab for at least the previous 6 months

- Intervention:
  - 63 patients were randomized in a 2:1 ratio for 12 weeks to receive Voydeya™ or placebo in addition to background ravulizumab or eculizumab treatment.
- Primary Outcome and Results:
  - Mean change from baseline to week 12 in Hb level
    - 2.9g/dL in Voydeya™ group vs. 0.5g/dL in the placebo group (difference: 2.4; 95% CI: 1.7, 3.2; P<0.0007)

Cost Comparison: PNH Therapies

Medication	Cost Per Unit	Cost Per Year
Fabhalta® (iptacopan) 200mg capsule	**$776.03**	**$558,741.60α**
Voydeya™ (danicopan) 100mg tablet	**$30.60**	**$66,096.00β**
Piasky® (crovalimab-akkz) 340mg/2mL	**$8,845.00**	**$459,940.00+**
Empaveli® (pegcetacoplan) 1,080mg/20mL	$242.95	$505,336.00*
Soliris® (eculizumab) 300mg/30mL	$217.43	$508,786.20±
Ultomiris® (ravulizumab-cwvz) 1,100mg/11mL	$2,177.36	$502,970.16∞

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
Unit = capsule, mL, or tablet
αCost based on the FDA approved dose of 200mg twice daily.
βCost based on the FDA approved maximum dose of 200mg 3 times daily.
+Cost based on the FDA approved maintenance dose of 680mg sub-Q every 4 weeks for patients weighing ≥40kg to <100kg.
*Cost based on the FDA approved dose of 1,080mg twice weekly.
±Cost based on the FDA approved maintenance dose of 900mg every 2 weeks.
∞Cost based on the FDA approved maintenance dose of 3,300mg every 8 weeks for patients weighing >60kg to <100kg.

Cost Comparison: IgAN Therapies

Medication	Cost Per Unit	Cost Per Year
Fabhalta® (iptacopan) 200mg capsule	**$776.03**	**$558,741.60α**
Tarpeyo® (budesonide delayed-release) 4mg capsule	$148.75	$160,650.00β

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
Unit = capsule or tablet
αCost based on the FDA approved dose of 200mg twice daily.
βCost based on the FDA approved dose of 16mg orally once daily for a duration of 9 months.

Recommendations

The College of Pharmacy recommends the prior authorization of Fabhalta® (iptacopan), Piasky® (crovalimab-akkz), and Voydeya™ (danicopan) with the following criteria (shown in red):

Fabhalta® (Iptacopan) Approval Criteria [Immunoglobulin A Nephropathy (IgAN) Diagnosis]:

1. An FDA approved indication to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression; and
2. The diagnosis of primary IgAN must be confirmed by the following:
   a. Kidney biopsy; and
   b. Secondary causes of IgAN have been ruled out (i.e., IgA vasculitis; IgAN secondary to virus, inflammatory bowel disease, autoimmune disease, or liver cirrhosis; IgA-dominant infection-related glomerulonephritis); and
3. Member must be 18 years of age or older; and
4. Must be prescribed by a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
5. Member must be at risk of disease progression as demonstrated by proteinuria ≥0.5g/day; and
6. Member must be on a stable dose of a maximally tolerated angiotensin convert enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB), unless contraindicated or intolerant; and
7. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Fabhalta® (Iptacopan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Fabhalta® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber and pharmacy must be enrolled in the Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
5. For members switching from Soliris® (eculizumab) to Fabhalta®, the prescriber must verify the member will start Fabhalta® no later than 1 week after the last dose of Soliris®; and
6. For members switching from Ultomiris® (ravulizumab-cwvz) to Fabhalta®, the prescriber must verify the member will start Fabhalta® no later than 6 weeks after the last dose of Ultomiris®; and
7. Member must not be receiving Fabhalta® in combination with another complement inhibitor used to treat PNH (i.e., Empaveli®, Piasky®, Soliris®, Ultomiris®, Voydeya®); and

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

Piasky® (Crovalimab-akkz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 13 years of age or older and must weigh ≥40kg; and
3. Piasky® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Piasky® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from another C5 inhibitor (i.e., Soliris® or Ultomiris®), the prescriber must verify the first intravenous (IV) loading dose of Piasky® will be administered no sooner than the time of the next scheduled C5 inhibitor dose and member will be monitored for Type III hypersensitivity reactions; and
7. Member must not be receiving Piasky® in combination with another complement inhibitor used to treat PNH (i.e., Empaveli®, Fabhalta®, Soliris®, Ultomiris®, Voydeya®); and
8. A quantity limit override for the loading dose will be approved upon meeting Piasky® approval criteria. A quantity limit of 6mL per 28 days will apply for the maintenance dose; 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 approvals will be for 1 year.

Voydeya™ (Danicopan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Voydeya™ must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Member must have been treated with Soliris® (eculizumab) or Ultomiris® (ravulizumab-cwvz) for at least the previous 6 months; and
5. Prescriber must verify member is experiencing clinically significant extravascular hemolysis (EVH) while on Soliris® or Ultomiris®; and
6. Member must remain on treatment with Soliris® or Ultomiris® while on Voydeya™; and

7. Member must not be receiving Voydeya® in combination with another complement protein C3 inhibitor (i.e., Empaveli®) or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Voydeya™ Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment through therapy; and
10. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy recommends the addition of prior authorization criteria for Ultomiris® (ravulizumab) for a diagnosis of NMOSD and for Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) for a diagnosis of CIDP based on the new FDA approved indications with the following criteria (shown in red):

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 1 relapse in the last 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Ultomiris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
8. Member must not be receiving Ultomiris® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Soliris®, Uplizna®); 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 approvals will be for 1 year.

Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Approval Criteria [Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Diagnosis]:

1. An FDA approved diagnosis of CIDP; and

2. Member must be 18 years of age or older; and
3. Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
4. Member must have previously failed treatment with intravenous immunoglobulin (IVIG) or a patient specific, clinically significant reason why the member cannot use intravenous immunoglobulin (IVIG) must be provided; and
5. Initial approvals will be for 12 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy also recommends the prior authorization of Bkemv™ (eculizumab-aeeb) and Epysqli® (eculizumab-aagh) with criteria similar to the Soliris® (eculizumab) approval criteria for aHUS, gMG, and PNH with the following additional criteria (changes shown in red):

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
3. Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS;
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of Bkemv™ or Epysqli®, a patient-specific, clinically significant reason why the member cannot use Soliris® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
7. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement inhibitor used to treat aHUS (i.e., Ultomiris®); and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
3. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
4. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet 1 of the following:
    a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
    b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG); and
6. Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
7. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
8. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. For use of Bkemv™ or Epysqli®, a patient-specific, clinically significant reason why the member cannot use Soliris® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
10. Use of Bkemv™, Epysqli®, or Soliris® will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and
11. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo) or another complement inhibitor used to treat gMG (i.e., Ultomiris®, Zilbrysq®); and
12. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Bkemv™ (Eculizumab-aeeb), Epysqli® (Eculizumab-aagh), and Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Bkemv™, Epysqli®, or Soliris® must be prescribed by, or in consultation with, a ~~gastroenterologist, geneticist,~~ hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Bkemv™, Epysqli®, or Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For use of Bkemv™ or Epysqli®, a patient-specific, clinically significant reason why the member cannot use Soliris® must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products; and
7. Member must not be receiving Bkemv™, Epysqli®, or Soliris® in combination with another complement protein C5 inhibitor (i.e., Piasky®, Ultomiris®), complement protein C3 inhibitor (i.e., Empaveli®), or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Additionally, the College of Pharmacy recommends the following change to the Empaveli® (pegcetacoplan) and Ultomiris® (ravulizumab-cwvz) PNH approval criteria based on the new FDA approvals and to be consistent with clinical practice (changes shown in red):

Empaveli® (Pegcetacoplan) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Empaveli® must be prescribed by, or in consultation with, a ~~gastroenterologist,~~ hematologist, oncologist, ~~geneticist,~~ or a specialist with expertise in the treatment of PNH; and
4. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and

5. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
7. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®; and
8. Member must not be receiving Empaveli® in combination with another complement inhibitor used to treat PNH (i.e., Fabhalta®, Piasky®, Soliris®, Ultomiris®, Voydeya®); 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 approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be:
   a. 1 month of age or older for the intravenous (IV) formulation; or
   b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Ultomiris® must be prescribed by, or in consultation with, a ~~gastroenterologist, geneticist~~, hematologist, oncologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
7. Member must not be receiving Ultomiris® in combination with another complement protein C5 inhibitor (i.e., Piasky®, Soliris®), complement protein C3 inhibitor (i.e., Empaveli®), or complement factor B inhibitor (i.e., Fabhalta®) used to treat PNH; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends the following changes to the Enspryng® (satralizumab-mwge), Rystiggo® (rozanolixizumab-noli), Soliris®

(eculizumab), Ultomiris® (ravulizumab-cwvz), Uplizna® (inebilizumab-cdon), Veopoz® (pozelimab-bbfg), Vyvgart® (efgartigimod Alfa-fcab), Vyvgart® Hytrulo (efgartigimod alfa/Hyaluronidase-qvfc), and Zilbrysq® (zilucoplan) approval criteria to be consistent with clinical practice (changes shown in red):

Enspryng® (Satralizumab-mwge) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and
5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Enspryng® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
8. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
9. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
10. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
11. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
12. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and
13. Member must not be receiving Enpsryng® in combination with other immunomodulators to treat NMOSD (i.e., Soliris®, Ultomiris®, Uplizna®); and
14. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
15. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Rystiggo® (Rozanolixizumab-noli) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies or anti-muscle-specific tyrosine kinase (MuSK) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IVa; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥3 (with at least 3 points from non-ocular symptoms); and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Rystiggo® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Rystiggo® in combination with a complement inhibitor (i.e., Soliris®, Ultomiris®, Zilbrysq®) or with another neonatal Fc receptor blocker used to treat gMG (i.e., Vyvgart®, Vyvgart® Hytrulo); and
9. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Soliris® (Eculizumab) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 2 NMOSD attacks in last 12 months or 3 attacks in the last 24 months, with at least 1 attack in the past 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Soliris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
7. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and

8. Member must not be receiving Soliris® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Ultomiris®, Uplizna®); 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 approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Member must be:
   a. 1 month of age or older for the intravenous (IV) formulation; or
   b. 18 years of age or older for the subcutaneous (sub-Q) formulation; and
3. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
4. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS; and
5. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
6. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. For the sub-Q formulation, prescriber must verify the member or caregiver has been trained by a health care provider on the proper administration and storage of Ultomiris®; and
8. Member must not be receiving Ultomiris® in combination with another complement inhibitor used to treat aHUS (i.e., Soliris®); 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 approvals will be for 1 year.

Ultomiris® (Ravulizumab-cwvz) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and

6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Ultomiris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. The subcutaneous (sub-Q) formulation of Ultomiris® will not be approved for a diagnosis of gMG; and
11. Member must not be receiving Ultomiris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo) or another complement inhibitor used to treat gMG (i.e., Soliris®, Zilbrysq®); and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Uplizna® (Inebilizumab-cdon) Approval Criteria [Neuromyelitis Optica Spectrum Disorder (NMOSD) Diagnosis]:

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and
5. Uplizna® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and

9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
15. Member must not be receiving Uplizna® in combination with other immunomodulators to treat NMOSD (i.e., Enspryng®, Soliris®, Ultomiris®); and
16. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
17. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Veopoz® (Pozelimab-bbfg) Approval Criteria [CD55-Deficient Protein-Losing Enteropathy (PLE) Diagnosis]:

1. An FDA approved diagnosis of CD55-deficient PLE confirmed by all of the following:
   a. Genetic testing identifying biallelic pathogenic mutations in the *CD55* gene (results of genetic testing must be submitted); and
   b. A history of PLE; and
2. Member has active disease defined by hypoalbuminemia (serum albumin concentration ≤3.2g/dL) with 1 or more of the following signs or symptoms within the last 6 months: abdominal pain, diarrhea, peripheral edema, or facial edema; and
3. Member must be 1 year of age or older; and
4. Prescriber must verify the member has received the meningococcal vaccine 2 weeks prior to treatment unless urgent treatment is needed; and

5. Veopoz® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or other specialist with expertise in the treatment of CD55-deficient PLE; and
6. The prescriber must verify that Veopoz® will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. 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 as indicated by a normalization of serum albumin or documentation of a positive clinical response to therapy. Subsequent approvals will be for 1 year.

Vyvgart® (Efgartigimod Alfa-fcab) and Vyvgart® Hytrulo (Efgartigimod alfa/Hyaluronidase-qvfc) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥5; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Vyvgart® or Vyvgart® Hytrulo must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Member must not be receiving Vyvgart® or Vyvgart® Hytrulo in combination with a complement inhibitor (i.e., Soliris®, Ultomiris®, Zilbrysq®) or with another neonatal Fc receptor blocker used to treat gMG (i.e., Rystiggo®); and
9. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Zilbrysq® (Zilucoplan) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and

3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Zilbrysq® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber and pharmacy must be enrolled in the Zilbrysq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. Member must not be receiving Zilbrysq® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo) or another complement inhibitor used to treat gMG (i.e., Soliris®, Ultomiris®); and
11. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Zilbrysq®; and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

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[1] Novartis. Novartis Receives FDA Approval for Fabhalta® (Iptacopan), Offering Superior Hemoglobin Improvement in the Absence of Transfusions as the First Oral Monotherapy for Adults with PNH. Available online at: https://www.novartis.com/news/media-releases/novartis-receives-fda-approval-fabhalta-iptacopan-offering-superior-hemoglobin-improvement-absence-transfusions-first-oral-monotherapy-adults-pnh. Issued 12/06/2023. Last accessed 01/08/2025.

[2] AstraZeneca. Voydeya™ Approved in the U.S. as Add-on Therapy to Ravulizumab or Eculizumab for Treatment of Extravascular Haemolysis in Adults with the Rare Disease PNH. Available online at: https://www.astrazeneca.com/media-centre/press-releases/2024/voydeya-approved-in-us.html. Issued 04/01/2024. Last accessed 01/08/2025.

[3] AstraZeneca. Ultomiris® Approved in the U.S. for the Treatment of Adults with Neuromyelitis Optica Spectrum Disorder (NMOSD). Available online at: https://www.astrazeneca.com/media-centre/press-releases/2024/ultomiris-approved-in-the-us-for-nmosd.html#. Issued 03/25/2024. Last accessed 01/08/2025.
[4] Pittock S, Barnett M, Bennett J, et al. Ravulizumab in Aquaporin-4-Positive Neuromyelitis Optica Spectrum Disorder. *Ann Neurol* 2023; 93:1053–1068. doi: 10.1002/ana.26626.
[5] Ultomiris® (Ravulizumab-cwvz) Prescribing Information. Alexion Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761108s036lbl.pdf. Last revised 06/2024. Last accessed 01/08/2025.
[6] U.S. Food and Drug Administration (FDA). FDA Approves First Interchangeable Biosimilar for Two Rare Diseases. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-two-rare-diseases. Issued 05/28/2024. Last accessed 01/08/2025.
[7] Bkemv™ (Eculizumab-aeeb) Prescribing Information. Amgen, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761333s000lbl.pdf. Last revised 05/2024. Last accessed 01/08/2025.
[8] Argenx. Argenx Announces FDA Approval of Vyvgart® Hytrulo for Chronic Inflammatory Demyelinating Polyneuropathy. Available online at: https://www.argenx.com/news/argenx-announces-fda-approval-vyvgart-hytrulo-chronic-inflammatory-demyelinating-polyneuropathy. Issued 06/21/2024. Last accessed 01/08/2025.
[9] Vyvgart® Hytrulo (Efgartigimod-alfa and Hyaluronidase-qvfc) Prescribing Information. Argenx US, Inc. Available online at: https://www.argenx.com/product/vyvgart-hytrulo-prescribing-information.pdf. Last revised 08/2024. Last accessed 01/08/2025.
[10] OptumRx®. Piasky® (Crovalimab-akkz)—New Orphan Drug Approval. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-recalls-shortages/drugapproval_piasky_2024-0624.pdf. Issued 06/20/2024. Last accessed 01/08/2025.
[11] Samsung Bioepis Co., Ltd. FDA Approves Samsung Bioepis' Epysqli® (Eculizumab-aagh) as a Biosimilar to Soliris® (Eculizumab). *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2024/07/22/2916428/0/en/FDA-Approves-Samsung-Bioepis-EPYSQLI-eculizumab-aagh-as-a-Biosimilar-to-Soliris-eculizumab.html. Issued 07/22/2024. Last accessed 01/08/2025.
[12] Epysqli® (Eculizumab-aagh) Prescribing Information. Samsung Bioepis Co., Ltd. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761340s000lbl.pdf. Last revised 07/2024. Last accessed 01/08/2025.
[13] Novartis. Novartis Receives FDA Accelerated Approval for Fabhalta® (Iptacopan), the First and Only Complement Inhibitor for the Reduction of Proteinuria in Primary IgA Nephropathy (IgAN). Available online at: https://www.novartis.com/news/media-releases/novartis-receives-fda-accelerated-approval-fabhalta-iptacopan-first-and-only-complement-inhibitor-reduction-proteinuria-primary-iga-nephropathy-igan. Issued 08/08/2024. Last accessed 01/08/2025.
[14] Kidney Diseases: Improving Global Outcomes (KDIGO). KDIGO 2024 Clinical Practice Guidelines for the Management of Immunoglobin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Available at: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2024-IgAN-IgAV-Guideline-Public-Review-Draft.pdf. Issued 08/2024. Last accessed 01/08/2025.
[15] Bkemv™ (Eculizumab-aeeb) Prescribing Information. Amgen, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761333s001lbl.pdf. Last revised 10/2024. Last accessed 01/08/2025.
[16] Epysqli® (Eculizumab-aagh) Prescribing Information. Samsung Bioepis Co., Ltd. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761340s003lbl.pdf. Last revised 11/2024. Last accessed 01/08/2025.
[17] Fabhalta® (Iptacopan) Prescribing Information. Novartis. Available online at: https://www.novartis.com/us-en/sites/novartis_us/files/fabhalta.pdf. Last revised 08/2024. Last accessed 01/08/2025.
[18] Piasky® (Crovalimab-akkz) Prescribing Information. Genentech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761388s000lbl.pdf. Last revised 06/2024. Last accessed 01/08/2025.
[19] Voydeya™ (Danicopan) Prescribing Information. Alexion Pharmaceuticals, Inc. Available online at: https://alexion.com/Documents/VOYDEYA_USPI.pdf. Last revised 03/2024. Last accessed 01/08/2025.

Appendix H

Vote to Prior Authorize Labetalol Hydrochloride 400mg Tablet, Nexiclon™ XR [Clonidine Extended-Release (ER)], and Tryvio™ (Aprocitentan) and Update the Approval Criteria for the Antihypertensive Medications

Oklahoma Health Care Authority
February 2025

Market News and Updates[1,2,3]

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

- **December 2009:** Nexiclon™ XR (clonidine ER tablet) was approved for the treatment of hypertension. Per package labeling, the 0.17mg daily dose of Nexiclon™ XR is equivalent to 0.1mg twice daily of immediate release (IR) clonidine hydrochloride.
- **March 2024:** Tryvio™ (aprocitentan) tablet was approved by the FDA for the treatment of hypertension in combination with other antihypertensive drugs to lower blood pressure (BP) in patients who are not adequately controlled by other drugs.
- **November 2024:** A marketing start date of December 2, 2024, was published for labetalol hydrochloride 400mg film-coated tablets in an updated Abbreviated New Drug Application (ANDA) submitted by Appco Pharma, LLC.

Tryvio™ (Aprocitentan) Product Summary[4,5]

Therapeutic Class: Endothelin receptor antagonist (ERA)

Indication(s): Treatment of hypertension in combination with other antihypertensive drugs, to lower BP in adult patients who are not adequately controlled on other drugs

- **Boxed Warning:** Embryo-fetal toxicity
  - Tryvio™ can cause major birth defects if used by pregnant patients and is contraindicated in pregnancy.

How Supplied: 12.5mg tablet

Dosing and Administration: 12.5mg orally once daily, with or without food

Efficacy: The efficacy of Tryvio™ was supported by results from a multipart, multicenter, blinded, randomized, parallel-group Phase 3 clinical trial (PRECISION).

- Key Inclusion Criteria:
  - Uncontrolled BP despite use of ≥3 antihypertensive medications for ≥1 year (all from different pharmacologic classes for ≥4 weeks)
    - Sitting systolic blood pressure (SiSBP) ≥140mmHg at screening
- Key Exclusion Criteria:
  - Confirmed severe hypertension (grade 3)
  - Major cardiovascular (CV), renal, or cerebrovascular medical complications within the previous 6 months
  - Heart failure [New York Heart Association (NYHA) Stage III-IV]
  - N-terminal Pro B-type Natriuretic Peptide (NT-proBNP) ≥500pg/mL
  - Estimated glomerular filtration rate (eGFR) <15mL/min/1.73m^2
- Intervention(s):
  - In Part 1 of the trial, patients were randomized 1:1:1 to receive aprocitentan 12.5mg daily, aprocitentan 25mg daily, or placebo
- Primary Endpoint(s):
  - Change in SiSBP from baseline to week 4 during Part 1
- Results:
  - The least squares (LS) mean difference of -3.8 [97.5% confidence limits (CL): -6.8, -0.8); P<0.0043] indicated that the 12.5mg dose of aprocitentan was statistically superior to placebo for the primary endpoint.
  - The 25mg dose of aprocitentan did not demonstrate any additional statistically or clinically meaningful improvement in SiSBP as compared to the 12.5mg dose.

Cost: The Wholesale Acquisition Cost (WAC) of Tryvio™ is $25.83 per tablet, resulting in a cost of $774.90 per 30 days or a cost of $9,298.80 per year based on recommended dosing.

Cost Comparison: Clonidine Products

Product	Cost Per Unit	Cost Per 28 Days
Nexiclon™ XR (clonidine ER) 0.17mg tablet	**$18.30**	**$512.40***
Clonidine ER 0.17mg tablet (authorized generic)	**$12.89**	**$360.92***
clonidine 0.1mg tablet (generic)	$0.02	$1.12[+]
clonidine 0.1mg/24hr patch (generic)	$5.80	$23.20[α]

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ER = extended-release; hr = hour
Unit = tablet or patch
*Cost per day based on FDA-approved initial dosing of 0.17mg once daily
[+]Cost per day based on the FDA-approved initial dosing of 0.1mg twice daily.
[α]Cost per day based on the FDA-approved initial dosing of a 0.1mg/24hr patch applied once every 7 days

Cost Comparison: Labetalol Products

Product	Cost Per Tablet	Cost Per 30 Days
labetalol 400mg tablet (authorized generic)	**$1.89**	**$113.40***
labetalol 200mg tablet (generic)	$0.14	$16.80*

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per day based on an FDA-approved maintenance dosing regimen of 400mg twice daily.

Recommendations

The College of Pharmacy recommends the prior authorization of labetalol hydrochloride 400mg tablet, Nexiclon™ XR (clonidine ER tablet) and Tryvio™ (aprocitentan) with the following criteria (shown in red):

Labetalol Hydrochloride 400mg Tablet Approval Criteria:

1. An FDA-approved indication of the management of hypertension; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use labetalol hydrochloride 200mg tablets, which are available without prior authorization, to achieve a 400mg dose must be provided.

Nexiclon™ XR [Clonidine Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved diagnosis of hypertension; and
2. A patient-specific, clinically significant reason why the member cannot utilize clonidine immediate-release tablet and clonidine transdermal patch, which are available without a prior authorization, must be provided; and
3. Request must be for an FDA-approved once-daily dosing regimen, according to package labeling.

Tryvio™ (Aprocitentan) Approval Criteria:

1. An FDA approved diagnosis of hypertension; and
2. Member has a reported systolic blood pressure of ≥140mmHg confirmed on at least 2 separate blood pressure readings on 2 separate occasions within the last month (documentation of blood pressure readings with dates must be submitted); and
3. Prescriber must rule out other causes of elevated blood pressure including:
    a. Inaccurate readings due to faulty or inappropriate equipment (i.e., cuff size) or improper technique; and
    b. White coat hypertension; and
    c. Prescription non-adherence. Compliance with antihypertensive medications will be evaluated prior to initiation of Tryvio™; and

4. Member must be currently on at least 3 antihypertensive medications at optimal (or maximally tolerated) doses for at least 4 weeks prior to systolic blood pressure reading of ≥140mmHg; and
5. Member must have tried at least 6 different classes of medications, including a diuretic, in the past 12 months that did not yield adequate blood pressure control. Medications can include, but are not limited to, angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, or diuretics; and
6. Female members of reproductive potential must not be pregnant or breastfeeding during treatment with aprocitentan and must be willing to use an effective method of contraception during treatment and for 1 month after discontinuing aprocitentan; and
7. Female members of reproductive potential must have a negative pregnancy test prior to initiation of aprocitentan and must agree to take pregnancy tests monthly during treatment and for 1 month after discontinuing aprocitentan; and
8. Member, pharmacy, and provider must be registered under the Tryvio™ Risk Evaluation and Mitigation Strategy (REMS) program; and
9. Member must not have elevated aminotransferases >3 times the upper limit of normal (ULN) or moderate to severe hepatic impairment (Child Pugh class B or C); and
10. Prescriber must attest that they will monitor liver transaminase levels during treatment and discontinue Tryvio™ if a sustained, unexplained, clinically relevant elevation occurs or if elevations occur with an increase in bilirubin that is >2 times the ULN; and
11. Member must not have severe anemia prior to initiation of aprocitentan; and
12. A quantity limit of 30 tablets per 30 days will apply; and
13. Initial approvals will be for the duration of 3 months. After 3 months, compliance with all antihypertensive medications, including aprocitentan, will be evaluated and the provider must provide documentation that the member has had a positive response to treatment, including a decrease in blood pressure. Inadequate compliance or a lack of positive response will result in denial of continuation. Subsequent approvals will be for 1 year.

Next, the College of Pharmacy recommends moving Atacand® (candesartan) 32mg from Tier 2 to Tier 1 within the Antihypertensive Medications Product Based Prior Authorization (PBPA) category based on net costs (changes noted in red in the following tier chart):

Angiotensin I Converting Enzyme Inhibitors (ACEIs)		
Tier-1	**Tier-2**	**Special PA**
benazepril (Lotensin®)	captopril (Capoten®)	enalapril oral solution (Epaned®)
enalapril (Vasotec®)		lisinopril oral solution (Qbrelis®)
enalaprilat (Vasotec® IV)		
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
moexipril (Univasc®)		
perindopril (Aceon®)		
quinapril (Accupril®)		
ramipril (Altace®)		
trandolapril (Mavik®)		
ACEI/Hydrochlorothiazide (HCTZ) Combination Products		
Tier-1	**Tier-2**	**Special PA**
benazepril/HCTZ (Lotensin® HCT)	captopril/HCTZ (Capozide®)	fosinopril/HCTZ (Monopril-HCT®)
enalapril/HCTZ (Vaseretic®)		
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		
Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	**Tier 3**
candesartan (Atacand®)+	~~candesartan 32mg (Atacand®)~~	azilsartan (Edarbi®)
irbesartan (Avapro®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	azilsartan/chlorthalidone (Edarbyclor®)
irbesartan/HCTZ (Avalide®)	telmisartan/HCTZ (Micardis® HCT)	candesartan/HCTZ (Atacand® HCT)
losartan (Cozaar®)		eprosartan (Teveten®)
losartan/HCTZ (Hyzaar®)		eprosartan/HCTZ (Teveten® HCT)
olmesartan (Benicar®)		telmisartan/amlodipine (Twynsta®)
olmesartan/amlodipine (Azor®)		valsartan 4mg/mL oral solution
olmesartan/HCTZ (Benicar HCT®)		
telmisartan (Micardis®)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		

valsartan/amlodipine/HCTZ (Exforge® HCT)		
valsartan/HCTZ (Diovan HCT®)		
Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine oral solution (Norliqva®)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	amlodipine oral suspension (Katerzia®)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	amlodipine/celecoxib (Consensi®)
diltiazem CD (Cardizem® CD)*	isradipine (Dynacirc®, Dynacirc CR®)	diltiazem CD 360mg (Cardizem® CD)
diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene®)	levamlodipine (Conjupri®)
diltiazem XR (Dilacor® XR)	nicardipine (Cardene® SR)	
felodipine (Plendil®)	nisoldipine (Sular®)	
nifedipine (Adalat®, Procardia®)	verapamil (Covera-HS®)	
nifedipine ER (Adalat® CC)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		
verapamil (Calan®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		
ACEI/CCB Combination Products		
Tier-1	**Tier-2**	**Special PA**
Tier-1 ACEI + Tier-1 CCB	trandolapril/verapamil (Tarka®)	perindopril/amlodipine (Prestalia®)
benazepril/amlodipine (Lotrel®)		

[+]~~**All strengths other than 32mg.**~~

*All strengths other than 360mg.

CD = controlled-delivery; ER, XR, XL = extended-release; LA = long-acting; SR = sustained-release

Lastly, the College of Pharmacy recommends the following additions and changes to the Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria based on clinical practice and to clarify formulation and clinical exceptions for age restrictions in existing criteria (changes shown in red):

Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:

1. **Angiotensin I Converting Enzyme Inhibitors (ACEIs):**
    a. **Epaned® (Enalapril Solution) Approval Criteria:**
        i. An age restriction of 7 years or older will apply with the following criteria:
            1. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation in place of the oral solution formulation, even when the tablets are crushed or used to prepare an oral suspension, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and
            2. Clinical exceptions for the age restriction (younger than the FDA-approved age) may be considered; and
        ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.
    b. **Qbrelis® (Lisinopril Oral Solution) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use lisinopril oral tablets in place of the oral solution formulation, even when the tablets are crushed, must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and
        ii. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.
2. **ACEI/Hydrochlorothiazide (HCTZ) Combination Products:**
    a. **Monopril-HCT® (Fosinopril/HCTZ) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided.
3. **Calcium Channel Blockers (CCBs):**
    a. **Cardizem® CD (Diltiazem CD 360mg Capsules) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use (2) 180mg Cardizem® CD (diltiazem CD) capsules must be provided.
    b. **Conjupri® (Levamlodipine Tablets) Approval Criteria:**
        i. A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets, which are available without prior authorization, must be provided.
    c. **Consensi® (Amlodipine/Celecoxib Tablets) Approval Criteria:**

i. A patient-specific, clinically significant reason why the member cannot use the individual components separately, which are available without prior authorization, must be provided; and
ii. A quantity limit of 30 tablets per 30 days will apply.

d. Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine Oral Solution) Approval Criteria:

i. An FDA approved diagnosis of 1 of the following:
1. Hypertension in adults and pediatric members 6 years of age and older; or
2. Coronary artery disease; or
3. Chronic stable angina; or
4. Vasospastic angina; and

ii. A patient specific, clinically significant reason why the member cannot use amlodipine oral tablets, even when the tablets are crushed, must be provided; and
iii. Clinical exceptions for age restrictions may be considered for doses stabilized inpatient or for clinically indicated doses that cannot be achieved by splitting available tablet formulations; and
iv. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
v. A quantity limit of 300mL per 30 days will apply.

4. ACEI/CCB Combination Products:

a. Prestalia® (Perindopril/Amlodipine) Approval Criteria:

i. An FDA approved diagnosis; and
ii. Documented trials of inadequate response to 2 Tier-1 angiotensin I converting enzyme inhibitors (ACEIs) in combination with amlodipine; and
iii. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided; and
iv. A quantity limit of 30 tablets per 30 days will apply.

CaroSpir® (Spironolactone Oral Suspension) Approval Criteria:

1. An FDA approved indication; and
2. A patient-specific, clinically significant reason why the member cannot use spironolactone oral tablets must be provided, including, but not limited to the following:
   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. Dose was stabilized inpatient; and
3. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request.

Sotylize® (Sotalol Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of life-threatening ventricular arrhythmias or for the maintenance of normal sinus rhythm in members with highly symptomatic atrial fibrillation/flutter; and
2. A patient-specific, clinically significant reason why the member cannot use sotalol oral tablets in place of the oral solution formulation must be provided (e.g., dose was stabilized inpatient, clinically indicated dose cannot be achieved by splitting available tablet formulations); and
3. For pediatric members, a recent weight or body surface area (BSA) must be provided on the prior authorization request; and
4. A quantity limit of 64mL per day or 1,920mL per 30 days will apply.

Valsartan 4mg/mL Oral Solution Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Hypertension in adults and pediatric members 6 years of age and older; or
   b. Heart failure; or
   c. Post-myocardial infarction; and
2. A patient specific, clinically significant, reason why the member cannot use valsartan tablets or the oral suspension prepared from the tablets must be provided (i.e., dose was stabilized inpatient); and
3. For members who require weight-based dosing, the member's recent weight must be provided on the prior authorization request; and
4. A quantity limit of 360mL per 36 days will apply.

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[1] Nexiclon™ XR (Clonidine) Extended-Release Tablets Prescribing Information. Athena. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022500s001lbl.pdf. Last revised 09/23/2010. Last accessed 01/08/2025.

[2] Indorsia Pharmaceuticals U.S., Inc. U.S. FDA Approves Idorsia's Once-Daily Tryvio™ (Aprocitentan) - The First and Only Endothelin Receptor Antagonist for The Treatment of High Blood Pressure Not Adequately Controlled in Combination with Other Antihypertensives. *PRNewswire*. Available online at: https://www.prnewswire.com/news-releases/us-fda-approves-idorsias-once-daily-tryvio-aprocitentan--the-first-and-only-endothelin-receptor-antagonist-for-the-treatment-of-high-blood-pressure-not-adequately-controlled-in-combination-with-other-antihypertensives-302094474.html. Issued 03/20/2024. Last accessed 01/08/2025.

[3] Labetalol Hydrochloride Tablet, Film Coated Prescribing Information. U.S. National Library of Medicine: DailyMed. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=27e4ab03-c17b-4268-912c-e45a5e8f8dd8. Last revised 11/19/2024. Last accessed 01/08/2025.

[4] Tryvio™ (Aprocitentan) Prescribing Information. Idorsia Pharmaceuticals U.S., Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217686s000lbl.pdf. Last revised 03/19/2024. Last accessed 01/08/2025.

[5] Danaietash P, Verweij, P, Wang J, et. al. Identifying and Treating Resistant Hypertension in PRECISION: A Randomized Long-Term Clinical Trial with Aprocitentan. *J Clin Hypertens*. 2022; 24(7):804-813. doi: 0.1111/jch.14517.

Appendix I

Vote to Prior Authorize Acthar® Gel SelfJect™ (Repository Corticotropin Auto-Injector) and Purified Cortrophin® Gel (Repository Corticotropin Injection) and Update the Approval Criteria for the Adrenocorticotropic Hormone (ACTH) Products

Oklahoma Health Care Authority
February 2025

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

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

- **November 2021:** The FDA approved a supplemental New Drug Application (sNDA) for Purified Cortrophin® Gel (repository corticotropin injection) for all indications of Acthar® Gel except infantile spasms. Purified Cortrophin® Gel is supplied as 1mL and 5mL multi-dose vials (80units/mL) for subcutaneous (sub-Q) or intramuscular injection.
- **March 2024:** Mallinckrodt announced the FDA approval of an sNDA for Acthar® Gel SelfJect™ (repository corticotropin injection) in February 2024 for use in all indications of Acthar® Gel except infantile spasms due to the need for specific dosing based on body surface area (BSA). Acthar® Gel SelfJect™ comes as single-dose, pre-filled auto-injectors in 80units/mL or 40units/0.5mL strengths for sub-Q injection. In August 2024, Mallinckrodt also announced that Acthar® Gel SelfJect™ is available in the U.S.

Recommendations

The College of Pharmacy recommends the prior authorization of Purified Cortrophin® Gel (repository corticotropin injection) and Acthar® Gel SelfJect™ (repository corticotropin auto-injector) and recommends the following changes to the ACTH products prior authorization criteria based on the new FDA approvals, net costs, and to be consistent with clinical practice (changes shown in red):

~~**H.P. Acthar® Gel (**~~**Repository Corticotropin Injection**~~**)**~~ **Approval Criteria**:

1. An FDA approved diagnosis of infantile spasms; and
   a. Member must be 2 years of age or younger; and
   b. Must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); ~~or~~ and

c. Only the multi-dose vial will be approved. Acthar® Gel SelfJect™ auto-injector will not be approved for this indication; or

2. An FDA approved diagnosis of multiple sclerosis (MS); and
   a. Member is experiencing an acute exacerbation; and
   b. Must be prescribed by, or in consultation with, a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist) or a prescriber who specializes in MS; and
   c. Prescriber must rule out pseudo-exacerbation from precipitating factors (e.g., pain, stress, infection, premenstrual syndrome); and
   d. Symptoms of acute exacerbation last at least 24 hours; and
   e. Member must be currently stable within the last 30 days on an immunomodulator agent, unless contraindicated; and
   f. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy [e.g., intravenous (IV) methylprednisolone, IV dexamethasone, oral prednisone] must be provided; and
   g. A quantity limit of daily doses of up to 120 units for up to 3 weeks for acute exacerbation will apply; or
3. An FDA approved diagnosis of nephrotic syndrome without uremia of the idiopathic type or that is due to lupus erythematosus to induce diuresis or remission of proteinuria; and
   a. Must be prescribed by, or in consultation with, a nephrologist (or an advanced care practitioner with a supervising physician who is a nephrologist); and
   b. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy (e.g., prednisone) must be provided; or
4. An FDA approved diagnosis of the following disorders or diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; or edematous states; and
   a. Must be prescribed by or in consultation with a specialist appropriate to the member's disease state (or an advanced care practitioner with a supervising physician who is a specialist appropriate to the member's disease state); and
   b. A patient-specific, clinically significant reason why the member cannot use alternative corticosteroid therapy must be provided.; and
5. Requests for Purified Cortrophin® Gel (repository corticotropin injection) will require a patient-specific, clinically significant reason why Acthar® Gel (repository corticotropin injection) or Acthar® Gel SelfJect™ (repository corticotropin auto-injector) cannot be used.

[1] ANI Pharmaceuticals. ANI Pharmaceuticals Announces FDA Approval of Purified Cortrophin® Gel for Multiple Indications Including Multiple Sclerosis, Rheumatoid Arthritis and Nephrotic Syndrome. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20211101005292/en/ANI-Pharmaceuticals-Announces-FDA-Approval-of-Purified-Cortrophin%E2%84%A2-Gel-for-Multiple-Indications-Including-Multiple-Sclerosis-Rheumatoid-Arthritis-and-Nephrotic-Syndrome. Issued 11/01/2021. Last accessed 01/17/2025.

[2] Purified Cortrophin® Gel (Repository Corticotrophin Injection) Prescribing Information. ANI Pharmaceuticals, Inc. Available online at: https://cortrophin.com/pdfs/purified-cortrophin-gel-prescribing-information.pdf. Last revised 10/2023. Last accessed 01/17/2025.

[3] Mallinckrodt. Mallinckrodt Announces U.S. FDA Approval of Supplemental New Drug Application for Acthar® Gel (Repository Corticotropin Injection) Single-Dose Pre-filled SelfJect™ Injector. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/mallinckrodt-announces-us-fda-approval-of-supplemental-new-drug-application-for-acthar-gel-repository-corticotropin-injection-single-dose-pre-filled-selfject-injector-302077212.html. Issued 03/01/2024. Last accessed 01/17/2025.

[4] Mallinckrodt. Mallinckrodt Announces Availability of Acthar® Gel (Repository Corticotropin Injection) Single-Dose Pre-filled SelfJect™ Injector in the U.S. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/mallinckrodt-announces-availability-of-acthar-gel-repository-corticotropin-injection-single-dose-pre-filled-selfject-injector-in-the-us-302214582.html. Issued 08/06/2024. Last accessed 01/17/2025.

[5] Acthar® Gel (Repository Corticotropin Injection) Prescribing Information. Mallinckrodt. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/008372s074lbl.pdf. Last revised 02/2024. Last accessed 01/17/2025.

Appendix J

Vote to Prior Authorize Diflunisal 500mg Tablet, Dolobid™ (Diflunisal) 250mg and 375mg Tablet, and Indomethacin 50mg Suppository and Update the Approval Criteria for the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Oklahoma Health Care Authority
February 2025

Market News and Updates[1,2,3]

News:

- **June 2012:** The U.S. Food and Drug Administration (FDA) withdrew their previous approval for Celebrex® (celecoxib) for the indication to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP), as an adjunct to usual care.
- **August 2024:** New formulations of Dolobid™ (diflunisal), available as 250mg and 375mg tablets, are being marketed by INA Pharmaceutics; however, only the 250mg strength is available at this time. Diflunisal is also available generically as 500mg tablets.
- **October 2024:** IBSA Pharma, the manufacturer of Flector® (diclofenac epolamine patch) and Licart® (diclofenac epolamine patch) voluntarily ended their Federal Drug Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS). As a result, SoonerCare no longer covers any of the IBSA Pharma products per regulatory requirements. There are authorized generics available for Flector® that remain on the market, but there are no generic equivalents for Licart®.
- **December 2024:** As of December 2024, the FDA Orange Book lists Anjeso® (meloxicam injection), Dyloject™ (diclofenac sodium injection), Qmiiz ODT™ [meloxicam orally disintegrating tablet (ODT)], Tivorbex® (indomethacin), and Zorvolex® (diclofenac) as discontinued products. Additionally, there are no generic equivalents for these products.

Dolobid™ (Diflunisal) Product Summary[4]

Therapeutic Class: NSAID

Indication(s): Acute or long-term use for symptomatic treatment of mild to moderate pain, osteoarthritis, or rheumatoid arthritis

How Supplied: 250mg and 375mg oral tablets

Dosing and Administration:

- For mild to moderate pain, an initial dose of 1,000mg followed by 500mg every 12 hours is recommended for most patients. Following the initial dose, some patients may require 500mg every 8 hours.
- A lower dosage may be appropriate depending on such factors as pain severity, patient response, weight, or advanced age; for example, 500mg initially followed by 250mg every 8 to 12 hours.
- For osteoporosis and rheumatoid arthritis, the suggested dosage range is 500mg to 1,000mg daily in 2 divided doses. The dosage may be increased or decreased according to patient response. Maintenance doses higher than 1,500mg per day are not recommended.
- The tablets should be swallowed whole, not crushed or chewed.

Cost Comparison:

Product	Cost Per Unit	Cost Per 30 Days	Cost Per Year
Dolobid™ (diflunisal) 250mg tablet	**$41.75**	**$5,010.00***	**$60,120.00**
diflunisal 500mg tablet (generic)	**$0.84**	**$50.40***	**$604.80**
celecoxib 200mg capsule (generic)	$0.09	$5.40[+]	$64.80
diclofenac sodium 75mg tablet (generic)	$0.08	$4.80[Δ]	$57.60
ibuprofen 800mg tablet (generic)	$0.06	$5.40[§]	$64.80
meloxicam 15mg tablet (generic)	$0.02	$0.60[±]	$7.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost based on use of 500mg twice daily
[+]Cost based on use of 200mg twice daily
[Δ]Cost based on use of 75mg twice daily
[§]Cost based on use of 800mg 3 times daily
[±]Cost based on use of 15mg once daily
Unit = Each capsule or tablet
Please note: Cost is not yet available for the Dolobid™ 375mg tablet.

Cost Comparison: Indomethacin Products

Product	Cost Per Unit	Cost Per Day*	Cost Per Month
indomethacin 50mg suppository (generic)	**$343.81**	**$1,031.43**	**$30,942.90**
indomethacin 25mg/5mL suspension (generic)	$7.99	$239.70	$7,191.00
indomethacin 50mg capsule (generic)	$0.11	$0.33	$9.90

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 based on a total daily dose of 150mg
Unit = Each capsule, mL, or suppository

Recommendations

The College of Pharmacy recommends the following changes to the NSAIDs Product Based Prior Authorization (PBPA) category based on net cost and

the additional factors noted below (changes noted in red in the following PBPA Tier chart and approval criteria):

1. Prior authorization and placement of Dolobid™ (diflunisal) 250mg tablet and 375mg tablet into the Special PA Tier with the additional criteria listed below; and
2. Prior authorization and placement of diflunisal 500mg tablet into Tier-2; and
3. Prior authorization and placement of Indocin® (indomethacin) suppository into the Special PA Tier; and
4. Removing the brand preferred status for Flector® (diclofenac epolamine patch) and moving the authorized generics to the Special PA Tier; and
5. Moving Ansaid® (flurbiprofen) and EC-Naprosyn® (naproxen) 500mg tablet from Tier-1 to Tier-2; and
6. Moving Tolectin® (tolmetin) from Tier-2 to the Special PA Tier; and
7. Moving Cataflam® (diclofenac potassium) and Lodine® (etodolac) 200mg capsule and 300mg capsule from Tier-2 to Tier-1; and
8. Moving Indocin® SR (indomethacin extended-release capsule) and Ponstel® (mefenamic acid) from the Special PA Tier to Tier-2; and
9. Moving Celebrex® (celecoxib) 400mg capsule from the Special PA Tier to Tier-1 and removing the unique approval criteria for the 400mg strength based on the FDA's withdrawal of the FAP indication and net cost; and
10. Removing Anjeso® (meloxicam injection), Dyloject™ (diclofenac sodium injection), Licart® (diclofenac epolamine patch), Qmiiz ODT™ [meloxicam orally disintegrating tablet (ODT)], Tivorbex® (indomethacin), and Zorvolex® (diclofenac) based on product discontinuations or lack of manufacturer rebate participation.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
celecoxib (Celebrex®) ~~**50mg, 100mg, & 200mg**~~ caps	diclofenac ER (Voltaren® XR)	~~**celecoxib (Celebrex®) 400mg caps**~~
~~**diclofenac epolamine (Flector® Patch) – Brand Preferred**~~	~~**diclofenac potassium (Cataflam®)**~~	celecoxib (Elyxyb®) oral solution
diclofenac potassium (Cataflam®)	diclofenac sodium/ misoprostol (Arthrotec®)	~~**diclofenac (Zorvolex®)**~~
diclofenac sodium (Voltaren®) 50mg & 75mg tabs	diclofenac sodium (Voltaren®) 25mg tabs	**diclofenac epolamine (generic Flector® Patch)**
diclofenac sodium 1% (Voltaren® Gel)	**diflunisal 500mg tabs**	~~**diclofenac epolamine (Licart®) topical system**~~
etodolac (Lodine®) ~~**400mg & 500mg tabs**~~	~~**etodolac (Lodine®) 200mg & 300mg caps**~~	diclofenac potassium (Cambia®) powder pack

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)		
Tier-1	**Tier-2**	**Special PA**
~~**flurbiprofen (Ansaid®)**~~	etodolac ER (Lodine® XL)	diclofenac potassium (Lofena™) tabs
ibuprofen (Motrin®)	**flurbiprofen (Ansaid®)**	diclofenac potassium (Zipsor®) caps
indomethacin (Indocin®) caps	**indomethacin (Indocin® SR) ER caps**	~~**diclofenac sodium (Dyloject™) inj**~~
meloxicam (Mobic®)	**mefenamic acid (Ponstel®)**	diclofenac sodium (Pennsaid®) topical drops
nabumetone (Relafen®)	**naproxen DR (EC-Naprosyn®) 500mg tab**	**diflunisal (Dolobid™) 250mg and 375mg tabs**
naproxen* (Naprosyn®)	naproxen sodium (Anaprox®) 275mg & 550mg tabs	fenoprofen (Nalfon®)
naproxen DR (EC-Naprosyn®) **375mg tab**	oxaprozin (Daypro®)	ibuprofen (Caldolor®) inj
sulindac (Clinoril®)	piroxicam (Feldene®)	ibuprofen/acetaminophen (Combogesic® IV) inj+
	~~**tolmetin (Tolectin®)**~~	ibuprofen/famotidine (Duexis®)
		indomethacin (Indocin®) **supp &** susp ~~**& ER caps**~~
		~~**indomethacin (Tivorbex®)**~~
		ketoprofen (Orudis®) caps
		ketoprofen ER (Oruvail®)
		ketorolac tromethamine (Sprix®) nasal spray
		meclofenamate (Meclomen®)
		~~**mefenamic acid (Ponstel®)**~~
		~~**meloxicam (Anjeso®) inj+**~~
		meloxicam (Vivlodex®) caps
		~~**meloxicam ODT (Qmiiz ODT™)**~~
		nabumetone 1,000mg (Relafen DS®)
		naproxen sodium ER (Naprelan®)
		naproxen/esomeprazole (Vimovo®)
		tolmetin (Tolectin®)

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
*Naproxen oral suspension is available without prior authorization for members 12 years of age and younger. Members older than 12 years of age require a reason why a special formulation product is needed in place of the regular tablet formulation.
+Unique criteria applies.
caps = capsules; DR = delayed-release; ER = extended-release; EC = enteric-coated; inj = injection; ODT = orally disintegrating tablet; PA = prior authorization; supp = suppository; susp = suspension; tabs = tablets

NSAIDs Special Prior Authorization (PA) Approval Criteria:

1. A unique indication for which a Tier-1 or Tier-2 medication is not appropriate; or
2. Previous use of at least 2 Tier-1 NSAID products (from different product lines); and
3. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 product; and
4. ~~Additionally, use of Celebrex® (celecoxib) 400mg capsules will require a diagnosis of Familial Adenomatous Polyposis (FAP) and a patient-specific, clinically significant reason why the member cannot use 2 celecoxib 200mg capsules to achieve a 400mg dose; and~~
5. Additionally, use of Dolobid™ (diflunisal) 250mg or 375mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic diflunisal 500mg tablets; and
6. Additionally, use of Elyxyb® (celecoxib oral solution) will require a diagnosis of acute migraine treatment in adults 18 years of age and older and a patient-specific, clinically significant reason why the member cannot use Cambia® (diclofenac potassium powder); and
7. Additionally, use of Lofena™ (diclofenac potassium) will require a patient-specific, clinically significant reason why the member cannot use all other available generic diclofenac products. ~~; and~~
8. ~~Additionally, use of Tivorbex® will require a patient-specific, clinically significant reason why the member cannot use all other available generic indomethacin products.~~

~~**Anjeso® (Meloxicam Injection) Approval Criteria:**~~

1. ~~An FDA approved diagnosis of management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics; and~~
2. ~~Member must be 18 years of age or older; and~~
3. ~~Member must be well hydrated before Anjeso® administration to reduce the risk of renal toxicity; and~~
4. ~~Anjeso® should be used for the shortest duration consistent with individual patient treatment goals; and~~
5. ~~A patient-specific, clinically significant reason the member cannot use oral meloxicam tablets or other Tier-1 NSAID products must be provided; and~~
6. ~~A quantity limit of 3 vials per 3 days will apply; and~~
7. ~~For consideration of a longer duration of use, a patient-specific, clinically significant reason why the member cannot transition to an oral Tier-1 NSAID product must be provided, along with the anticipated duration of treatment.~~

[1] Federal Register. Pfizer, Inc.; Withdrawal of Approval of Familial Adenomatous Polyposis Indication for Celebrex®. Available online at: https://www.federalregister.gov/documents/2012/06/08/2012-13900/pfizer-inc-withdrawal-of-approval-of-familial-adenomatous-polyposis-indication-for-celebrex. Issued 06/08/2012. Last accessed 01/17/2025.
[2] U.S. Food and Drug Administration (FDA). National Drug Code Directory. Available online at: https://dps.fda.gov/ndc. Last accessed 01/17/2025.
[3] U.S. 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 12/2024 Last accessed 12/19/2024.
[4] Dolobid™ (Diflunisal) Prescribing Information. INA Pharmaceutics, Inc. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=725234b2-0e23-45c3-a42d-eb4e62273f9b. Last revised 08/2024. Last accessed 01/17/2025.

Appendix K

Vote to Prior Authorize Tryngolza™ (Olezarsen) and Update the Approval Criteria for the Antihyperlipidemics

Oklahoma Health Care Authority
February 2025

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

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

- **March 2024:** Praluent® (alirocumab) received FDA approval for an age expansion for those 8 years of age or older with heterozygous familial hypercholesterolemia (HeFH) to reduce low-density lipoprotein cholesterol (LDL-C). Previously, Praluent® was only approved for HeFH in patients 18 years of age or older.
- **March 2024:** The FDA approved a label expansion for Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe) to include indications for cardiovascular (CV) risk reduction for both primary and secondary prevention in adults who are unable to take recommended statin therapy. The label expansion also includes the use of Nexletol® or Nexlizet® alone or in combination with statins or other LDL-C lowering therapies for primary hyperlipidemia, including HeFH. This label expansion will make Nexletol® and Nexlizet® the only LDL-C lowering non-statin medications indicated for primary prevention. The label expansion is based on the results from the CLEAR outcomes trial that assessed the effect of Nexletol® on CV outcomes in almost 14,000 patients who had established CV disease (CVD) or were at high risk of CVD. The primary composite endpoint, time to first occurrence of CV death, nonfatal myocardial infarction (MI), nonfatal stroke, or coronary revascularization, showed a 13% lower risk of occurrence vs. placebo [hazard ratio: 0.87; 95% confidence interval (CI): 0.79, 0.96; P=0.004]. Additionally, a reduction of LDL-C by 20% was seen in the bempedoic acid group when compared to placebo.
- **December 2024:** The FDA approved Tryngolza™ (olezarsen) as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). FCS, also known as hyperlipoproteinemia type 1, is a rare autosomal recessive disorder caused by impaired function in the lipoprotein lipase (LPL) enzyme leading to disruptions in the normal breakdown of fats in the body causing severe hypertriglyceridemia, triglycerides >880mg/dL, due to the accumulation of chylomicrons. FCS has an estimated prevalence of

1 in 300,000 people in the United States and Europe and is expected to impact approximately 3,000 people in the United States. Patients with FCS will also have recurrent episodes of pancreatitis, fatty deposits in the skin, abdominal pain, nausea, fatigue, hepatosplenomegaly, eruptive xanthomas, lipemia retinalis, and failure to thrive. Prior to the approval of Tryngolza™, there have been no FDA approved treatment options for FCS. The mainstay of treatment is a fat restricted diet of ≤20g/day in combination with weight maintenance, exercise, and avoidance of processed foods, alcohol, and smoking. Standard lipid-lowering medications and plasmapheresis have been shown to be ineffective for FCS, and treatment has relied on diet, management of triglyceride levels, and keeping acute pancreatitis controlled.

News:

- **April 2024:** Amgen announced that the Repatha® Pushtronex® (evolocumab) on-body infusor system would be discontinued on June 30, 2024. The Repatha® SureClick® autoinjector and prefilled syringes will still be available, and patients were instructed to reach out to their health care providers about transitioning to a different product.
- **December 2024:** As of December 2024, the FDA Orange Book lists Epanova® (omega-3-carboxylic acids) as a discontinued product. There are no generic equivalents for this product.

Tryngolza™ (Olezarsen) Product Summary[9,10]

Therapeutic Class: Apolipoprotein C-III (APOC3) directed antisense oligonucleotide (ASO)

Indication(s): Adjunct to diet to reduce triglycerides in adults with FCS

How Supplied: 80mg/0.8mL single-dose autoinjector

Dosing and Administration:

- The recommended dose is 80mg subcutaneously (sub-Q) once monthly.
- Tryngolza™ should be administered in the abdomen or the front of the thigh. The back of the upper arm can also be used if administered by a health care provider or caregiver.

Mechanism of Action: Olezarsen binds to APOC3 mRNA leading to mRNA degradation and a reduction of serum APOC3. The reduction of APOC3 protein leads to an increased clearance of plasma triglycerides and very-low-density lipoprotein (VLDL).

Efficacy: The efficacy of Tryngolza™ was studied in a randomized, placebo-controlled, double-blind, Phase 3 trial in 66 patients with genetically identified FCS and fasting triglyceride levels ≥880mg/dL.

- Key Inclusion Criteria:
  - Genetically confirmed diagnosis of FCS
  - Fasting triglycerides ≥880mg/dL
  - Stable low-fat diet with ≤20g of fat per day
  - Stable doses of statins, omega-3 fatty acids, or other lipid-lowering medications were allowed
- Intervention(s):
  - Randomized 1:1 to Tryngolza™ 80mg once every 4 weeks or placebo
- Primary Endpoint(s) and Results:
  - Percent change in fasting triglycerides from baseline to month 6
    - 30% reduction in the Tryngolza™ group vs. 12% increase in the placebo group (treatment difference: -42.5%; 95% CI: -74.1%, -10.9%; P=0.0084)
  - Key secondary endpoints showed a consistent fasting triglyceride lowering effect and a lower incidence of acute pancreatitis (5% in Tryngolza™ group vs. 30% in placebo group) during the 12-month treatment period.

Cost: The Wholesale Acquisition Cost (WAC) of Tryngolza™ is $49,584 per dose resulting in an estimated cost of $644,592 per year based on the recommended dosing.

Recommendations

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

Tryngolza™ (Olezarsen) Approval Criteria:

1. An FDA approved indication to reduce triglyceride levels in adults with familial chylomicronemia syndrome (FCS); and
2. Diagnosis of FCS must be confirmed by the following:
   a. Genetic testing identifying biallelic pathogenic variants in the *LPL, GPIHBP1, APOA5, APOC2*, or *LMF1* genes (results of genetic testing must be submitted); and
   b. Fasting triglyceride levels ≥880mg/dL; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify the member is on a low-fat diet of ≤20g of fat per day and will continue the low-fat diet while on treatment with Tryngolza™; and

4. Member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tryngolza™; and
5. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment, as indicated by a reduction in fasting triglyceride levels, decreased episodes of acute pancreatitis, and/or other documentation of a positive clinical response to therapy. Subsequent approvals will be for the duration of 1 year.

Additionally, the College of Pharmacy recommends the following changes to the Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe) approval criteria based on the new FDA approved label expansion and to be consistent with clinical practice (changes shown in red):

Nexletol® (Bempedoic Acid) and Nexlizet® (Bempedoic Acid/Ezetimibe) Approval Criteria:

1. An FDA approved indication ~~as an adjunct to diet and statin therapy for the treatment~~ of 1 of the following:
    a. As an adjunct to diet and other low-density lipoprotein cholesterol (LDL-C) lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with heterozygous familial hypercholesterolemia (HeFH). HeFH must be ~~as~~ confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    ~~b. Established atherosclerotic cardiovascular disease (ASCVD); and~~
        ~~i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; or~~
    c. As an adjunct to diet and other LDL-C lowering therapies or alone when concomitant LDL-C lowering therapies are not possible to reduce LDL-C in those with primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and

   d. To reduce the risk of myocardial infarction and coronary revascularization in those unable to take recommended statin therapy with 1 of the following:
      i. High risk for a cardiovascular disease (CVD) event without established atherosclerotic CVD (ASCVD); or
      ii. Established ASCVD; and
      iii. Supporting diagnoses/conditions/risk factors and dates of occurrences must be submitted; and
2. Member must be 18 years of age or older; and
3. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
   a. LDL-C levels should be included following at least 4 weeks of treatment; and
   b. Member must not be taking simvastatin at doses >20mg or pravastatin at doses >40mg due to drug interactions with Nexletol® and Nexlizet®; and
4. Members with statin intolerance must meet 1 of the following:
   a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or
   c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
   d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
6. A quantity limit of 30 tablets per 30 days will apply; and
7. ~~Initial approvals will be for the duration of 3 months, after which time compliance and recent LDL-C levels to demonstrate the effectiveness of this medication will be required for continued approval. Subsequent approvals will be for the duration of 1 year.~~
8. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. Additionally, compliance will be checked for continued approval.

Next, the College of Pharmacy recommends the following changes to the PCSK9 inhibitors criteria based on the new FDA approved age expansion, product discontinuation, and to be consistent with clinical practice (changes shown in red):

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitors [Praluent® (Alirocumab) and Repatha® (Evolocumab)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles know to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    b. Homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
        i. Documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
        ii. An untreated LDL >500mg/dL and at least 1 of the following:
            1. Documented evidence of definite HeFH in both parents; or
            2. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; or
    c. As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease (CVD); and
        i. Documentation of established CVD; and
        ii. Supporting diagnoses/conditions and date of occurrence signifying established CVD; or
    d. Primary hyperlipidemia; and
        i. Member's untreated LDL-C level must be ≥190mg/dL; and
        ii. Current LDL-C level is ≥100mg/dL; and
2. For the use of Repatha® in members with HeFH or HoFH, member must be 10 years of age or older; and
3. For the use of Praluent® in members with HeFH, member must be 8 years of age or older; and
4. For the use of Repatha® for FDA approved indications other than HeFH or HoFH or for the use of Praluent® for ~~all~~ FDA approved indications other than HeFH, the member must be 18 years of age or older; and

5. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
    a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
    b. LDL-C levels should be included following at least 12 weeks of treatment; and
6. Members with statin intolerance must meet 1 of the following:
    a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
7. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
8. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
9. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
10. A quantity limit of 2 syringes or pens per 28 days will apply for Praluent®. A quantity limit of 2 syringes or auto-injectors per 28 days will apply for Repatha® 140mg ~~and a quantity limit of 1 auto-injector per 28 days will apply for Repatha® 420mg. Requests for the Repatha® 420mg dose will not be approved for multiple 140mg syringes or auto-injectors, but instead members need to use (1) 420mg auto-injector~~; and
11. Initial approvals will be for the duration of 6 ~~3~~ months (subsequent approvals for 1 year). Continued authorization ~~at that time~~ will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. ~~and~~ Additionally, compliance will be checked for continued approval. ~~at that time and every 6 months thereafter for continued approval.~~

Next, the College of Pharmacy recommends the following changes to the Evkeeza® (evinacumab-dgnb) and Leqvio® (inclisiran) criteria to be consistent with clinical practice and the other antihyperlipidemic medications (changes shown in red):

Evkeeza® (Evinacumab-dgnb) Approval Criteria:

1. An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following:
    a. Documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
    b. An untreated LDL >500mg/dL and at least 1 of the following:
        i. Documented evidence of definite HeFH in both parents; or
        ii. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and
2. Member must be 5 years of age or older; and
3. Documented trial of high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy at least 12 weeks in duration; and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Documented trial of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®) at least 12 weeks in duration; and
6. Member requires additional lowering of LDL-cholesterol (LDL-C) (baseline, current, and goal LDL-C levels must be provided); and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy and for 5 months after discontinuation of therapy; and
8. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization ~~at that time~~ will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. ~~and~~ Additionally, compliance will be checked for continued approval. ~~at that time and every 6 months thereafter for continued approval.~~

Leqvio® (Inclisiran) Approval Criteria:

1. An FDA approved indication as an adjunct to diet and statin therapy for the treatment of 1 of the following:

a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
    i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing (results of genetic testing must be submitted); or
    ii. Both of the following:
        1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
        2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
    iii. Dutch Lipid Clinic Network Criteria score of >8; or
b. Established atherosclerotic cardiovascular disease (ASCVD); and
    i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; or
c. Primary hyperlipidemia; and
    i. Member's untreated LDL-C level must be ≥190mg/dL; and
    ii. Current LDL-C level is ≥100mg/dL; and

2. Member must be 18 years of age or older; and
3. Documented trial of all of the following for at least 12 weeks in duration each:
    a. High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and
    b. Ezetimibe; and
    c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C must be provided); and
6. Leqvio® must be administered by a health care professional. Approvals will not be granted for self-administration; and
    a. Prior authorization requests must indicate how Leqvio® will be administered (e.g., prescriber, pharmacist, home health care provider); and
        i. Leqvio® must be shipped to the facility where the member is scheduled to receive treatment; or

ii. Prescriber must verify the member has been counseled on the proper storage of Leqvio®; and

7. Initial approvals will be for the duration of 6 months (subsequent approvals for 1 year). Continued authorization ~~at that time~~ will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication. ~~and~~ Additionally, compliance will be checked for continued approval. ~~at that time and every 6 months thereafter for continued approval.~~

Next, the College of Pharmacy recommends the removal of Epanova® (omega-3-carboxylic acids) from the omega-3 fatty acids approval criteria based on product discontinuation (changes shown in red):

~~Omega-3 Fatty Acids [Epanova® (Omega-3-Carboxylic Acids) and~~ Vascepa® (Icosapent Ethyl)~~]~~ Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Severe hypertriglyceridemia; and
      i. Laboratory documentation of severe hypertriglyceridemia (fasting triglycerides ≥500mg/dL) and controlled diabetes (fasting glucose <150mg/dL at the time of triglycerides measurement and HgA1c <7.5%); and
      ii. Previous failure with fibric acid medications; and
      iii. ~~Use of Vascepa® (icosapent ethyl) or Epanova® (omega-3-carboxylic acids) requires a~~ Previous failure of or a patient-specific, clinically significant reason why the member cannot use omega-3-acid ethyl esters (generic Lovaza®), which is available without prior authorization; or
   b. ~~For the use of Vascepa® (icosapent ethyl)~~ As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult members with elevated triglyceride levels; and
      i. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
      ii. Laboratory documentation of fasting triglycerides ≥150mg/dL; and
      iii. Member must have 1 of the following:
         1. Established cardiovascular disease; or
         2. Diabetes mellitus and ≥2 additional risk factors for cardiovascular disease; and
2. Use of Vascepa® 0.5 gram requires a patient-specific, clinically significant reason why the member cannot use Vascepa® 1 gram.

Finally, the College of Pharmacy recommends moving Lofibra® (fenofibrate micronized) 200mg capsules from Tier-2 to Tier-1 based on net cost (changes shown in red):

Fibric Acid Derivative Medications	
Tier-1	**Tier-2**
choline fenofibrate DR cap 45mg (Trilipix®)	choline fenofibrate DR cap 135mg (Trilipix®)
fenofibrate micronized cap 67mg, 134mg (Lofibra®)	fenofibrate cap 50mg, 150mg (Lipofen®)
fenofibrate tab 160mg (Triglide®)	~~**fenofibrate micronized cap 200mg (Lofibra®)**~~
fenofibrate tab 48mg, 145mg (Tricor®)	fenofibrate micronized cap 30mg, 43mg, 90mg, 130mg (Antara®)
fenofibrate tab 54mg, 160mg (Lofibra®)	fenofibrate tab 40mg, 120mg (Fenoglide®)
fenofibrate micronized cap 200mg (Lofibra®)	fenofibric acid tab (Fibricor®) 105mg
fenofibric acid tab 35mg (Fibricor®)	
gemfibrozil tab 600mg (Lopid®)	

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).
cap = capsule; DR = delayed release; tab = tablet

[1] Praluent® (Alirocumab) – Expanded Indication. *OptumRx*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/clinical-updates/clinicalupdate_praluent_2024-0312.pdf. Issued 03/11/2024. Last accessed 01/17/2025.
[2] Esperion Therapeutics. U.S. FDA Approves Broad New Labels for Nexletol® and Nexlizet® to Prevent Heart Attacks and Cardiovascular Procedures in Both Primary and Secondary Prevention Patients, Regardless of Statin Use. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2024/03/22/2851118/0/en/U-S-FDA-Approves-Broad-New-Labels-for-NEXLETOL-and-NEXLIZET-to-Prevent-Heart-Attacks-and-Cardiovascular-Procedures-in-Both-Primary-and-Secondary-Prevention-Patients-Regardless-of-S.html. Issued 03/22/2024. Last accessed 01/17/2025.
[3] Nexletol® (Bempedoic Acid) Prescribing Information. Esperion Therapeutics. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211616s012s013lbl.pdf. Last revised 03/2024. Last accessed 01/17/2025.
[4] Ionis Pharmaceuticals. Tryngolza™ (Olezarsen) Approved in U.S. As First-Ever Treatment for Adults Living with Familial Chylomicronemia Syndrome as an Adjunct to Diet. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/tryngolza-olezarsen-approved-in-us-as-first-ever-treatment-for-adults-living-with-familial-chylomicronemia-syndrome-as-an-adjunct-to-diet-302336747.html. Issued 12/19/2024. Last accessed 01/17/2025.
[5] Orphanet. Familial Chylomicronemia Syndrome. Available online at: https://www.orpha.net/en/disease/detail/444490. Last updated 03/2023. Last accessed 01/17/2025.
[6] U.S. Food and Drug Administration (FDA). FDA Drug Shortages: Discontinuations. Available online at: https://dps.fda.gov/drugshortages/discontinuations/evolocumab-injection. Issued 04/12/2024. Last accessed 01/17/2025.
[7] Amgen. Important Notice for Patients: Discontinuation of Repatha® (Evolocumab) Pushtronex® System (Single-dose On-body Infusor with Prefilled Cartridge). Available online at: https://www.repatha.com/pushtronexsystemupdate. Last accessed 01/17/2025.
[8] 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 12/2024. Last accessed 12/18/2024.
[9] Tryngolza™ (Olezarsen) Prescribing Information. Ionis Pharmaceuticals. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218614s000lbl.pdf. Last revised 12/2024. Last accessed 01/17/2025.
[10] Stroes E, Alexander V, Karwatowska-Prokopczuk E, et al. Olezarsen, Acute Pancreatitis, and Familial Chylomicronemia Syndrome. *N Engl J Med* 2024; 390:1781-1792. doi: 10.1056/NEJMoa2400201.

Appendix L

Vote to Prior Authorize Wyost® (Denosumab-bbdz)

Oklahoma Health Care Authority
February 2025

Market News and Updates[1]

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

- **March 2024:** The FDA approved Wyost® (denosumab-bbdz) as an interchangeable biosimilar to Xgeva® (denosumab) for all the currently approved indications for Xgeva®. The cost for Wyost® (denosumab-bbdz) is not available at this time.

Recommendations

The College of Pharmacy recommends the prior authorization of Wyost® (denosumab-bbdz) with criteria similar to Xgeva® (denosumab) with the following additional criteria (changes shown in red):

Wyost® (Denosumab-bbdz) and Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors; or
    b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and
        i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or
    c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and
        i. Member must have albumin-corrected calcium of >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of Xgeva® therapy.; and
2. For Wyost® (denosumab-bbdz), a patient-specific, clinically significant reason why the member cannot use Xgeva® (denosumab) must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Interchangeable Biosimilars to Prolia® and Xgeva® to Treat Certain Types of Osteoporosis and Prevent Bone Events in Cancer. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-prolia-and-xgeva-treat-certain-types-osteoporosis-and. Issued 03/05/2024. Last accessed 01/07/2025.

Appendix M

Vote to Update the Approval Criteria for the Ophthalmic Antibiotic Medications

Oklahoma Health Care Authority
February 2025

Market News and Updates[1]

News:

- **December 2024:** As of December 2024, the U.S. Food and Drug Administration (FDA) Orange Book lists Blephamide® (sulfacetamide/prednisolone) ointment and suspension, Gentak® (gentamicin) ointment, Moxeza® (moxifloxacin) solution, Pred-G® (gentamicin/prednisolone) ointment and suspension, and Quixin® (levofloxacin) solution as discontinued products. Additionally, there are no generic equivalents available for these products.

Recommendations

The College of Pharmacy recommends the following changes to the Ophthalmic Antibiotic Medications Product Based Prior Authorization (PBPA) category based on net cost and product discontinuations (changes noted in red in the following PBPA Tier chart and approval criteria):

1. Removing the brand preferred status for Tobradex® (tobramycin/dexamethasone) suspension; and
2. Moving Bleph-10® (sulfacetamide sodium) solution and Neosporin® (neomycin/polymyxin B/gramicidin) solution from Tier-1 to Tier-2; and
3. Moving Ciloxan® (ciprofloxacin) ointment, Neo-Polycin® HC (bacitracin/polymyxin B/neomycin/hydrocortisone) ointment, Tobradex® (tobramycin/dexamethasone) ointment, and Zylet® (tobramycin/loteprednol) suspension from Tier-2 to Tier-1; and
4. Moving Azasite® (azithromycin), Besivance® (besifloxacin), and Vigamox® (moxifloxacin) from Tier-3 to Tier-1; and
5. Moving Zymaxid® (gatifloxacin) from Tier-3 to Tier-2; and
6. Removing Blephamide® (sulfacetamide/prednisolone) ointment and suspension, Gentak® (gentamicin) ointment, Moxeza® (moxifloxacin) solution, Pred-G® (gentamicin/prednisolone) ointment and suspension, and Quixin® (levofloxacin) solution based on product discontinuations.

Ophthalmic Antibiotic Medications: Liquids		
Tier-1	**Tier-2**	**Tier-3**
azithromycin (Azasite®)	~~**levofloxacin (Quixin®)**~~	~~**azithromycin (Azasite®)**~~
besifloxacin (Besivance®)	**gatifloxacin (Zymaxid®)**	~~**besifloxacin (Besivance®)**~~
ciprofloxacin (Ciloxan®)	**neomycin/polymyxin B/gramicidin (Neosporin®)**	~~**gatifloxacin (Zymaxid®)**~~
gentamicin (Gentak®)	**sulfacetamide sodium (Bleph-10®)**	~~**moxifloxacin (Vigamox®, Moxeza®)**~~
moxifloxacin (Vigamox®)		
~~**neomycin/polymyxin B/gramicidin (Neosporin®)**~~		
ofloxacin (Ocuflox®)		
polymyxin B/trimethoprim (Polytrim®)		
~~**sulfacetamide sodium (Bleph-10®)**~~		
tobramycin (Tobrex®)		

Ophthalmic Antibiotic Medications: Ointments	
Tier-1	**Tier-2**
bacitracin/polymyxin B (AK-Poly-Bac®, Polycin®)	bacitracin (AK-Tracin®)
ciprofloxacin (Ciloxan®)	~~**ciprofloxacin (Ciloxan®)**~~
erythromycin (Ilotycin™, Romycin®)	sodium sulfacetamide (Bleph-10®)
~~**gentamicin (Gentak®)**~~	
neomycin/polymyxin B/bacitracin (Neosporin®)	
tobramycin (Tobrex®)	

Ophthalmic Antibiotic/Steroid Combination Products	
Tier-1	**Tier-2**
bacitracin/polymyxin B/neomycin/ hydrocortisone (Neo-Polycin® HC) oint	~~**bacitracin/polymyxin B/neomycin/ hydrocortisone (Neo-Polycin® HC) oint**~~
neomycin/polymyxin B/dexamethasone (Maxitrol®) oint & susp	~~**gentamicin/prednisolone (Pred-G®) oint & susp**~~
sulfacetamide/prednisolone 10%/0.23% solution	neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp
tobramycin/dexamethasone 0.3%/0.1% (Tobradex®) **oint &** susp ~~**– Brand Preferred**~~	~~**sulfacetamide/prednisolone (Blephamide®) oint & susp**~~
tobramycin/dexamethasone 0.3%/0.05% (Tobradex® ST) susp	~~**tobramycin/dexamethasone (Tobradex®) oint**~~
tobramycin/loteprednol (Zylet®) susp	~~**tobramycin/loteprednol (Zylet®) susp**~~

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).
HC= hydrocortisone; oint= ointment; susp= suspension

[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 12/2024. Last Accessed 12/20/2024.

Appendix N

Fiscal Year 2024 Annual Review of Short-Acting Beta$_2$ Agonists (SABAs)

Oklahoma Health Care Authority
February 2025

Current Prior Authorization Criteria

Short-Acting Beta$_2$ Agonists	
Tier-1	**Tier-2**
albuterol HFA (ProAir® HFA) – **Brand Preferred**	albuterol HFA (generic)
albuterol inhalation powder (ProAir® RespiClick®)	albuterol inhalation powder (ProAir® Digihaler®)*
albuterol HFA (Proventil® HFA) – **Brand Preferred**	levalbuterol HFA (generic)
albuterol HFA (Ventolin® HFA) – **Brand Preferred**	
levalbuterol HFA (Xopenex® HFA) – **Brand Preferred**	

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).
*Additional criteria applies.
HFA = hydrofluoroalkane

Short-Acting Beta$_2$ Agonists Tier-2 Approval Criteria:

1. An FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member cannot use all available Tier-1 medications must be provided; and
3. Approval of generic albuterol HFA or levalbuterol HFA requires a patient-specific, clinically significant reason the member cannot use the brand formulation.

Airsupra® (Albuterol/Budesonide) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 18 years of age or older; and
3. Member must be using maintenance therapy per the Global Initiative for Asthma (GINA) guidelines; and
4. A patient-specific, clinically significant reason why the member cannot use a long-acting beta$_2$ agonist (LABA), inhaled corticosteroid (ICS)/LABA combination, or specific individual ICS and short-acting beta$_2$ agonist (SABA) components must be provided; and
5. Initial approvals will be for the duration of 3 months. For continued consideration, prescriber must verify the member has had a positive clinical response to therapy; and

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

ProAir® Digihaler® (Albuterol Inhalation Powder) Approval Criteria:

1. An FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member requires the ProAir® Digihaler® formulation over all available Tier-1 medications must be provided; and
3. The prescriber agrees to closely monitor member adherence; and
4. The member should be capable and willing to use the Companion Mobile App and follow the Instructions for Use and ensure the ProAir® Digihaler® Companion Mobile App is compatible with their specific smartphone; and
5. Member's phone camera must be functional and able to scan the inhaler QR code and register the ProAir® Digihaler® inhaler; and
6. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance >80% with prescribed therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier-1 medications must be provided. Tier structure rules continue to apply.

Xopenex® (Levalbuterol) Nebulizer Solution Approval Criteria:

1. A free-floating 90 days of therapy per 365 days will be in place.
2. Use of this product in excess of 90 days of therapy in a 365-day period will require a patient-specific, clinically significant reason why the member is unable to use long-acting bronchodilator and/or inhaled corticosteroid (ICS) therapy for long-term control as recommended in the National Asthma Education and Prevention Program (NAEPP) guidelines; and
3. A patient-specific, clinically significant reason why the member cannot use a metered-dose inhaler (MDI) must be provided; and
4. Clinical exceptions will be made for members with chronic obstructive pulmonary disease (COPD); and
5. A quantity limit of 288mL per 30 days will apply.

Utilization of SABAs: Fiscal Year 2024

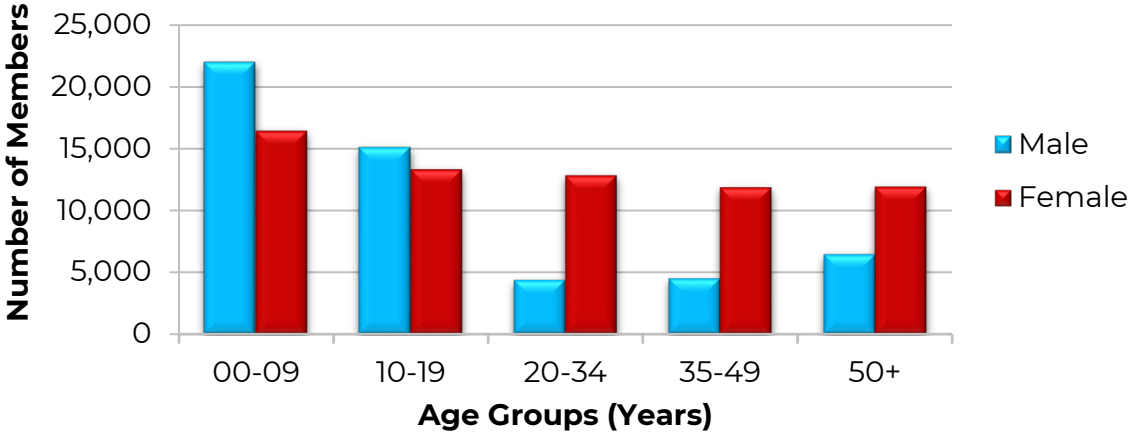
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	127,784	291,692	$13,271,382.31	$45.50	$2.02	12,997,672	6,575,290
2023 Total	**127,784**	**291,692**	**$13,271,382.31**	**$45.50**	**$2.02**	**12,997,672**	**6,575,290**
Fiscal Year 2024							
FFS	109,285	234,944	$8,406,495.27	$35.78	$1.63	9,692,553	5,163,705
Aetna	7,881	11,614	$407,878.98	$35.12	$1.77	421,517	230,142
Humana	8,792	13,190	$482,992.01	$36.62	$1.69	452,690	286,516
OCH	8,441	12,053	$444,929.08	$36.91	$1.70	448,037	262,276
2024 Total	**118,995**	**271,801**	**$9,742,295.34**	**$35.84**	**$1.64**	**11,014,797**	**5,942,639**
% Change	**-6.90%**	**-6.80%**	**-26.60%**	**-21.20%**	**-18.80%**	**-15.30%**	**-9.60%**
Change	**-8,789**	**-19,891**	**-$3,529,086.97**	**-$9.66**	**-$0.38**	**-1,982,875**	**-632,651**

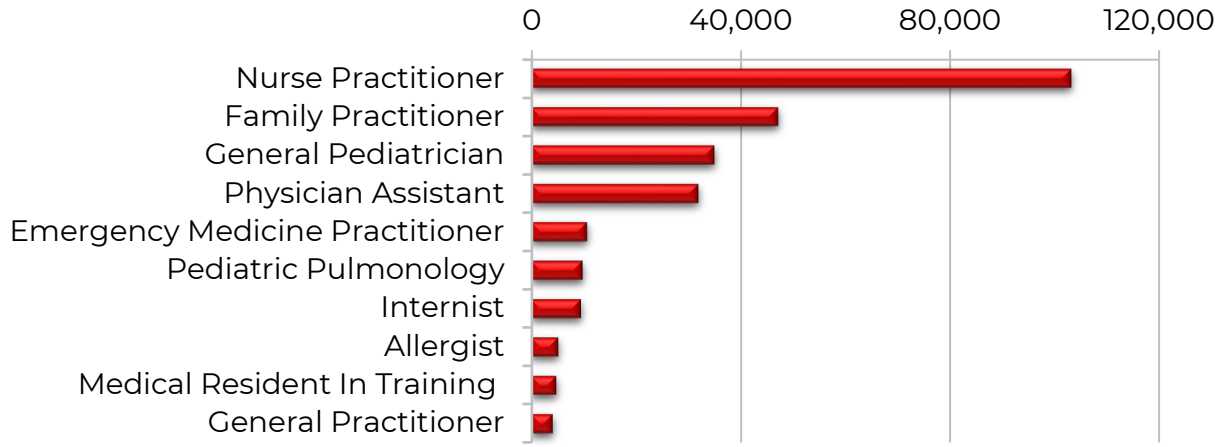
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available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

- Aggregate drug rebates collected during fiscal year 2024 for SABAs totaled $1,755,550.94.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing SABAs: Pharmacy Claims (All Plans)



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



Prior Authorization of SABAs

There were 775 prior authorization requests submitted for SABAs during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	166	25%	438	65%	72	11%	**676**
Aetna	1	1%	60	72%	22	27%	**83**
Humana	0	0%	0	0%	2	100%	**2**
OCH	12	86%	0	0%	2	14%	**14**
Total	**179**	**23%**	**498**	**64%**	**98**	**13%**	**775**

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

Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- ProAir RespiClick® (albuterol sulfate inhalation powder): January 2032
- ProAir® Digihaler® (albuterol sulfate inhalation powder): December 2038

News:

- **October 2022:** Teva announced they would be discontinuing the manufacturing of brand name ProAir® HFA (albuterol sulfate). The generic formulation will still be available.
- **April 2024:** It was announced that Teva discontinued the Digihaler® products, including Airduo® Digihaler®, Armonair® Digihaler®, and ProAir® Digihaler®, on June 1, 2024. The products are still available until the last lot expiration date; however, the software component of these products was officially discontinued on June 1. The Asthma and Allergy Foundation of America recommended that anyone currently using the Digihaler® products reach out to their provider to determine the best alternative treatment options.

Recommendations[4]

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

1. Removing the brand preferred status from ProAir® HFA, Proventil® HFA, and Ventolin® HFA based on net costs and the discontinuation of brand name ProAir® HFA; and
2. Updating the Airsupra® (albuterol/budesonide) approval criteria for clarity and to be consistent with the Global Initiative for Asthma (GINA) guidelines; and
3. Updating the Xopenex® (levalbuterol) nebulizer solution approval criteria to be consistent with the GINA guidelines; and
4. Removal of ProAir® Digihaler® (albuterol inhalation powder) due to product discontinuation.

Short-Acting Beta$_2$ Agonists	
Tier-1	**Tier-2**
albuterol HFA (ProAir® HFA**, Proventil® HFA, Ventolin® HFA**) **– ~~Brand Preferred~~**	**~~albuterol HFA (generic)~~**
albuterol inhalation powder (ProAir® RespiClick®)	**~~albuterol inhalation powder (ProAir® Digihaler®)*~~**
~~albuterol HFA (Proventil® HFA) –~~ **~~Brand Preferred~~**	levalbuterol HFA (generic)
~~albuterol HFA (Ventolin® HFA) –~~ **~~Brand Preferred~~**	

levalbuterol HFA (Xopenex® HFA) – **Brand Preferred**	

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).
~~*Additional criteria applies.~~
HFA = hydrofluoroalkane

Short-Acting Beta$_2$ Agonists Tier-2 Approval Criteria:

1. An FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member cannot use all available Tier-1 medications must be provided; and
3. Approval of generic ~~albuterol HFA or~~ levalbuterol HFA requires a patient-specific, clinically significant reason the member cannot use the brand formulation.

Airsupra® (Albuterol/Budesonide) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be 18 years of age or older; and
~~3. Member must be using maintenance therapy per the Global Initiative for Asthma (GINA) guidelines; and~~
4. A patient-specific, clinically significant reason why the member cannot use a combination inhaled corticosteroid (ICS) and formoterol [e.g., Symbicort® (budesonide/formoterol), Dulera® (mometasone/formoterol)] as recommend by the Global Initiative for Asthma (GINA) guidelines; and
5. A patient-specific, clinically significant reason why the member cannot use specific individual ICS and short-acting beta$_2$ agonist (SABA) components; and
~~6. A patient-specific, clinically significant reason why the member cannot use a long-acting beta$_2$ agonist (LABA), inhaled corticosteroid (ICS)/LABA combination, or specific individual ICS and short-acting beta$_2$ agonist (SABA) components must be provided; and~~
7. Initial approvals will be for the duration of 3 months. For continued consideration, prescriber must verify the member has had a positive clinical response to therapy; and
8. Subsequent approvals will be for the duration of 1 year.

Xopenex® (Levalbuterol) Nebulizer Solution Approval Criteria:

1. A free-floating 90 days of therapy per 365 days will be in place.
2. Use of this product in excess of 90 days of therapy in a 365-day period will require a patient-specific, clinically significant reason why the member is unable to use a preferred controller and reliever treatment option [e.g., combination inhaled corticosteroid (ICS) and formoterol or ICS and short-acting beta$_2$ agonist (SABA)] appropriate to the member's age ~~long-acting bronchodilator and/or inhaled corticosteroid (ICS) therapy for long-term control~~ as recommended in the Global Initiative

for Asthma (GINA) ~~National Asthma Education and Prevention Program (NAEPP~~) guidelines; and
3. A patient-specific, clinically significant reason why the member cannot use a metered-dose inhaler (MDI) must be provided; and
4. Clinical exceptions will be made for members with chronic obstructive pulmonary disease (COPD); and
5. A quantity limit of 288mL per 30 days will apply.

~~**ProAir® Digihaler® (Albuterol Inhalation Powder) Approval Criteria:**~~

~~1. An FDA approved or clinically accepted indication; and~~
~~2. A patient-specific, clinically significant reason why the member requires the ProAir® Digihaler® formulation over all available Tier 1 medications must be provided; and~~
~~3. The prescriber agrees to closely monitor member adherence; and~~
~~4. The member should be capable and willing to use the Companion Mobile App and follow the Instructions for Use and ensure the ProAir® Digihaler® Companion Mobile App is compatible with their specific smartphone; and~~
~~5. Member's phone camera must be functional and able to scan the inhaler QR code and register the ProAir® Digihaler® inhaler; and~~
~~6. Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance >80% with prescribed therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier 1 medications must be provided. Tier structure rules continue to apply.~~

Utilization Details of SABAs: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SABA TIER-1 PRODUCTS						
VENTOLIN HFA 90MCG/ACT	16,944	7,338	$1,222,713.51	$72.16	2.31	12.55%
PROAIR RESPICLICK 90MCG/ACT	1,258	738	$100,892.12	$80.20	1.7	1.04%
XOPENEX HFA 45MCG/ACT	798	334	$69,688.11	$87.33	2.39	0.72%
PROAIR HFA 90MCG/ACT	110	39	$9,568.90	$86.99	2.82	0.10%
PROVENTIL HFA 90MCG/ACT	35	32	$3,325.69	$95.02	1.09	0.03%
SUBTOTAL	**19,145**	**8,481**	**$1,406,188.33**	**$73.45**	**2.26**	**14.43%**
SABA TIER-2 PRODUCTS						
ALBUTEROL HFA 90MCG/ACT	197,616	96,339	$6,967,759.20	$35.26	2.05	71.52%
LEVALBUTEROL HFA 45MCG/ACT	105	80	$6,521.48	$62.11	1.31	0.07%
PROAIR DIGIHALER 108MCG/ACT	18	17	$1,931.31	$107.30	1.06	0.02%
SUBTOTAL	**197,739**	**96,436**	**$6,976,211.99**	**$35.28**	**2.05**	**71.61%**
SABA NEBULIZER SOLUTION PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALBUTEROL NEB 2.5MG/3ML	37,006	23,248	$677,900.86	$18.32	1.59	6.96%
ALBUTEROL NEB 1.25MG/3ML	9,297	6,878	$323,572.93	$34.80	1.35	3.32%
ALBUTEROL NEB 0.63MG/3ML	6,096	4,504	$210,673.33	$34.56	1.35	2.16%
LEVALBUTEROL NEB 0.63MG/3ML	1,010	637	$42,757.57	$42.33	1.59	0.44%
LEVALBUTEROL NEB 1.25MG/3ML	817	428	$39,725.52	$48.62	1.91	0.41%
LEVALBUTEROL NEB 0.31MG/3ML	390	291	$15,171.56	$38.90	1.34	0.16%
ALBUTEROL NEB 5MG/ML	202	165	$6,021.33	$29.81	1.22	0.06%
LEVALBUTEROL NEB 1.25MG/0.5ML	14	12	$1,970.14	$140.72	1.17	0.02%
SUBTOTAL	**54,832**	**36,163**	**$1,317,793.24**	**$24.03**	**1.52**	**13.53%**
ALBUTEROL/BUDESONIDE PRODUCTS						
AIRSUPRA 90-80MCG/ACT	85	64	$42,101.78	$495.32	1.33	0.43%
SUBTOTAL	**85**	**64**	**$42,101.78**	**$495.32**	**1.33**	**0.43%**
TOTAL	**271,801**	**118,995***	**$9,742,295.34**	**$35.84**	**2.28**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; HFA = hydrofluoroalkane inhaler; NEB = nebulizer; SABA = short-acting beta$_2$ agonist
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 01/2025. Last accessed 01/17/2025.
[2] Asthma and Allergy Foundation of America. Albuterol Sulfate – ProAir® HFA. Available online at: https://aafa.org/asthma-medicine/albuterol-sulfate-proair-hfa/. Issued 10/2022. Last accessed 01/17/2025.
[3] Asthma and Allergy Foundation of America. Teva's Digihaler Products to Be Discontinued. Available online at: https://community.aafa.org/blog/teva-digihaler-discontinued. Issued 04/15/2024. Last accessed 01/17/2025.
[4] Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention 2024. Available online at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf. Last revised 05/2024. Last accessed 02/05/2025.

Appendix O

30-Day Notice to Prior Authorize Kebilidi™ (Eladocagene Exuparvovec-tneq)

Oklahoma Health Care Authority
February 2025

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

Aromatic L-amino acid decarboxylase (AADC) deficiency is an ultra-rare disorder estimated to affect fewer than 50 patients in the United States. AADC deficiency is caused by pathogenic variants in the DOPA Decarboxylase (*DDC*) gene, which results in a deficit of AADC enzyme expression. This deficit leads to decreased synthesis of monoamine neurotransmitters (e.g., dopamine, epinephrine, norepinephrine, serotonin) which causes neurological dysfunctions, including but not limited to motor impairment, movement disorders, autonomic dysfunction, and developmental and cognitive delays. While the phenotypic expression of AADC deficiency is variable, published literature suggests that most patients have very limited gross and fine motor milestone development. These developmental debilitations typically manifest during the first months of life, with a mean age of onset of 2.7 months, and can lead to life-threatening sequalae such as dystonic crisis, feeding difficulties, and seizures.

Historically, treatment options have been limited to symptom management with both pharmacological and nonpharmacological interventions. The International Working Group on Neurotransmitter Related Disorders (iNTD) Consensus Guidelines for the Diagnosis and Treatment of AADC Deficiency recommend non-ergot derived dopamine antagonists, monoamine oxidase inhibitors (MAOIs), and pyridoxine as first-line agents plus additional symptom treatment with anticholinergic agents, melatonin, and benzodiazepines as clinically indicated. However, the extent of the clinical benefits of these pharmacological options varies. Additionally, concurrent nonpharmacological interventions such as physical therapy, speech therapy, and occupational therapy also benefit patients with AADC deficiency.

In November 2024, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Kebilidi™ (eladocagene exuparvovec-tneq), the first gene therapy and first targeted treatment for adults and pediatric patients with AADC deficiency. Kebilidi™ is administered intraoperatively directly into the putamen in a single treatment session.

Kebilidi™ (Eladocagene Exuparvovec-tneq) Product Summary[4]

Therapeutic Class: Adeno-associated viral vector serotype 2 (AAV2) vector-based gene therapy

Indication(s): Treatment of adult and pediatric patients with AADC deficiency

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

How Supplied: 2mL single-dose vial (SDV) containing an extractable suspension volume of 0.5mL with a concentration of $2.8x10^{11}$ vector genomes (vg)/0.5mL (nominal concentration: $5.6x10^{11}$vg/mL) for intraputaminal administration

Dosing and Administration:

- Single-dose intraputaminal infusion
- Recommended total dose is $1.8x10^{11}$vg (0.32mL) as (4) 0.08mL ($0.45x10^{11}$vg) infusions (bilaterally anterior and posterior putamen) at 0.003mL/min for a total of 27 minutes per site
- Administration should occur during a single stereotactic surgery using a cannula that is FDA-authorized for intraparenchymal infusion

Efficacy: The FDA granted accelerated approval to Kebilidi™ based on results from an ongoing, open-label, single-arm, global Phase 2 trial.

- Key Inclusion Criteria:
  - Pediatric patients (1-17 years of age) with genetically confirmed, severe AADC deficiency, defined as having no motor milestone achievement at baseline and no clinical response to standard of care therapies
  - Presence of clinical symptoms and decreased AADC enzyme activity in plasma
  - Skull maturity as assessed by neuroimaging
- Key Exclusion Criteria:
  - Significant brain structure abnormality
- Intervention(s):
  - Intraputaminal administration of Kebilidi™ via the SmartFlow® MR-compatible ventricular cannula in a single operative session compared to an external untreated natural history cohort
- Primary Endpoint(s):
  - Gross motor milestone achievement measured by Peabody Developmental Motor Scale, Second Edition (PDMS-2) from baseline to week 48

- Results:
  - Eight of 12 (67%) patients achieved a new gross motor milestone at week 48 vs. none of the 43 untreated patients in the natural history cohort

Cost: The Wholesale Acquisition Cost (WAC) of Kebilidi™ is $3.95 million per 1-time treatment.

Recommendations

The College of Pharmacy recommends the prior authorization of Kebilidi™ (eladocagene exuparvovec-tneq) with the following criteria (shown in red):

Kebilidi™ (Eladocagene Exuparvovec-tneq) Approval Criteria:

1. An FDA approved diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency; and
2. Diagnosis must be confirmed by
   a. Genetic testing confirming biallelic pathogenic or likely pathogenic mutations in the *DDC* gene (results of genetic testing must be submitted); and
   b. Functional confirmation with measured diagnostic variations in AADC enzyme activity in plasma and/or levels of neurotransmitters in cerebrospinal fluid (CSF) (results of testing must be submitted); and
3. Member must be 16 months of age or older; and
4. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to Kebilidi™ administration; and
5. Must be prescribed by a neurologist, neurosurgeon, or a specialist with expertise in the treatment of AADC deficiency; and
6. Prescriber must verify the member has confirmed skull maturity as assessed by neuroimaging; and
7. Must be administered by intraputaminal infusion in a medical center that specializes in stereotactic neurosurgery in addition to the preparation and infusion of Kebilidi™; and
8. Must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment, and the facility must be capable of adhering to the storage, handling, and preparation requirements as described in the package labeling; and
9. Must only be administered using an FDA-authorized cannula for intraparenchymal infusion (e.g., ClearPoint® SmartFlow® Neuro Cannula); and
10. Approvals will be for 1 treatment per member per lifetime.

[1] DiBacco ML, Hinahara J, Goss TF, Pearl PL. Burden of Illness in Aromatic L-amino Acid Decarboxylase Deficiency. *Ann Child Neurol Soc.* 2023; 1:75-81. doi: 10.1002/cns3.20010.
[2] Wassenberg T, Molera-Luis M, Jeltsch K, et al. Consensus Guidelines for the Diagnosis and Treatment of Aromatic L-amino Acid Decarboxylase (AADC) Deficiency. *Orphanet J Rare Dis.* 2017; 12(1):12. doi: 10.1186/s13023-016-0522-z.
[3] Lee H, Mercimek-Andrews S, Horvath G, et al. A Position Statement on the Post Gene-therapy Rehabilitation of Aromatic L-amino Acid Decarboxylase Deficiency Patients. *Orphanet J Rare Dis*. 2024; 19(1):17. doi: 10.1186/s13023-024-03019-x.
[4] Kebilidi™ (Eladocagene Exuparvovec-tneq) Suspension, For Intraputaminal Infusion Prescribing Information. PTC Therapeutics, Inc. Available online at: https://www.fda.gov/media/183530/download?attachment. Last revised 11/13/2024. Last accessed 01/15/2025.
[5] U.S. Food and Drug Administration (FDA). FDA Approves First Gene Therapy for Treatment of Aromatic L-amino Acid Decarboxylase Deficiency. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treatment-aromatic-l-amino-acid-decarboxylase-deficiency. Issued 11/14/2024. Last accessed 01/15/2025.

Appendix P

Fiscal Year 2024 Annual Review of Anti-Migraine Medications and 30-Day Notice to Prior Authorize Symbravo® (Meloxicam/Rizatriptan)

Oklahoma Health Care Authority
February 2025

Current Prior Authorization Criteria

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	frovatriptan tablet (Frova®)	almotriptan tablet (Axert®)	dihydroergotamine injection (D.H.E. 45®)
naratriptan tablet (Amerge®)		sumatriptan/ naproxen tablet (Treximet®)	dihydroergotamine nasal spray (Migranal®)
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)			dihydroergotamine nasal spray (Trudhesa®)
sumatriptan tablet (Imitrex®)			ergotamine sublingual tablet (Ergomar®)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			lasmiditan tablet (Reyvow®)
			rimegepant ODT (Nurtec® ODT)
			rizatriptan film (RizaFilm®)
			sumatriptan injection (Imitrex®)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal powder (Onzetra® Xsail®)
			sumatriptan nasal spray (Imitrex®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			zavegepant nasal spray (Zavzpret™)
			zolmitriptan nasal spray (Zomig® nasal spray)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Tier-2 Approval Criteria:

1. A trial of all available Tier-1 products with inadequate response or a patient-specific, clinically significant reason why a Tier-1 product is not appropriate for the member must be provided; or
2. Documented adverse effect(s) to all available Tier-1 products; or
3. Previous success with a Tier-2 product within the last 60 days.

Anti-Migraine Medications Tier-3 Approval Criteria:

1. A trial of all available Tier-1 and Tier-2 products with inadequate response or a patient-specific, clinically significant reason why a lower tiered product is not appropriate for the member must be provided; or
2. Documented adverse effect(s) to all available Tier-1 and Tier-2 products; or
3. Previous success with a Tier-3 product within the last 60 days; and
4. Use of any non-oral formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation.

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and
    b. A quantity limit of 20 tablets per 28 days will apply.
2. Use of D.H.E. 45® [dihydroergotamine (DHE) injection] or Trudhesa® (DHE nasal spray) will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray), and lower-tiered triptan medications.

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

    *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.

    ⁺Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.
5. Use of Reyvow® (lasmiditan), Ubrelvy® (ubrogepant), or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow®, Ubrelvy®, and Zavzpret™ will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor
6. Use of RizaFilm® (rizatriptan film) will require a patient-specific, clinically significant reason why the member cannot use the ODT formulation and lower-tiered triptan medications.
7. Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.
8. Use of Zembrace® SymTouch® (sumatriptan injection) or Tosymra® (sumatriptan nasal spray) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
9. Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.

Aimovig® (Erenumab-aooe), Ajovy® (Fremanezumab-vfrm) and Emgality® (Galcanezumab-gnlm) Approval Criteria [Migraine Diagnosis]:

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and
        i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and
4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
6. The member has failed medical migraine preventive therapy with at least 2¥ agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. [¥The manufacturers of Ajovy® and Emgality® have currently provided a supplemental rebate to be the preferred calcitonin gene-related peptide (CGRP) inhibitor(s) and require a trial with 2 other migraine preventative therapies; however, Ajovy® and Emgality® will follow the original criteria and require trials with 3 other migraine preventative therapies if the manufacturers choose not to participate in supplemental rebates.] This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:

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

8. Member is not taking any medications that are likely to be the cause of the headaches; and
9. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative CGRP inhibitor; and
10. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
11. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
12. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
13. Quantity limits will apply based on FDA-approved dosing:
    a. For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and
    b. For Ajovy® prefilled syringe and autoinjector, a quantity limit of 1 syringe or 1 autoinjector per 30 days will apply. Requests for quarterly dosing (675mg every 3 months) will be approved for a quantity limit override upon meeting Ajovy® approval criteria; and
    c. For Emgality®, a quantity limit of 1 syringe or pen per 30 days will apply. Requests for an initial loading dose (240mg administered as 2 consecutive 120mg injections) will be approved for a quantity limit override upon meeting Emgality® approval criteria.

Emgality® (Galcanezumab-gnlm) Approval Criteria [Episodic Cluster Headache Diagnosis]:

1. An FDA approved indication for the treatment of episodic cluster headache in adults; and
2. Member must be 18 years of age or older; and

3. Member has a diagnosis of episodic cluster headache as defined by the International Headache Society (IHS) International Classification of Headache Disorders (ICHD) guideline and meets the following criteria:
    a. Member has a history of episodic cluster headache with at least 2 cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of ≥3 months; and
4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
    b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
    c. Opioids (≥10 days/month for >3 months); and
    d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
    e. Ergotamine-containing medications (≥10 days/month for >3 months); and
    f. Triptans (≥10 days/month for >3 months); and
6. Member has failed prophylactic therapy with at least 1 other medication (e.g., verapamil, select anticonvulsants, corticosteroids); and
7. Member will not use Emgality® concurrently with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
8. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
9. Initial approvals will be for the duration of 3 months. Continuation approvals will be granted until the end of the cluster period if the prescriber documents that the member is responding well to treatment as indicated by a reduction in cluster headache attack frequency; and
10. A quantity limit of (3) 100mg/mL syringes per 30 days will apply.

Nurtec® ODT (Rimegepant)*, Qulipta® (Atogepant), and Vyepti® (Eptinezumab-jjmr) Approval Criteria:

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months (*Nurtec® ODT is only FDA approved for the preventive treatment of episodic migraines.); and
        i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and
4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
6. The member has failed medical migraine preventive therapy with at least 3 agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
    b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
    c. Opioids (≥10 days/month for >3 months); and

    d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
    e. Ergotamine-containing medications (≥10 days/month for >3 months); and
    f. Triptans (≥10 days/month for >3 months); and
8. Member is not taking any medications that are likely to be the cause of the headaches; and
9. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
10. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
11. For Vyepti®, prescriber must verify the medication will be prepared and administered according to the Vyepti® package labeling; and
12. A patient-specific, clinically significant reason why member cannot use Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), or Emgality® (galcanezumab-gnlm) must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement); and
13. For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and
14. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
15. Quantity limits will apply based on FDA-approved dosing:
    a. For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
    b. For Qulipta®, a quantity limit of 30 tablets per 30 days will apply; and
    c. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Utilization of Anti-Migraine Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	11,454	27,638	$3,591,427.48	$129.95	$6.38	282,955	562,983
2023 Total	**11,454**	**27,638**	**$3,591,427.48**	**$129.95**	**$6.38**	**282,955**	**562,983**
Fiscal Year 2024							
FFS	10,423	23,419	$3,687,059.39	$157.44	$7.43	238,052	496,507
Aetna	1,119	1,701	$419,673.19	$246.72	$15.96	16,584	26,301
Humana	1,507	2,633	$1,063,064.81	$403.75	$19.77	28,403	53,777
OCH	1,128	1,682	$466,027.21	$277.07	$14.03	18,489	33,215
2024 Total	**12,039**	**29,435**	**$5,635,824.60**	**$191.47**	**$9.24**	**301,527**	**609,800**
% Change	**5.10%**	**6.50%**	**56.90%**	**47.30%**	**44.80%**	**6.60%**	**8.30%**
Change	**585**	**1,797**	**$2,044,397.12**	**$61.52**	**$2.86**	**18,572**	**46,817**

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

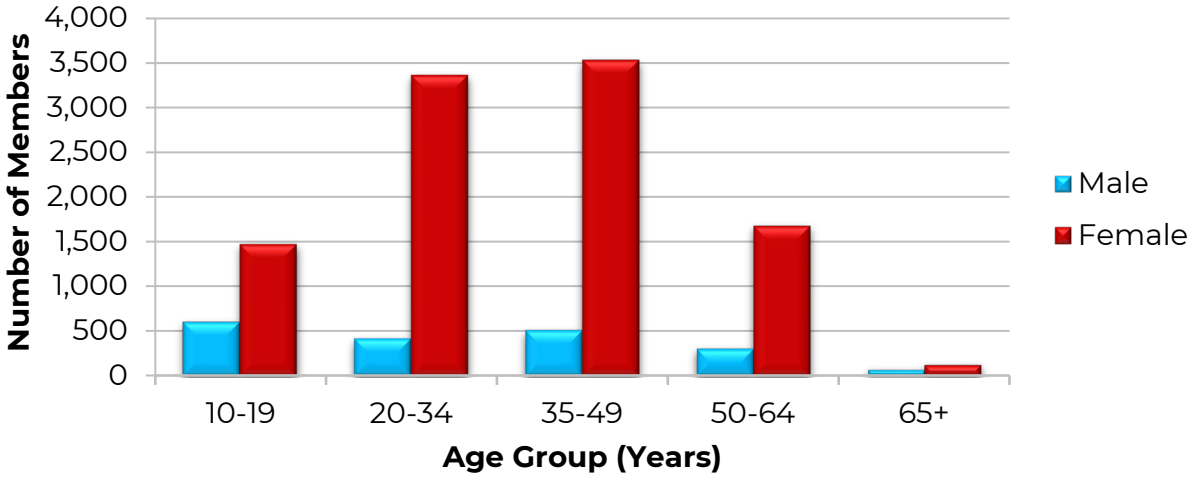
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	8	13	$31,513.80	$2,424.14	1.63
2023 Total	**8**	**13**	**$31,513.80**	**$2,424.14**	**1.63**
Fiscal Year 2024					
FFS	19	32	$104,696.30	$3,271.76	1.68
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	1	1	$1,805.00	$1,805.00	1
2024 Total	**20**	**33**	**$106,501.30**	**$3,227.31**	**1.65**
% Change	**150.00%**	**153.85%**	**237.95%**	**33.13%**	**1.23%**
Change	**12**	**20**	**$74,987.50**	**$803.17**	**0.02**

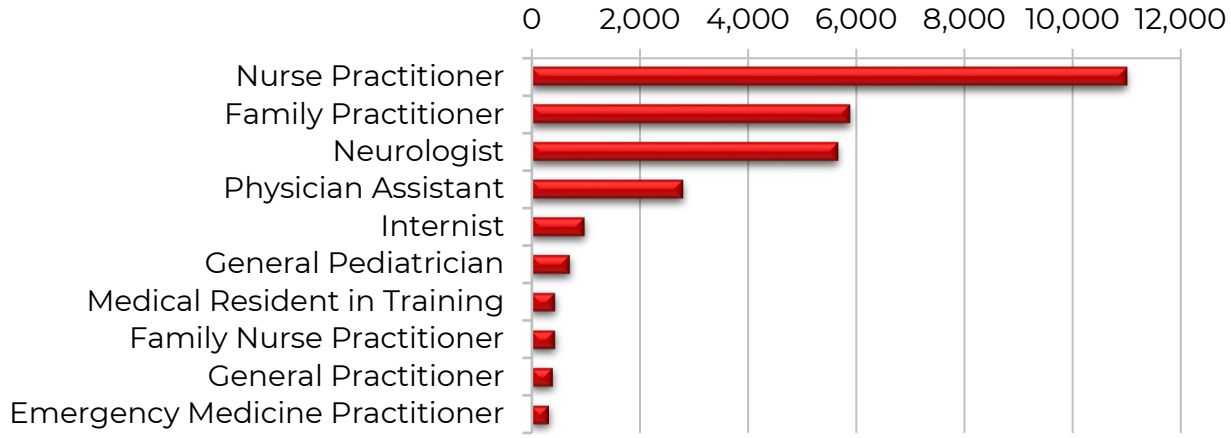
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data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

- Aggregate drug rebates collected during fiscal year 2024 for the anti-migraine medications totaled $4,126,854.72.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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



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

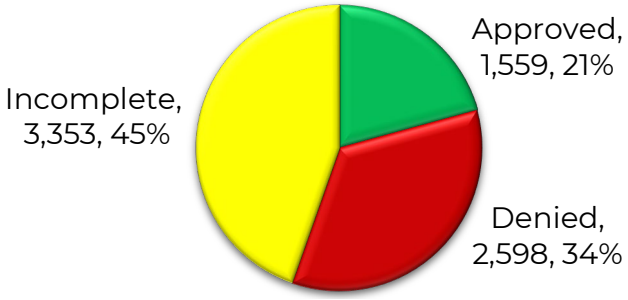


Prior Authorization of Anti-Migraine Medications

There were 7,510 prior authorization requests submitted for anti-migraine medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

[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	1,406	20%	3,313	48%	2,212	32%	**6,931**
Aetna	66	20%	40	12%	222	68%	**328**
Humana	45	38%	0	0%	74	62%	**119**
OCH	42	32%	0	0%	90	68%	**132**
Total	**1,559**	**21%**	**3,353**	**45%**	**2,598**	**34%**	**7,510**

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

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

Anticipated Patent Expiration(s):

- Tosymra® (sumatriptan nasal spray): July 2031
- Zavzpret™ (zavegepant nasal spray): October 2031
- RizaFilm® (rizatriptan film): July 2034
- Onzetra® Xsail® (sumatriptan nasal powder): October 2034
- Qulipta® (atogepant tablet): January 2035
- Zembrace® SymTouch® [sumatriptan subcutaneous (sub-Q) injection]: January 2036
- Trudhesa® [dihydroergotamine (DHE) nasal spray]: January 2039
- Nurtec® ODT [rimegepant orally disintegrating tablet (ODT)]: March 2039
- Reyvow® (lasmiditan tablet): July 2040
- Ubrelvy® (ubrogepant tablet): December 2041

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

- **January 2025:** The FDA approved Symbravo® (meloxicam/rizatriptan) for the acute treatment of migraine with or without aura in adults. The safety and efficacy of Symbravo® were studied in 2 clinical trials, the Phase 3 MOMENTUM trial and the Phase 3 INTERCEPT trial. The MOMENTUM trial, which studied Symbravo® for the treatment of migraines with moderate to severe pain intensity, showed the percentage of patients achieving headache pain freedom and most

bothersome symptom (MBS) freedom 2 hours after a single dose was statistically significantly greater among patients receiving Symbravo® compared to those who received placebo [pain free at hour 2 (19.9% vs. 6.7%; P<0.01) and MBS free at hour 2 (36.9% vs. 24.4%; P<0.01)]. Additionally, the secondary endpoint of sustained pain freedom up to 24 hours was statistically significantly greater among patients who received Symbravo® (16.1 %) compared to those who received meloxicam (9%; P=0.001) or rizatriptan (11%; P=0.038) alone. The results of the INTERCEPT trial, which studied Symbravo® for the treatment of migraines with mild pain intensity, showed the percentage of patients achieving headache pain freedom and MBS freedom at 2 hours after a single dose was statistically significantly greater in the Symbravo® treated group versus placebo [pain free at hour 2 (32.6% vs. 16.3%; P=0.002) and MBS free at hour 2 (43.9% vs. 26.7%; P=0.003)]. The Wholesale Acquisition Cost (WAC) of Symbravo® is not available at this time.

News:

- **December 2024:** Teva announced the results from the Phase 3 SPACE trial that looked at the safety and efficacy of Ajovy® (fremanezumab-vfrm) for the prevention of episodic migraine in children and adolescent patients aged 6-17 years over 12 weeks. The results showed Ajovy® significantly reduced monthly migraine days (-2.5 vs. -1.4; P=0.0210) and monthly headache days (-2.6 vs. -1.5; P=0.0172) compared to placebo with a safety profile consistent with that observed in the adult population. Teva is continuing to study Ajovy® in chronic migraines for pediatric patients.

Guidelines:

- **<u>American Headache Society (AHS):</u>**
  - In March 2024, the AHS issued a position statement update regarding the use of calcitonin gene-related peptide (CGRP) targeting therapies. The key updates included:
    - CGRP-targeting therapies are considered a first-line option for migraine prevention.
    - All therapies previously recommended by the AHS as first-line preventive options are still considered first-line options. Additionally, candesartan was added.
    - CGRP-targeting therapies have additional evidence supporting their use that previous therapies do not, including responder rates, efficacy in patients with multiple prior treatment failures, efficacy in those with acute medication overuse, and those who do and do not have aura.

- Cost considerations should include not only the direct cost of treatments, but also the indirect costs of health care utilization and acute therapies, as well as socioeconomic costs for those who are disabled by migraines.

Pipeline:

- **DHE Autoinjector:** In November 2024, Amneal Pharmaceuticals announced the resubmission of an NDA for their DHE prefilled syringe autoinjector used for the acute treatment of migraines with or without aura and cluster headache in adults. A Prescription Drug User Fee Act (PDUFA) target date has not been set; however, the review is expected to be completed in the second quarter of 2025.
- **STS101 (DHE Nasal Powder):** STS101 is a dry powder nasal formulation of DHE used for the treatment of acute migraine. In November 2024, the FDA accepted a resubmission of the NDA for STS101. The NDA addresses issues from a Complete Response Letter (CRL) issued by the FDA in January 2024 related to Chemistry, Manufacturing, and Controls (CMC). A new PDUFA target date of April 30, 2025 has been set for the application.

Recommendations

The College of Pharmacy recommends the following changes to the current Anti-Migraine Medications Product Based Prior Authorization (PBPA) category based on the new FDA approval and net costs (changes shown in red):

1. Adding Symbravo® (meloxicam/rizatriptan) to the Special PA Tier with the following additional criteria; and
2. Updating the approval criteria for Reyvow® (lasmiditan), Ubrelvy® (ubrogepant), and Zavzpret™ (zavegepant nasal spray).

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	frovatriptan tablet (Frova®)	almotriptan tablet (Axert®)	dihydroergotamine injection (D.H.E. 45®)
naratriptan tablet (Amerge®)		sumatriptan/ naproxen tablet (Treximet®)	dihydroergotamine nasal spray (Migranal®)
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)			dihydroergotamine nasal spray (Trudhesa®)
sumatriptan tablet (Imitrex®)			ergotamine sublingual tablet (Ergomar®)
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			lasmiditan tablet (Reyvow®)

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			meloxicam/rizatriptan (Symbravo®)
			rimegepant ODT (Nurtec® ODT)
			rizatriptan film (RizaFilm®)
			sumatriptan injection (Imitrex®)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal powder (Onzetra® Xsail®)
			sumatriptan nasal spray (Imitrex®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zavegepant nasal spray (Zavzpret™)
			zolmitriptan nasal spray (Zomig® nasal spray)

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and
    b. A quantity limit of 20 tablets per 28 days will apply.
2. Use of D.H.E. 45® [dihydroergotamine (DHE) injection] or Trudhesa® (DHE nasal spray) will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray), and lower-tiered triptan medications.

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

    *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.

    ⁺Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.
5. Use of Reyvow® (lasmiditan)~~, Ubrelvy® (ubrogepant), or Zavzpret™ (zavegepant nasal spray)~~ will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow®~~, Ubrelvy®, and Zavzpret™~~ will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor.
6. Use of RizaFilm® (rizatriptan film) will require a patient-specific, clinically significant reason why the member cannot use the ODT formulation and lower-tiered triptan medications.
7. Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.
8. Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID).
9. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications, Nurtec® ODT (rimegepant), and Reyvow® (lasmiditan); and
    a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.

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

Additionally, the College of Pharmacy also recommends updating the approval criteria for the CGRP therapies to be consistent with clinical practice and to be in line with current guideline recommendations (changes shown in red):

Aimovig® (Erenumab-aooe), Ajovy® (Fremanezumab-vfrm) and Emgality® (Galcanezumab-gnlm) Approval Criteria [Migraine Diagnosis]:

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and
        ~~i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and~~
4. Member has been evaluated for all of the following, ~~red flags or possible indicators of secondary headache,~~ as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:
    a. Red flags; and
    b. Possible indicators of secondary headache; and
    c. Medication overuse; and
~~5. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:~~
    ~~a. Hormone replacement therapy or hormone-based contraceptives; and~~
    ~~b. Chronic insomnia; and~~
    ~~c. Obstructive sleep apnea; and~~
6. The member has failed medical migraine preventive therapy with at least 2¥ agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects). ~~within the~~

~~last 365 days.~~ [¥The manufacturers of Ajovy® and Emgality® have currently provided a supplemental rebate to be the preferred calcitonin gene-related peptide (CGRP) inhibitor(s) and require a trial with 2 other migraine preventative therapies; however, Ajovy® and Emgality® will follow the original criteria and require trials with 3 other migraine preventative therapies if the manufacturers choose not to participate in supplemental rebates.] This includes, but is not limited to:

a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
b. Select anticonvulsant therapy; or
c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and

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

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

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

9. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative CGRP inhibitor; and

~~10. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and~~

11. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
12. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
13. Quantity limits will apply based on FDA-approved dosing:

a. For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and
b. For Ajovy® prefilled syringe and autoinjector, a quantity limit of 1 syringe or 1 autoinjector per 30 days will apply. Requests for quarterly dosing (675mg every 3 months) will be approved for a quantity limit override upon meeting Ajovy® approval criteria; and
c. For Emgality®, a quantity limit of 1 syringe or pen per 30 days will apply. Requests for an initial loading dose (240mg administered as 2 consecutive 120mg injections) will be approved for a quantity limit override upon meeting Emgality® approval criteria.

Emgality® (Galcanezumab-gnlm) Approval Criteria [Episodic Cluster Headache Diagnosis]:

1. An FDA approved indication for the treatment of episodic cluster headache in adults; and
2. Member must be 18 years of age or older; and
3. Member has a diagnosis of episodic cluster headache as defined by the International Headache Society (IHS) International Classification of Headache Disorders (ICHD) guideline and meets the following criteria:
   a. Member has a history of episodic cluster headache with at least 2 cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of ≥3 months; and
4. Member has been evaluated for red flags or possible indicators of secondary headache, as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated; and
5. ~~Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:~~
   ~~a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and~~
   ~~b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and~~
   ~~c. Opioids (≥10 days/month for >3 months); and~~
   ~~d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and~~
   ~~e. Ergotamine-containing medications (≥10 days/month for >3 months); and~~
   ~~f. Triptans (≥10 days/month for >3 months); and~~

6. Member has failed prophylactic therapy with at least 1 other medication (e.g., verapamil, select anticonvulsants, corticosteroids); and
7. Member will not use Emgality® concurrently with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
8. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
9. Initial approvals will be for the duration of 3 months. Continuation approvals will be granted until the end of the cluster period if the prescriber documents that the member is responding well to treatment as indicated by a reduction in cluster headache attack frequency; and
10. A quantity limit of (3) 100mg/mL syringes per 30 days will apply.

Nurtec® ODT (Rimegepant)*, Qulipta® (Atogepant), and Vyepti® (Eptinezumab-jjmr) Approval Criteria:

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:
    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month for more than 3 months; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months (*Nurtec® ODT is only FDA approved for the preventive treatment of episodic migraines.); and
        ~~i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and~~
4. Member has been evaluated for all of the following, ~~red flags or possible indicators of secondary headache,~~ as defined by the American Headache Society, and these conditions have been ruled out and/or have been treated:
    a. Red flags; and
    b. Possible indicators of secondary headache; and
    c. Medication overuse; and

~~5. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:~~
    ~~a. Hormone replacement therapy or hormone-based contraceptives; and~~
    ~~b. Chronic insomnia; and~~
    ~~c. Obstructive sleep apnea; and~~

6. The member has failed medical migraine preventive therapy with at least 3 agents with different mechanisms of action. Trials must be at

least 8 weeks in duration (or documented adverse effects). ~~within the last 365 days.~~ This includes, but is not limited to:
   a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
   b. Select anticonvulsant therapy; or
   c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and

~~7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:~~
   ~~a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and~~
   ~~b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and~~
   ~~c. Opioids (≥10 days/month for >3 months); and~~
   ~~d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and~~
   ~~e. Ergotamine-containing medications (≥10 days/month for >3 months); and~~
   ~~f. Triptans (≥10 days/month for >3 months); and~~

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

9. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative CGRP inhibitor; and

~~10. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and~~

11. For Vyepti®, prescriber must verify the medication will be prepared and administered according the Vyepti® package labeling; and
12. A patient-specific, clinically significant reason why member cannot use Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), or Emgality® (galcanezumab-gnlm) must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement); and
13. For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and
14. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly

migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and

15. Quantity limits will apply based on FDA-approved dosing:
    a. For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
    b. For Qulipta®, a quantity limit of 30 tablets per 30 days will apply; and
    c. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Utilization Details of Anti-Migraine Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 MEDICATIONS						
SUMATRIPTAN PRODUCTS						
SUMATRIPTAN TAB 50MG	6,036	3,457	$88,049.22	$14.59	1.75	1.56%
SUMATRIPTAN TAB 100MG	5,205	2,252	$79,937.70	$15.36	2.31	1.42%
SUMATRIPTAN TAB 25MG	3,431	2,067	$48,665.35	$14.18	1.66	0.86%
IMITREX TAB 100MG	1	1	$1,978.54	$1,978.54	1	0.04%
SUBTOTAL	**14,673**	**7,777**	**$218,630.81**	**$14.90**	**1.89**	**3.88%**
RIZATRIPTAN PRODUCTS						
RIZATRIPTAN TAB 10MG	3,844	1,853	$60,192.60	$15.66	2.07	1.07%
RIZATRIPTAN ODT 10MG	2,147	1,100	$37,080.33	$17.27	1.95	0.66%
RIZATRIPTAN TAB 5MG	862	471	$15,057.68	$17.47	1.83	0.27%
RIZATRIPTAN ODT 5MG	620	352	$11,049.00	$17.82	1.76	0.20%
SUBTOTAL	**7,473**	**3,776**	**$123,379.61**	**$16.51**	**1.98**	**2.19%**
ELETRIPTAN PRODUCTS						
ELETRIPTAN TAB 40MG	738	295	$25,563.23	$34.64	2.5	0.45%
ELETRIPTAN TAB 20MG	190	97	$6,995.85	$36,82	1.96	0.12%
RELPAX TAB 40MG	9	2	$9,464.35	$1,051.59	4.5	0.17%
SUBTOTAL	**937**	**394**	**$42,023.43**	**$44.85**	**2.38**	**0.75%**
ZOLMITRIPTAN PRODUCTS						
ZOLMITRIPTAN TAB 5MG	49	39	$1,541.85	$31.47	1.26	0.03%
ZOLMITRIPTAN TAB 2.5MG	16	11	$266.67	$16.67	1.45	0.00%
ZOLMITRIPTAN ODT 2.5MG	10	7	$307.43	$30.74	1.43	0.01%
ZOLMITRIPTAN ODT 5MG	9	7	$341.16	$37.91	1.29	0.01%
SUBTOTAL	**84**	**64**	**$2,457.11**	**$29.25**	**1.31**	**0.04%**
NARATRIPTAN PRODUCTS						
NARATRIPTAN TAB 2.5MG	66	31	$1,412.78	$21.41	2.13	0.03%
NARATRIPTAN TAB 1MG	9	6	$222.93	$24.77	1.5	0.00%
SUBTOTAL	**75**	**37**	**$1,635.71**	**$21.81**	**2.03**	**0.03%**
TIER-1 SUBTOTAL	**23,242**	**12,048**	**$388,126.67**	**$16.70**	**1.93**	**6.89%**
TIER-2 MEDICATIONS						
FROVATRIPTAN PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FROVATRIPTAN TAB 2.5MG	6	4	$338.20	$56.37	1.5	0.01%
TIER-2 SUBTOTAL	**6**	**4**	**$338.20**	**$56.37**	**1.5**	**0.01%**
TIER-3 MEDICATIONS						
SUMATRIPTAN/NAPROXEN COMBINATION PRODUCTS						
SUMAT-NAPROX TAB 85-500MG	57	30	$7,808.11	$136.98	1.9	0.14%
SUBTOTAL	**57**	**30**	**$7,808.11**	**$136.98**	**1.9**	**0.14%**
ALMOTRIPTAN PRODUCTS						
ALMOTRIPTAN TAB 12.5MG	3	3	$632.59	$210.86	1	0.01%
ALMOTRIPTAN TAB 6.25MG	1	1	$138.99	$138.99	1	0.00%
SUBTOTAL	**4**	**4**	**$771.58**	**$192.90**	**1**	**0.01%**
TIER-3 SUBTOTAL	**61**	**34**	**$8,579.69**	**$140.65**	**1.79**	**0.15%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
SUMATRIPTAN PRODUCTS						
SUMAT AUTO-INJ 6MG/0.5ML	46	16	$7,966.75	$173.19	2.88	0.14%
SUMATRIPTAN SPR 20MG/ACT	19	12	$3,044.22	$160.22	1.58	0.05%
SUMATRIPTAN SPR 5MG/ACT	11	10	$1,938.83	$176.26	1.1	0.03%
SUMATRIPTAN INJ 6MG/0.5ML	6	4	$308.06	$51.34	1.5	0.01%
TOSYMRA SOL 10MG	1	1	$621.87	$621.87	1	0.01%
IMITREX AUTO-INJ 6MG/0.5ML	1	1	$471.68	$471.68	1	0.01%
ZEMBRACE SYM INJ 3MG/0.5ML	1	1	$732.22	$732.22	1	0.01%
IMITREX CARTRIDGE 6MG/0.5ML	1	1	$2,224.80	$2,224.80	1	0.04%
SUBTOTAL	**86**	**46**	**$17,308.43**	**$201.26**	**1.87**	**0.31%**
ZOLMITRIPTAN PRODUCTS						
ZOLMITRIPTAN SPR 5MG	40	24	$16,263.95	$406.60	1.67	0.29%
ZOMIG SPR 5MG	18	13	$10,440.30	$580.02	1.38	0.19%
ZOMIG SPR 2.5MG	16	14	$9,535.68	$595.98	1.14	0.17%
SUBTOTAL	**74**	**51**	**$36,239.93**	**$489.73**	**1.45**	**0.64%**
LASMIDITAN PRODUCTS						
REYVOW TAB 100MG	13	8	$8,645.88	$665.07	1.63	0.15%
REYVOW TAB 50MG	13	11	$8,561.38	$658.57	1.18	0.15%
SUBTOTAL	**26**	**19**	**$17,207.26**	**$661.82**	**1.37**	**0.31%**
DIHYDROERGOTAMINE PRODUCTS						
DIHYDROERGOT SPR 4MG/ML	3	3	$906.61	$302.20	1	0.02%
MIGRANAL SPR 4MG/ML	2	2	$7,664.68	$3,832.34	1	0.14%
SUBTOTAL	**5**	**5**	**$8,571.29**	**$1,714.26**	**1**	**0.15%**
SPECIAL PA SUBTOTAL	**191**	**121**	**$79,326.91**	**$415.32**	**1.58**	**1.41%**
CALCITONIN GENE-RELATED PEPTIDE (CGRP) PRODUCTS⁺						
GALCANEZUMAB PRODUCTS						
EMGALITY INJ 120MG/ML	1,817	408	$1,257,861.15	$692.27	4.45	22.32%
EMGALITY SYR 120MG/ML	179	51	$116,208.28	$649.21	3.51	2.06%
EMGALITY SYR 100MG/ML	19	4	$32,034.50	$1,686.03	4.75	0.57%
SUBTOTAL	**2,015**	**463**	**$1,406,103.93**	**$697.82**	**4.35**	**24.95%**
RIMEGEPANT PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NURTEC ODT 75MG	1,658	612	$1,726,754.98	$1,041.47	2.71	30.64%
SUBTOTAL	**1,658**	**612**	**$1,726,754.98**	**$1,041.47**	**2.71**	**30.64%**
FREMANEZUMAB PRODUCTS						
AJOVY INJ 225MG/1.5ML	613	179	$427,398.62	$697.22	3.42	7.58%
AJOVY SYR 225MG/1.5ML	225	66	$159,345.40	$708.20	3.41	2.83%
SUBTOTAL	**838**	**245**	**$586,744.02**	**$700.17**	**3.42**	**10.41%**
ERENUMAB PRODUCTS						
AIMOVIG INJ 140MG/ML	401	98	$306,333.63	$763.92	4.09	5.44%
AIMOVIG INJ 70MG/ML	189	53	$147,536.52	$780.62	3.57	2.62%
SUBTOTAL	**590**	**151**	**$453,870.15**	**$769.27**	**3.91**	**8.05%**
UBROGEPANT PRODUCTS						
UBRELVY TAB 100 MG	427	188	$543,804.92	$1,273.55	2.27	9.65%
UBRELVY TAB 50 MG	78	44	$90,560.64	$1,161.03	1.77	1.61%
SUBTOTAL	**505**	**232**	**$634,365.56**	**$1,256.17**	**2.18**	**11.26%**
ATOGEPANT PRODUCTS						
QULIPTA TAB 60MG	283	116	$295,679.70	$1,044.80	2.44	5.25%
QULIPTA TAB 30MG	22	16	$22,421.04	$1,019.14	1.38	0.40%
QULIPTA TAB 10MG	12	3	$12,157.26	$1,013.11	4	0.22%
SUBTOTAL	**317**	**135**	**$330,258.00**	**$1,041.82**	**2.35**	**5.86%**
ZAVEGEPANT PRODUCTS						
ZAVZPRET SPR 10MG	10	7	$10,727.29	$1,072.73	1.43	0.19%
SUBTOTAL	**10**	**7**	**$10,727.29**	**$1,072.73**	**1.43**	**0.19%**
EPTINEZUMAB PRODUCTS						
VYEPTI INJ 100MG/ML	2	2	$10,629.20	$5,314.60	1	0.19%
SUBTOTAL	**2**	**2**	**$10,629.20**	**$5,314.60**	**1**	**0.19%**
CGRP SUBTOTAL	**5,935**	**1,847**	**$5,159,453.13**	**$869.33**	**3.21**	**91.55%**
TOTAL	**29,435**	**12,039***	**$5,635,824.60**	**$191.47**	**2.44**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Please note: Nurtec® ODT and Ubrelvy® are CGRP products but are included in the Anti-Migraine Medications Special PA Tier for acute migraine treatment. Nurtec® ODT is also FDA approved for the preventive treatment of episodic migraine and has separate criteria for preventive treatment.
ACT = actuation; DIHYDROERGOT = dihydroergotamine; INJ = injection; NAPROX = naproxen; ODT = orally disintegrating tablet; SOL = solution; SPR = nasal spray; SUMAT = sumatriptan; SYM = SymTouch™; SYR = prefilled syringe; TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
EPTINEZUMAB-JJMR INJ 1MG	33	20	$106,501.30	$3,227.31	1.65
TOTAL	**33**	**20**	**$106,501.30**	**$3,227.31**	**1.65**

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 01/2025. Last accessed 01/03/2025.
[2] Axsome Therapeutics. Axsome Therapeutics Announces FDA Approval of Symbravo® (Meloxicam and Rizatriptan) for the Acute Treatment of Migraine with or without Aura in Adults. Available online at: https://axsometherapeuticsinc.gcs-web.com/news-releases/news-release-details/axsome-therapeutics-announces-fda-approval-symbravor-meloxicam. Issued 01/30/2025. Last access 01/31/2025.
[3] Symbravo™ (Meloxicam and Rizatriptan) Tablet Prescribing Information. Axsome Therapeutics, Inc. Available online at: https://www.axsome.com/wp-content/uploads/2025/01/SYM-USPI-001.000-20250130.pdf. Last revised 01/2025. Last accessed 01/31/2025.
[4] Teva Pharmaceutical Industries Ltd. Teva Presents Positive Efficacy and Safety Data of Ajovy® (Fremanezumab) for the Prevention of Episodic Migraine in Children and Adolescents from Phase 3 SPACE Trial. Available online at: https://www.tevausa.com/news-and-media/press-releases/teva-presents-positive-efficacy-and-safety-data-of-ajovy-fremanezumab-for-the-prevention-of-episodic-m/. Issued 12/04/2024. Last accessed 01/17/2025.
[5] Charles A, Digre K, Goadsby P, et al. Calcitonin Gene-Related Peptide-Targeting Therapies are a First-Line Option for the Prevention of Migraine: An American Headache Society Position Statement Update. *Headache* 2024; 64:333–341. doi: 10.1111/head.14692.
[6] Barrie R. Amneal Files Again for FDA Approval of First Dihydroergotamine Autoinjector. *Pharmaceutical Technology*. Available online at: https://www.pharmaceutical-technology.com/news/amneal-files-again-for-fda-approval-of-first-dihydroergotamine-autoinjector/. Issued 11/22/2024. Last accessed 01/08/2025.
[7] Kang J. FDA to Review Resubmitted Dihydroergotamine Nasal Powder NDA for Migraine. *Medical Professionals Reference*. Available online at: https://www.empr.com/news/fda-to-review-resubmitted-dihydroergotamine-nasal-powder-nda-for-migraine/. Issued 11/26/2024. Last accessed 01/08/2025.

Appendix Q

Fiscal Year 2024 Annual Review of Cholestatic Liver Disease Medications and 30-Day Notice to Prior Authorize Iqirvo® (Elafibranor) and Livdelzi® (Seladelpar)

Oklahoma Health Care Authority
February 2025

Current Prior Authorization Criteria

Bylvay® (Odevixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in either the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 12 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
7. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
8. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
9. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order

to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Bylvay® (Odevixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, or ABCB4* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Bylvay® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration ≥100micromol/L at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Bylvay®; and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Bylvay®; and
10. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order

to authorize the appropriate amount of drug required according to package labeling; and

11. Initial approvals will be for 40mcg/kg/day for a duration of 3 months. After 3 months of treatment, further approval may be granted at the 40mcg/kg/day dose if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate; or
12. Dose increases to 80mcg/kg/day (for 3 months) and 120mcg/kg/day (for 3 months) may be approved if there is no improvement in pruritus after 3 months of treatment with the lower dose(s). Further approval may be granted if the prescriber documents the member is responding well to treatment at the current dose and is still not a candidate for surgical intervention; and
13. If there is no improvement in pruritus after 3 months of treatment with the maximum 120mcg/kg/day dose, further approval of Bylvay® will not be granted.

Cholbam® (Cholic Acid) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs); or
    b. Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption; and
2. Treatment with Cholbam® should be initiated and monitored by a hepatologist or pediatric gastroenterologist; and
3. The prescriber must verify that AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR will be monitored every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next 3 years, and annually thereafter; and
4. Cholbam® should be discontinued if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; and
5. Initial approvals will be for the duration of 3 months to monitor for compliance and liver function tests; and
6. Continuation approvals will be granted for the duration of 1 year; and
7. A quantity limit of 120 capsules per 30 days will apply. Quantity limit requests will be based on the member's recent weight taken within the last 30 days.

Livmarli® (Maralixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have evidence of cholestasis demonstrated by ≥1 of the following:
    a. Total serum bile acid >3x upper limit of normal (ULN) for age; or
    b. Conjugated bilirubin >1mg/dL; or
    c. Fat soluble vitamin deficiency otherwise unexplainable; or
    d. Gamma-glutamyl transferase (GGT) >3x ULN for age; or
    e. Intractable pruritus explainable only by liver disease; and
6. Members with a history of liver transplantation will not generally be approved for Livmarli®; and
7. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
10. Prescriber must verify the member and/or member's caregiver has been counseled on appropriate storage, dosing, and administration of Livmarli®, including the use of a calibrated oral dosing dispenser for accurate measurement; and

11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Livmarli® (Maralixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B* genes (results of genetic testing must be submitted); and
2. Member must be 5 years of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Livmarli®; and
8. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
9. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
10. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and

international normalized ratio (INR) at baseline and during treatment with Livmarli®; and

11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Ocaliva® (Obeticholic Acid) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year and prescriber must confirm a lack of improvement in liver function tests; and
3. The prescriber must also confirm all of the following:
    a. PBC is not caused by a superimposed liver disease; and
    b. If the member has a superimposed liver disease, it is being adequately treated; and
    c. Proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and patient compliance with UDCA; and
4. Ocaliva® must be taken in combination with UDCA; or
    a. For Ocaliva® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
5. A quantity limit of 1 tablet per day will apply.

Utilization of Cholestatic Liver Disease Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

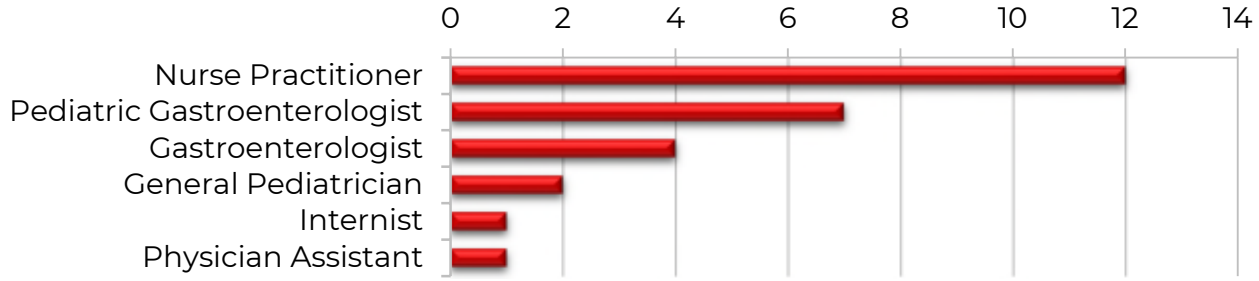
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	3	14	$117,040.90	$8,360.06	$278.67	420	420
2023 Total	**3**	**14**	**$117,040.90**	**$8,360.06**	**$278.67**	**420**	**420**
Fiscal Year 2024							
FFS	4	22	$274,510.48	$12,477.75	$415.92	690	660
Aetna	1	2	$14,502.82	$7,251.41	$241.71	60	60
Humana	1	2	$52,810.82	$26,405.41	$880.18	60	60
OCH	1	1	$9,565.46	$9,565.46	$318.85	30	30
2024 Total	**7**	**27**	**$351,389.58**	**$13,014.43**	**$433.81**	**840**	**810**
% Change	**133.30%**	**92.90%**	**200.20%**	**55.70%**	**55.70%**	**100.00%**	**92.90%**
Change	**4**	**13**	**$234,348.68**	**$4,654.37**	**$155.14**	**420**	**390**

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

Demographics of Members Utilizing Cholestatic Liver Disease Medications: Pharmacy Claims (All Plans)

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

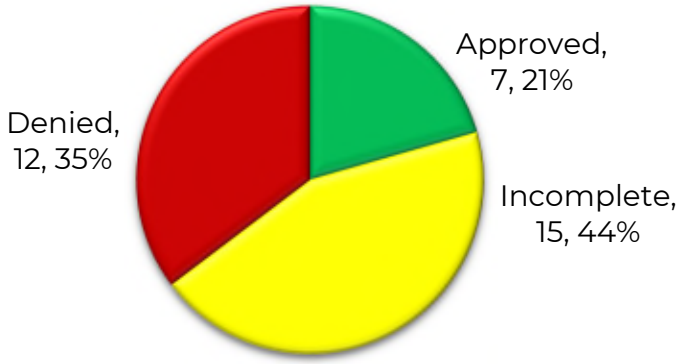
Top Prescriber Specialties of Cholestatic Liver Disease Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Cholestatic Liver Disease Medications

There were 34 prior authorization requests submitted for cholestatic liver disease medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	5	17%	15	50%	10	33%	**30**
Aetna	1	33%	0	0%	2	67%	**3**
Humana	1	100%	0	0%	0	0%	**1**
OCH	0	N/A	0	N/A	0	N/A	**0**
Total	**7**	**21%**	**15**	**44%**	**12**	**35%**	**34**

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

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

Anticipated Patent Expiration(s):

- Livdelzi® (seladelpar): March 2035
- Ocaliva® (obeticholic acid): April 2036
- Iqirvo® (elafibranor): March 2037
- Livmarli® (maralixibat): February 2040
- Bylvay® (odevixibat): November 2041

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

- **June 2024:** The FDA granted accelerated approval to Iqirvo® (elafibranor) for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
- **July 2024:** The FDA approved Livmarli® (maralixibat) for an age expansion for the treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Livmarli® was previously approved for this indication in patients 5 years of age and older. Additionally, a new 19mg/mL oral solution formulation of Livmarli® was approved, and the Livmarli® label has been updated to specify that the 19mg/mL solution should only be

used for patients with PFIC, while the original 9.5mg/mL solution should only be used for patients with Alagille syndrome (ALGS).
- **August 2024:** The FDA granted accelerated approval to Livdelzi® (seladelpar) for the treatment of PBC in combination with UDCA in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

News:
- **November 2024:** The FDA issued a Complete Response Letter (CRL) to Intercept Pharmaceuticals for their supplemental New Drug Application (sNDA) for Ocaliva® (obeticholic acid) seeking full FDA approval of the medication. Ocaliva® was granted accelerated approval in May 2016 for the treatment of PBC in combination with UDCA in adults with inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. In May 2021, due to an identified risk of serious liver injury in patients with advanced cirrhosis taking Ocaliva® to treat PBC, the indication was narrowed and new contraindications were added to the labeling for patients with decompensated cirrhosis (e.g., Child-Pugh class B or C) or a prior decompensation event, or patients with compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia). In September 2024, the FDA's Gastrointestinal Drugs Advisory Committee voted against recommending full approval of Ocaliva® based on concerns that the medication does not have a favorable benefit-risk profile.
- **December 2024:** The FDA issued a new drug safety communication warning of the risk of serious liver injury that has been observed in patients without cirrhosis who were taking Ocaliva® to treat PBC. Based on this, the FDA states that health care professionals should monitor liver tests frequently to detect and address worsening liver function early but notes that it is unclear if the monitoring will be sufficient to address the risk of serious liver injury. Ocaliva® should be discontinued if there is any sign of liver disease progression or if there is no demonstrated efficacy.

Iqirvo® (Elafibranor) Product Summary[11,12]

Therapeutic Class: Peroxisome proliferator-activated receptor (PPAR) agonist

Indication(s): Treatment of PBC in combination with UDCA in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA
- This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or

prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- **Limitation(s) of Use:** Use not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)

How Supplied: 80mg oral tablets

Dosing and Administration:
- 80mg once daily with or without food
- Before treatment, patients should be evaluated for muscle pain or myopathy
- Should verify that females of reproductive potential are not pregnant before treatment

Efficacy: The efficacy of Iqirvo® was assessed primarily in a Phase 3, randomized, double-blind, placebo-controlled study that enrolled a total of 161 adult patients with PBC.
- Key Inclusion Criteria:
  - ALP ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline
  - Use of UDCA for at least 12 months prior to randomization, unless unable to tolerate UDCA treatment
- Intervention(s): Patients were randomized 2:1 to receive elafibranor 80mg or placebo once daily.
- Primary Endpoint(s): Biochemical response (defined as ALP <1.67 times the ULN with ≥15% reduction from baseline plus TB ≤ the ULN) assessed at week 52
- Results: Biochemical response was achieved in 51% of patients receiving elafibranor and 4% of patients receiving placebo [treatment difference: 47%; 95% confidence interval (CI): 32%, 57%; P<0.0001].

Livdelzi® (Seladelpar) Product Summary[13,14]

Therapeutic Class: PPAR-delta agonist

Indication(s): Treatment of PBC in combination with UDCA in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA
- This indication is approved under accelerated approval based on a reduction of ALP. Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

- **Limitation(s) of Use:** Use not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)

How Supplied: 10mg oral capsules

Dosing and Administration: 10mg once daily with or without food

Efficacy: The efficacy of Livdelzi® was assessed primarily in a Phase 3, randomized, double-blind, placebo-controlled study that enrolled a total of 193 adult patients with PBC.

- Key Inclusion Criteria:
  - ALP ≥1.67 times the ULN and TB ≤2 times the ULN at baseline
  - Use of UDCA for at least 12 months prior to randomization, unless unable to tolerate UDCA treatment
- Intervention(s): Patients were randomized 2:1 to receive seladelpar 10mg or placebo once daily.
- Primary Endpoint(s): Biochemical response (defined as ALP <1.67 times the ULN with ≥15% reduction from baseline plus TB ≤ the ULN) assessed at month 12
- Results: Biochemical response was achieved in 62% of patients receiving seladelpar and 20% of patients receiving placebo (treatment difference: 42%; 95% CI: 28%, 53%; P<0.0001).

Cost Comparison: PBC Medications

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Iqirvo® (elafibranor) 80mg tablet	**$382.00**	**$11,460.00***	**$137,520.00**
Livdelzi® (seladelpar) 10mg capsule	**$420.20**	**$12,606.00⁺**	**$151,272.00**
Ocaliva® (obeticholic acid) 10mg tablet	$318.47	$9,554.10⁺	$114,649.20
ursodiol 250mg tablet (generic)	$0.34	$51.00Δ	$612.00

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per month based on 80mg once daily
⁺Cost per month based on 10mg once daily
ΔCost per month based on a total daily dose of 1,250mg
Unit = each capsule or tablet

Recommendations

The College of Pharmacy recommends the prior authorization of Iqirvo® (elafibranor) and Livdelzi® (seladelpar) with the following criteria (shown in red):

Iqirvo® (Elafibranor) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must be 18 years of age or older; and
3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and
4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and
5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and
    a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and
6. Iqirvo® must be taken in combination with UDCA; or
    a. For Iqirvo® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
7. Member must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); and
8. Prescriber must agree to monitor all of the following:
    a. Muscle pain or myopathy at baseline and periodically during treatment; and
    b. Fracture risk and bone health; and
    c. Liver function tests at baseline and thereafter; and
9. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy, must agree to use effective non-hormonal contraception (or add a barrier method when using hormonal contraception), and must not be breastfeeding during treatment and for 3 weeks following the last dose of Iqirvo®; and
10. A quantity limit of 30 tablets per 30 days will apply; and
11. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests.

Livdelzi® (Seladelpar) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must be 18 years of age or older; and

3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and
4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and
5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and
    a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and
6. Livdelzi® must be taken in combination with UDCA; or
    a. For Livdelzi® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
7. Member must not have decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy); and
8. Prescriber must agree to monitor all of the following:
    a. Fracture risk and bone health; and
    b. Liver function tests at baseline and thereafter; and
9. Member must not be taking OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors concurrently with Livdelzi®; and
10. A patient-specific, clinically significant reason why the member cannot use Iqirvo® (elafibranor) must be provided; and
11. A quantity limit of 30 capsules per 30 days will apply; and
12. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests.

Next, the College of Pharmacy recommends updating the Ocaliva® (obeticholic acid) approval criteria based on the FDA's safety alerts and to be consistent with the criteria for other PBC medications (changes shown in red):

Ocaliva® (Obeticholic Acid) Approval Criteria:

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must be 18 years of age or older; and
3. Member must have elevated alkaline phosphatase (ALP) ≥1.67 times the upper limit of normal (ULN) and total bilirubin (TB) ≤2 times the ULN at baseline; and

4. Must be prescribed by a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of PBC); and
5. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year (unless intolerance is documented) with inadequate improvement in liver function tests; and
    a. Prescriber must confirm proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and member compliance with UDCA; and
~~6. The prescriber must also confirm all of the following:~~
    ~~a. PBC is not caused by a superimposed liver disease; and~~
    ~~b. If the member has a superimposed liver disease, it is being adequately treated; and~~
    ~~c. Proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and patient compliance with UDCA; and~~
7. Ocaliva® must be taken in combination with UDCA; or
    a. For Ocaliva® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
8. Member must not have any of the following:
    a. Decompensated cirrhosis (e.g., Child-Pugh class B or C) or a prior decompensation event; or
    b. Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia); or
    c. Complete biliary obstruction; and
9. Prescriber must agree to monitor liver tests frequently and to discontinue Ocaliva® if there is any evidence of liver disease progression while on treatment; and
10. Initial approvals will be for a dose of 5mg once daily for a duration of 3 months. After 3 months of treatment, information regarding efficacy must be submitted; and
    a. If an adequate improvement in liver function tests is not achieved with the 5mg dose, a dose of 10mg once daily may be approved for a duration of 3 months; and
11. Subsequent approvals (for a duration of 1 year) may be granted if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests; and
12. A quantity limit of 1 tablet per day will apply.

The College of Pharmacy also recommends updating the Livmarli® (maralixibat) approval criteria based on the new FDA approved age expansion for the PFIC indication and to be consistent with the recent label updates regarding the recommended formulation for each indication (changes shown in red):

Livmarli® (Maralixibat) Approval Criteria [Alagille Syndrome (ALGS) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with ALGS; and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic variant in the *JAG1* or *NOTCH2* genes (results of genetic testing must be submitted); and
2. Member must be 3 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of ALGS); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have evidence of cholestasis demonstrated by ≥1 of the following:
    a. Total serum bile acid >3x upper limit of normal (ULN) for age; or
    b. Conjugated bilirubin >1mg/dL; or
    c. Fat soluble vitamin deficiency otherwise unexplainable; or
    d. Gamma-glutamyl transferase (GGT) >3x ULN for age; or
    e. Intractable pruritus explainable only by liver disease; and
6. Members with a history of liver transplantation will not generally be approved for Livmarli®; and
7. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and
8. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
9. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and

10. Prescriber must verify the member and/or member's caregiver has been counseled on appropriate storage, dosing, and administration of Livmarli®, including the use of a calibrated oral dosing dispenser for accurate measurement; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. The request must be for the 9.5mg/mL solution; and
13. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Livmarli® (Maralixibat) Approval Criteria [Progressive Familial Intrahepatic Cholestasis (PFIC) Diagnosis]:

1. An FDA approved indication for the treatment of cholestatic pruritus in members with PFIC; and
    a. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic variants in the *ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B* genes (results of genetic testing must be submitted); and
2. Member must be ~~5 years~~ 12 months of age or older; and
3. Livmarli® must be prescribed by a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC (or an advanced care practitioner with a supervising physician who is a gastroenterologist, hepatologist, geneticist, or other specialist with expertise in the treatment of PFIC); and
4. Prescriber must verify member has a history of significant pruritus that is unresponsive to treatment with ursodeoxycholic acid (UDCA) and at least 2 of the following medications, unless contraindicated:
    a. Cholestyramine; or
    b. Rifampin; or
    c. Sertraline; or
    d. Naltrexone; and
5. Member must have elevated serum bile acid concentration >3x the upper limit of normal (ULN) for age at baseline; and
6. Prescriber must verify member does not have known pathologic variants of the *ABCB11* gene predicting a non-functional or absent bile salt export pump protein (BSEP-3); and
7. Members with a history of liver transplantation will generally not be approved for Livmarli®; and
8. Member must not have prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy); and

9. Prescriber must verify surgical intervention (e.g., biliary diversion, liver transplantation) is not currently clinically appropriate for the member; and
10. Prescriber must agree to monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, direct bilirubin, and international normalized ratio (INR) at baseline and during treatment with Livmarli®; and
11. Member's current weight (taken within the past 3 weeks) must be provided on initial and subsequent prior authorization requests in order to authorize the appropriate amount of drug required according to package labeling; and
12. The request must be for the 19mg/mL solution; and
13. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted for a duration of 1 year if the prescriber documents the member is responding well to treatment and surgical intervention is still not clinically appropriate.

Lastly, the College of Pharmacy also recommends updating the Cholbam® (cholic acid) approval criteria to be consistent with other medications in this category (changes shown in red):

Cholbam® (Cholic Acid) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs); ~~or~~ and
        i. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *AKR1D1, AMACR, BAAT, CYP7A1, CYP7B1, CYP27A1, DHCR7, HSD3B7,* or *SLC27A5* gene, or other gene with significant supporting evidence of pathogenicity (results of genetic testing must be submitted); or
    b. Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption; and
        i. Diagnosis must be confirmed by genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *PEX1, PEX2, PEX3, PEX5, PEX6, PEX10, PEX11B, PEX12, PEX13, PEX14, PEX16, PEX19,* or *PEX26* gene (results of genetic testing must be submitted); and
2. Treatment with Cholbam® should be initiated and monitored by a hepatologist, ~~or~~ pediatric gastroenterologist, or other specialist with expertise in the treatment of SEDs or PDs; and

3. The prescriber must verify that AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR will be monitored every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next 3 years, and annually thereafter; and
4. Cholbam® should be discontinued if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; and
5. Initial approvals will be for the duration of 3 months to monitor for compliance and liver function tests; and
6. Continuation approvals will be granted for the duration of 1 year if the prescriber documents the member is responding well to treatment, as indicated by improvements in liver function tests; and
7. A quantity limit of 120 capsules per 30 days will apply. Quantity limit requests will be based on the member's recent weight taken within the last 30 days.

Utilization Details of Cholestatic Liver Disease Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OBETICHOLIC ACID PRODUCTS						
OCALIVA TAB 5MG	17	3	$155,752.48	$9,161.91	5.67	44.32%
SUBTOTAL	**17**	**3**	**$155,752.48**	**$9,161.91**	**5.67**	**44.32%**
CHOLIC ACID PRODUCTS						
CHOLBAM CAP 50MG	5	1	$41,432.05	$8,286.41	5	11.79%
CHOLBAM CAP 250MG	2	1	$52,810.82	$26,405.41	2	15.03%
SUBTOTAL	**7**	**2**	**$94,242.87**	**$13,463.27**	**3.5**	**26.82%**
ODEVIXIBAT PRODUCTS						
BYLVAY CAP 200MCG	2	1	$14,502.82	$7,251.41	2	4.13%
BYLVAY CAP 1,200MCG	1	1	$86,891.41	$86,891.41	1	24.73%
SUBTOTAL	**3**	**2**	**$101,394.23**	**$33,798.08**	**1.5**	**28.86%**
TOTAL	**27**	**7***	**$351,389.58**	**$13,014.43**	**3.86**	**100%**

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

[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 01/2025. Last accessed 01/06/2025.
[2] Ipsen. Ipsen's Iqirvo® Receives U.S. FDA Accelerated Approval as a First-In-Class PPAR Treatment for Primary Biliary Cholangitis. Available online at: https://www.ipsen.com/press-releases/ipsens-iqirvo-receives-u-s-fda-accelerated-approval-as-a-first-in-class-ppar-treatment-for-primary-biliary-cholangitis/. Issued 06/10/2024. Last accessed 01/06/2025.
[3] Mirum Pharmaceuticals, Inc. Mirum's Livmarli® Now Approved for PFIC in Patients 12 Months and Older. Available online at: https://ir.mirumpharma.com/news-events/News/news-details/2024/Mirums-LIVMARLI-Now-Approved-for-PFIC-in-Patients-12-Months-and-Older/default.aspx. Issued 07/25/2024. Last accessed 01/06/2025.
[4] Livmarli® (Maralixibat) Prescribing Information. Mirum Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/214662s011lbl.pdf. Last revised 11/2024. Last accessed 01/06/2025.
[5] Gilead Sciences, Inc. Gilead's Livdelzi® (Seladelpar) Granted Accelerated Approval for Primary Biliary Cholangitis by U.S. FDA. Available online at: https://www.gilead.com/news-and-press/press-room/press-releases/2024/8/gileads-livdelzi-seladelpar-granted-accelerated-approval-for-primary-biliary-cholangitis-by-us-fda. Issued 08/14/2024. Last accessed 01/06/2025.
[6] Intercept Pharmaceuticals, Inc. Intercept Receives Complete Response Letter from FDA Addressing Ocaliva® Supplemental New Drug Application (sNDA). Available online at: https://www.interceptpharma.com/about-us/news/?id=2979130. Issued 11/12/2024. Last accessed 01/09/2025.
[7] Ingram I. FDA Rejects Full Approval of Liver Disease Drug. *Medpage Today*. Available online at: https://www.medpagetoday.com/gastroenterology/generalhepatology/112874. Issued 11/12/2024. Last accessed 01/09/2025.
[8] U.S. FDA. Serious Liver Injury Being Observed in Patients Without Cirrhosis Taking Ocaliva® (Obeticholic Acid) to Treat Primary Biliary Cholangitis. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/serious-liver-injury-being-observed-patients-without-cirrhosis-taking-ocaliva-obeticholic-acid-treat. Issued 12/12/2024. Last accessed 01/09/2025.
[9] U.S. FDA. Due to Risk of Serious Liver Injury, FDA Restricts Use of Ocaliva® (Obeticholic Acid) in Primary Biliary Cholangitis (PBC) Patients with Advanced Cirrhosis. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious-liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary-cholangitis. Issued 05/26/2021. Last accessed 01/09/2025.
[10] Ocaliva® (Obeticholic Acid) Prescribing Information. Intercept Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/207999s008lbl.pdf. Last revised 02/2022. Last accessed 01/10/2025.
[11] Iqirvo® (Elafibranor) Prescribing Information. Ipsen Biopharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218860s000lbl.pdf. Last revised 06/2024. Last accessed 01/06/2025.
[12] Kowdley KV, Bowlus CL, Levy C, et al. Efficacy and Safety of Elafibranor in Primary Biliary Cholangitis. *N Engl J Med* 2024; 390:795-805. doi: 10.1056/NEJMoa2306185.
[13] Livdelzi® (Seladelpar) Prescribing Information. Gilead Sciences, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217899s000lbl.pdf. Last revised 08/2024. Last accessed 01/06/2025.
[14] Hirschfield GM, Bowlus CL, Mayo MJ, et al. A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis. *N Engl J Med* 2024; 390(9):783-794. doi: 10.1056/NEJMoa2312100.

Appendix R

Fiscal Year 2024 Annual Review of Anti-Ulcer Medications and 30-Day Notice to Prior Authorize Pantoprazole in 0.9% Sodium Chloride (NaCl) for Intravenous (IV) Injection

Oklahoma Health Care Authority
February 2025

Current Prior Authorization Criteria

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

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

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

Anti-Ulcer Medications Tier-2 Approval Criteria:

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

Anti-Ulcer Medications Tier-3 Approval Criteria:

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

Proton Pump Inhibitors for Pediatric Members Approval Criteria:

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

Axid® (Nizatidine Capsule) Approval Criteria:

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

Axid® (Nizatidine Solution) Approval Criteria:

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

2. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

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

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

Esomep-EZS™ (Esomeprazole Kit) Approval Criteria:

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

Glycate® (Glycopyrrolate Tablet) Approval Criteria:

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

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

1. Member must be 18 years of age or older; and
2. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided; and
3. For Konvomep™, requests for the 90mL or 150mL package will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size.

Pepcid® (Famotidine Suspension) Approval Criteria:

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

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

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

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

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components (bismuth subsalicylate, metronidazole, and tetracycline) plus a histamine type 2 receptor (H2) antagonist must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection [e.g., proton pump inhibitor (PPI)/H2 antagonist, amoxicillin, clarithromycin, and metronidazole], which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
5. A quantity limit of 120 capsules per 10 days will apply.

Tagamet® (Cimetidine Tablet) Approval Criteria:

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

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy regimens approved for the same diagnosis (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
3. A quantity limit of 168 capsules per 14 days will apply.

Voquezna® (Vonoprazan Fumarate) Approval Criteria:

1. An FDA approved diagnosis; and

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

Voquezna® Dual Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate) and Voquezna® Triple Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate/ Clarithromycin) Approval Criteria:

1. An FDA approved indication for the treatment of *Helicobacter pylori* (*H. pylori*) infection; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection [e.g., proton pump inhibitor (PPI)/ histamine type 2 receptor (H2) antagonist, amoxicillin, clarithromycin, and metronidazole], which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin) which are available without prior authorization, must be provided; and
5. A quantity limit of 112 tablets/capsules per 14 days will apply.

Utilization of Anti-Ulcer Medications: Fiscal Year 2024

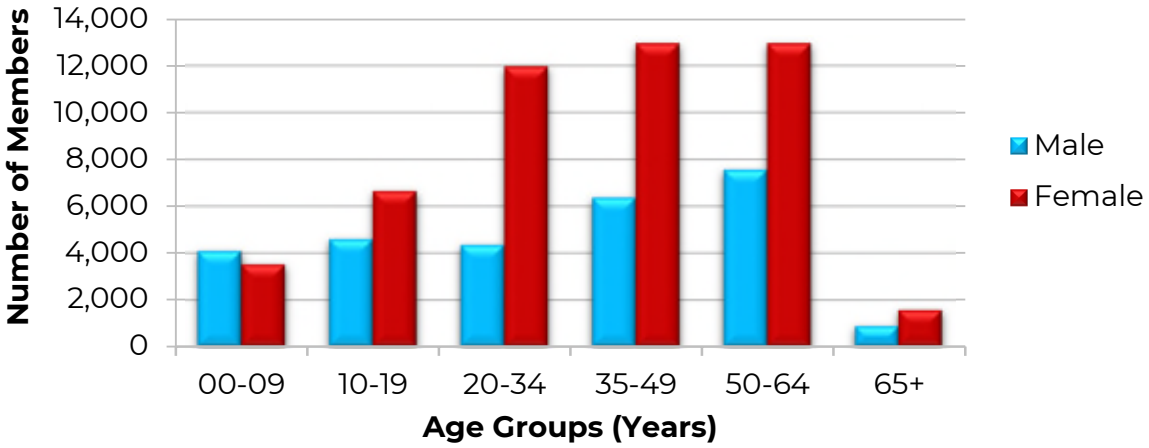
Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	79,808	242,138	$6,141,661.64	$25.36	$0.55	15,281,015	11,200,074
2023 Total	**79,808**	**242,138**	**$6,141,661.64**	**$25.36**	**$0.55**	**15,281,015**	**11,200,074**
Fiscal Year 2024							
FFS	70,369	196,343	$4,990,887.35	$25.42	$0.53	13,304,769	9,355,549
Aetna	6,492	9,321	$221,959.11	$23.81	$0.48	616,815	458,752
Humana	7,942	11,850	$285,869.83	$24.12	$0.48	812,039	591,701
OCH	6,593	9,268	$220,127.48	$23.75	$0.49	607,780	444,847
2024 Total	**77,277**	**226,782**	**$5,718,843.77**	**$25.22**	**$0.53**	**15,341,404**	**10,850,849**
% Change	**-3.20%**	**-6.30%**	**-6.90%**	**-0.60%**	**-3.60%**	**0.40%**	**-3.10%**
Change	**-2,531**	**-15,356**	**-$422,817.87**	**-$0.14**	**-$0.02**	**60,389**	**-349,225**

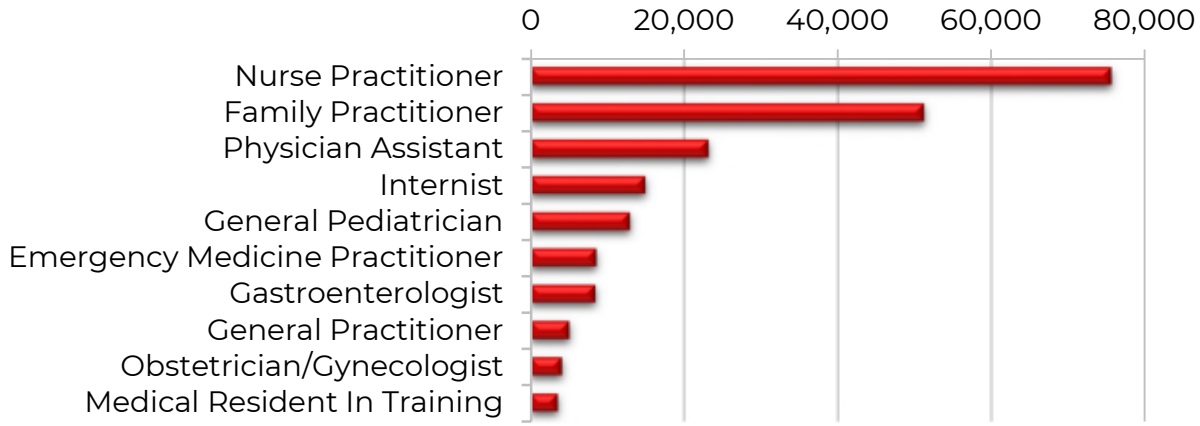
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2023 = 07/01/2022 to 06/30/2023; Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available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

- Aggregate drug rebates collected during fiscal year 2024 for anti-ulcer medications totaled $885,878.22.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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



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

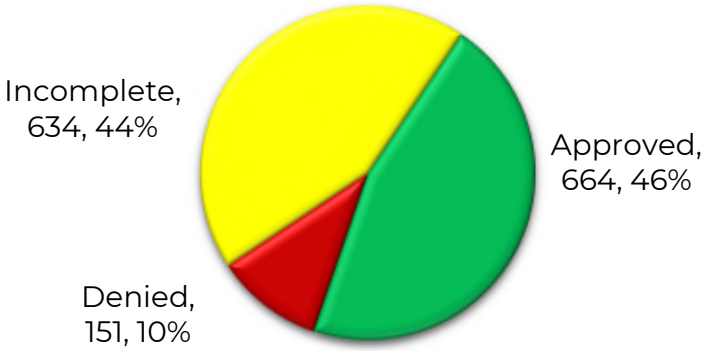


Prior Authorization of Anti-Ulcer Medications

There were 1,449 prior authorization requests submitted for anti-ulcer medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

[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	638	49%	564	43%	110	8%	**1,312**
Aetna	14	13%	70	64%	26	24%	**110**
Humana	0	0%	0	0%	5	100%	**5**
OCH	12	55%	0	0%	10	45%	**22**
Total	**664**	**46%**	**634**	**44%**	**151**	**10%**	**1,449**

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

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

Anticipated Patent Expiration(s):

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

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

- **February 2024:** A New Drug Application (NDA) was approved for pantoprazole sodium chloride (NaCl) 0.9% for intravenous (IV) injection for the short-term treatment of gastroesophageal reflux disease (GERD) associated with erosive esophagitis and pathological hypersecretion conditions, including Zollinger-Ellison Syndrome in adults. Pantoprazole NaCl 0.9% is available as a solution for IV infusion that does not require reconstitution versus Protonix® I.V. (pantoprazole) that is a freeze-dried powder. Pantoprazole NaCl 0.9% is available in 3 different strengths: 40mg/100mL, 40mg/50mL, and 80mg/100mL.

- **August 2024:** The FDA approved Protonix® I.V. (pantoprazole) for an age expansion for patients 3 months of age and older for the treatment of GERD and a history of erosive esophagitis for up to 7 days. The dose for pediatric patients is based on age and actual body weight. Protonix® I.V. was originally approved for this indication for adults only. The age expansion approval was based on evidence from studies of IV and oral pantoprazole in adults and oral pantoprazole in pediatrics with additional pharmacokinetic and safety data in patients 1 year of age and older for IV pantoprazole and oral pantoprazole in patients 3 months of age and older.

News:

- **January 2025:** As of January 2025, the FDA Orange Book lists esomeprazole strontium and Aciphex® sprinkles (rabeprazole) as discontinued products. Additionally, there are no generic equivalents for these products.

Guideline Update(s):

- **American College of Gastroenterology (ACG) Guideline Update(s):** The ACG released an update for the treatment of *Helicobacter pylori* (*H. pylori*) infection that includes changes from the 2017 guideline based on new data from North America including rising rates of resistance to clarithromycin and levofloxacin and studies that have been conducted with rifabutin and potassium-competitive acid blockers (PCABs) in treatment-naïve individuals. Some notable recommendations include:
  - Treatment-naïve patients:
    - Optimized bismuth quadruple therapy (BQT) for 14 days is the preferred option when the antibiotic susceptibility profile is unknown.
    - Rifabutin triple therapy or PCAB dual therapy for 14 days can be suitable alternatives in patients without a penicillin allergy.
    - 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 proton pump inhibitor (PPI)-clarithromycin triple therapy when no other obvious first line treatment option is available.
  - Treatment-experienced patients:
    - BQT for 14 days is the preferred option for patients who have not been treated with BQT previously and the *H. pylori* resistance profile is unknown.
    - For patients previously treated with BQT, rifabutin triple therapy is a suitable alternative.
    - For patients with persistent infection after optimized BQT and/or rifabutin triple therapy, or in whom rifabutin therapy

cannot be used (e.g., because of true penicillin allergy), antibiotic susceptibility testing is recommended to guide further therapy with salvage regimens containing clarithromycin or levofloxacin.

- In patients who are known to be infected with clarithromycin-sensitive *H. pylori* and who have not received clarithromycin triple therapy with recommended doses of clarithromycin and amoxicillin, optimized PPI or PCAB-clarithromycin triple therapy for 14 days is a viable option.

Recommendations

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

1. Prior authorization of pantoprazole in 0.9% NaCl for IV injection and placement into Special PA Tier with the following criteria; and
2. Moving Dexilant® (dexlansoprazole) from Tier-1 to Tier-2 based on net costs; and
3. Moving Carafate® (sucralfate) suspension from Tier-1 to the Special PA Tier with additional criteria based on net costs; and
4. Removing esomeprazole strontium and Aciphex® sprinkles (rabeprazole) due to product discontinuations; and
5. Updating Tagamet® (cimetidine tablets) criteria to allow for a clinical exception for a diagnosis of molluscum contagiosum; and
6. Updating Pylera® (bismuth subcitrate potassium/metronidazole/ tetracycline), Talicia® (omeprazole/amoxicillin/rifabutin), Voquezna® (vonoprazan fumarate) tablets, Voquezna® Dual Pak® (vonoprazan fumarate/amoxicillin trihydrate) and Voquezna® Triple Pak® (vonoprazan fumarate/amoxicillin trihydrate/clarithromycin) criteria based on ACG guideline recommendations.

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

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

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

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

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

Carafate (Sucralfate Suspension) Approval Criteria:

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

Tagamet® (Cimetidine Tablets) Approval Criteria:

1. An FDA approved diagnosis; and

2. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided; or
3. A clinical exception will apply for a diagnosis of molluscum contagiosum in which Tagamet® (cimetidine) tablets will be approved.

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

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
3. ~~A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus a histamine type 2 receptor (H2) antagonist], must be provided; and~~
4. ~~A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and~~
5. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori infection* (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and
6. A quantity limit of 120 capsules per 10 days will apply.

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

1. An FDA approved indication for the treatment of *Helicobacter pylori* (*H. pylori*) infection ~~diagnosis~~; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components ~~of other triple-therapy regimens approved for the same diagnosis~~ (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of potassium-competitive acid blocker

(PCAB) dual therapy (e.g., vonoprazan fumarate and amoxicillin) must be provided; and
5. A quantity limit of 168 capsules per 14 days will apply.

Voquezna® (Vonoprazan Fumarate) Approval Criteria [Erosive and Non-Erosive Esophagitis Diagnosis]:

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

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

1. An FDA approved indication for the treatment of *H. pylori* infection; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
4. ~~A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor/H2 antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and~~
5. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and rifabutin ~~clarithromycin~~), which are available without prior authorization, must be provided; and
6. For the Voquezna® Dual Pak® and Voquezna® Triple Pak®, a patient-specific, clinically significant reason why the member cannot use the individual components of the product requested must be provided; and
7. A quantity limit of 112 tablets/capsules per 14 days will apply.

Utilization Details of Anti-Ulcer Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
OMEPRAZOLE PRODUCTS						
OMEPRAZOLE CAP 20MG	42,238	17,632	$509,627.21	$12.07	2.4	8.91%
OMEPRAZOLE CAP 40MG	41,087	16,496	$542,106.98	$13.19	2.49	9.48%
OMEPRAZOLE CAP 10MG	1,781	765	$25,024.80	$14.05	2.33	0.44%
OMEPRAZOLE TAB 20MG DR	6	5	$132.67	$22.11	1.2	0.00%
OMEPRAZOLE TAB 20MG	4	4	$89.24	$22.31	1	0.00%
SUBTOTAL	**85,116**	**34,902**	**$1,076,980.90**	**$12.65**	**2.44**	**18.83%**
PANTOPRAZOLE PRODUCTS						
PANTOPRAZOLE TAB 40MG	54,585	22,253	$728,396.32	$13.34	2.45	12.74%
PANTOPRAZOLE TAB 20MG	8,022	3,578	$103,479.92	$12.90	2.24	1.81%
SUBTOTAL	**62,607**	**25,831**	**$831,876.24**	**$13.29**	**2.42**	**14.55%**
FAMOTIDINE PRODUCTS						
FAMOTIDINE TAB 20MG	23,446	11,564	$294,115.77	$12.54	2.03	5.14%
FAMOTIDINE TAB 40MG	7,804	3,829	$108,169.25	$13.86	2.04	1.89%
FAMOTIDINE INJ 20MG/2ML	155	8	$2,776.58	$17.91	19.38	0.05%
FAMOTIDINE INJ 200/20ML	136	9	$2,484.36	$18.27	15.11	0.04%
FAMOTIDINE INJ 40MG/4ML	52	3	$1,166.39	$22.43	17.33	0.02%
FAMOTIDINE INJ 10MG/ML	33	5	$601.58	$18.23	6.6	0.01%
FAMOTIDINE TAB 10MG	12	8	$116.59	$9.72	1.5	0.00%
HEARTBURN RELIEF TAB 10MG	5	4	$70.32	$14.06	1.25	0.00%
HEARTBURN TAB 20MG	2	2	$25.30	$12.65	1	0.00%
ACID REDUCER TAB 10MG	2	2	$24.50	$12.25	1	0.00%
ACID REDUCER TAB 20MG	1	1	$18.46	$18.46	1	0.00%
SUBTOTAL	**31,648**	**15,435**	**$409,569.10**	**$12.94**	**2.05**	**7.16%**
SUCRALFATE PRODUCTS						
SUCRALFATE TAB 1GM	10,858	6,367	$254,715.24	$23.46	1.71	4.45%
SUCRALFATE SUS 1GM/10ML	1,926	1,133	$394,993.79	$205.09	1.7	6.91%
CARAFATE SUS 1GM/10ML	18	18	$8,519.76	$473.32	1	0.15%
SUBTOTAL	**12,802**	**7,518**	**$658,228.79**	**$51.42**	**1.7**	**11.51%**
ESOMEPRAZOLE PRODUCTS						
ESOMEPRAZOLE CAP 40MG DR	5,624	1,954	$106,083.51	$18.86	2.88	1.85%
ESOMEPRAZOLE CAP 20MG DR	2,038	793	$41,587.53	$20.41	2.57	0.73%
NEXIUM GRA 10MG DR	615	210	$187,019.94	$304.10	2.93	3.27%
NEXIUM GRA 20MG DR	523	134	$156,531.60	$299.30	3.9	2.74%
NEXIUM GRA 5MG DR	315	128	$91,155.15	$289.38	2.46	1.59%
NEXIUM GRA 40MG DR	209	39	$61,386.01	$293.71	5.36	1.07%
NEXIUM GRA 2.5MG DR	105	62	$29,774.46	$283.57	1.69	0.52%
ESOMEPRAZOLE GRA 10MG DR	14	9	$3,111.46	$222.25	1.56	0.05%
ESOMEPRAZOLE GRA 20MG DR	11	5	$2,183.94	$198.54	2.2	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NEXIUM CAP 40MG	3	1	$814.02	$271.34	3	0.01%
SUBTOTAL	**9,457**	**3,335**	**$679,647.62**	**$71.87**	**2.84**	**11.88%**
DEXLANSOPRAZOLE PRODUCTS						
DEXLANSOPRAZOLE CAP 60MG DR	3,606	623	$726,866.42	$201.57	5.79	12.71%
DEXLANSOPRAZOLE CAP 30MG DR	932	191	$197,380.73	$211.78	4.88	3.45%
DEXILANT CAP 60MG DR	407	92	$118,748.65	$291.77	4.42	2.08%
DEXILANT CAP 30MG DR	78	24	$23,416.47	$300.21	3.25	0.41%
DEXLANSOPRAZOLE CAP 30MG	3	2	$634.16	$211.39	1.5	0.01%
SUBTOTAL	**5,026**	**932**	**$1,067,046.43**	**$212.31**	**5.39**	**18.66%**
LANSOPRAZOLE PRODUCTS						
LANSOPRAZOLE CAP 30MG DR	2,192	741	$32,924.27	$15.02	2.96	0.58%
LANSOPRAZOLE CAP 15MG DR	409	165	$7,848.01	$19.19	2.48	0.14%
PREVACID TAB 30MG STB	351	52	$154,027.13	$438.82	6.75	2.69%
PREVACID TAB 15MG STB	170	42	$73,806.04	$434.15	4.05	1.29%
LANSOPRAZOLE TAB 15MG ODT	156	58	$16,361.06	$104.88	2.69	0.29%
LANSOPRAZOLE TAB 30MG ODT	11	5	$1,842.37	$167.49	2.2	0.03%
SUBTOTAL	**3,289**	**1,063**	**$286,808.88**	**$87.20**	**3.09**	**5.02%**
GLYCOPYRROLATE PRODUCTS						
GLYCOPYRROLATE TAB 1MG	1,775	387	$30,863.52	$17.39	4.59	0.54%
GLYCOPYRROLATE TAB 2MG	1,140	187	$26,157.71	$22.95	6.1	0.46%
SUBTOTAL	**2,915**	**574**	**$57,021.23**	**$19.56**	**5.08**	**1.00%**
RABEPRAZOLE PRODUCTS						
RABEPRAZOLE TAB 20MG	664	241	$15,923.03	$23.98	2.76	0.28%
SUBTOTAL	**664**	**241**	**$15,923.03**	**$23.98**	**2.76**	**0.28%**
CIMETIDINE PRODUCTS						
CIMETIDINE SOL 300MG/5ML	2	2	$144.68	$72.34	1	0.00%
SUBTOTAL	**2**	**2**	**$144.68**	**$72.34**	**1**	**0.00%**
TIER-1 TOTAL	**213,526**	**89,833**	**$5,083,246.90**	**$23.81**	**2.38**	**88.89%**
TIER-2 UTILIZATION						
PANTOPRAZOLE PRODUCTS						
PANTOPRAZOLE INJ SOD 40MG	138	5	$3,671.10	$26.60	27	0.06%
PROTONIX INJ 40MG	3	1	$140.82	$46.94	3	0.00%
TIER-2 TOTAL	**141**	**6**	**$3,811.92**	**$27.03**	**23.5**	**0.07%**
TIER-3 UTILIZATION						
PANTOPRAZOLE PRODUCTS						
PANTOPRAZOLE PAK 40MG	15	10	$7,456.77	$497.12	1.5	0.13%
PROTONIX PAK 40MG	10	1	$4,659.02	$465.90	10	0.08%
SUBTOTAL	**25**	**11**	**$12,115.79**	**$484.63**	**2.27**	**0.21%**
OMEPRAZOLE PRODUCTS						
PRILOSEC POW 10MG	14	9	$7,353.53	$525.25	1.56	0.13%
PRILOSEC POW 2.5MG	1	1	$2,726.35	$2,726.35	1	0.05%
SUBTOTAL	**15**	**10**	**$10,079.88**	**$671.99**	**1.5**	**0.18%**
TIER-3 TOTAL	**40**	**21**	**$22,195.67**	**$554.89**	**1.9**	**0.39%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION						
FAMOTIDINE PRODUCTS						
FAMOTIDINE SUS 40MG/5ML	12,867	5,507	$556,530.81	$43.25	2.34	9.73%
SUBTOTAL	**12,867**	**5,507**	**$556,530.81**	**$43.25**	**2.34**	**9.73%**
CIMETIDINE PRODUCTS						
CIMETIDINE TAB 400MG	39	25	$1,216.35	$31.19	1.56	0.02%
CIMETIDINE TAB 800MG	28	14	$1,380.05	$49.29	2	0.02%
CIMETIDINE TAB 300MG	27	10	$671.17	$24.86	2.7	0.01%
CIMETIDINE TAB 200MG	18	8	$417.98	$23.22	2.25	0.01%
SUBTOTAL	**112**	**57**	**$3,685.55**	**$32.91**	**1.96**	**0.06%**
TRIPLE THERAPY COMBINATION PRODUCTS						
PYLERA CAP 140/125/125MG	71	67	$37,780.10	$532.11	1.06	0.66%
BISMTH/METR/TETRA CAP 140/125/125MG	5	5	$2,595.67	$519.13	1	0.05%
TALICIA CAP 250/12.5/10MG	2	2	$1,478.78	$739.39	1	0.03%
SUBTOTAL	**78**	**74**	**$41,854.55**	**$536.60**	**1.05**	**0.73%**
VONOPRAZAN PRODUCTS						
VOQUEZNA TAB 20MG	10	8	$6,363.72	$636.37	1.25	0.11%
SUBTOTAL	**10**	**8**	**$6,363.72**	**$636.37**	**1.25**	**0.11%**
OMEPRAZOLE/SODIUM BICARBONATE PRODUCTS						
OMEPRA/BICARB CAP 20-1,100MG	4	2	$170.87	$42.72	2	0.00%
KONVOMEP SUS 2-84MG/ML	2	2	$929.38	$464.69	1	0.02%
OMEPRA/BICARB CAP 40-1,100MG	2	2	$54.40	$27.20	1	0.00%
SUBTOTAL	**8**	**6**	**$1,154.65**	**$144.33**	**1.33**	**0.02%**
SPECIAL PA TOTAL	**13,075**	**5,652**	**$609,589.28**	**$46.62**	**2.31**	**10.66%**
TOTAL	**226,782**	**77,277***	**$5,718,843.77**	**$25.22**	**2.93**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BICARB = bicarbonate; BISMTH = bismuth subcitrate; CAP = capsule; DR = delayed-release; GRA = granules; INJ = injection; METR = metronidazole; ODT = orally disintegrating tablet; OMEPRA = omeprazole; PAK = pack; POW = powder; SOD = sodium; SOL = solution; STB = solutab; SUS = suspension; TAB = tablet; TETRA = tetracycline
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 01/2025. Last accessed 01/17/2025.
[2] Pantoprazole Sodium in Sodium Chloride Injection Prescribing Information. Baxter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217512s000lbl.pdf. Last revised 02/2024. Last accessed 01/17/2025.
[3] U.S. FDA. National Drug Code Directory Search. Available online at: https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=NONPROPRIETARYNAME&type=Pantoprazole+Sodium+in+0.9%25+Sodium+Chloride. Last revised 01/17/2025. Last accessed 01/17/2025.
[4] Protonix® I.V. Prescribing Information. Pfizer. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/020988s070lbl.pdf. Last revised 08/2024. Last accessed 01/17/2025.
[5] Protonix® I.V. (Pantoprazole) – Expanded Indication. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/clinical-updates/clinicalupdate_protonixiv_2024-0819.pdf. Issued 08/12/2024. Last accessed 01/17/2025.
[6] Chey W, Howden C, Moss S, et al. Olezarsen, ACG Clinical Guideline: Treatment of *Helicobacter pylori* Infection. *Am J Gastroenterol* 2024; 119:1730-1753. doi: 10.14309/ajg.0000000000002968.

Appendix S

Fiscal Year 2024 Annual Review of Heart Failure (HF) Medications and 30-Day Notice to Prior Authorize Entresto® Sprinkle (Sacubitril/Valsartan)

Oklahoma Health Care Authority
February 2025

Current Prior Authorization Criteria

Corlanor® (Ivabradine) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. To reduce the risk of hospitalization for worsening heart failure (HF) in adult members with stable, symptomatic chronic HF with reduced left ventricular ejection fraction (LVEF); or
    b. For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in members 6 months of age and older; and
2. For a diagnosis of worsening HF in adults:
    a. Prescriber must verify that the member has LVEF ≤35%; and
    b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥70 beats per minute (bpm); and
    c. Member must be on maximal/maximally tolerated doses of beta blockers or have a contraindication to beta blockers; and
3. For a diagnosis of DCM in members 6 months of age or older:
    a. Prescriber must verify that the member has LVEF ≤45%; and
    b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate (HR) as follows:
        i. Age 6 to 12 months, HR ≥105 bpm; or
        ii. Age 1 to 3 years, HR ≥95 bpm; or
        iii. Age 3 to 5 years, HR ≥75 bpm; or
        iv. Age 5 to 18 years, HR ≥70 bpm; and
    c. Prescriber must verify that dose titration will be followed according to package labeling; and
    d. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Authorization of Corlanor® solution for members >40kg requires a patient-specific, clinically significant reason why Corlanor® tablets cannot be used; and
5. For Corlanor® tablets, a quantity limit of 60 tablets per 30 days will apply; and

6. For Corlanor® solution, a quantity limit of 280mL (56 ampules) per 28 days will apply.

Entresto® (Sacubitril/Valsartan) Approval Criteria:

1. An FDA approved diagnosis of chronic heart failure [New York Heart Association (NYHA) Class II, III, or IV]; and
2. A quantity limit of 60 tablets per 30 days will apply.

Furoscix® (Furosemide On-Body Infusor) Approval Criteria:

1. An FDA approved indication for the treatment of congestion due to fluid overload in members with New York Heart Association (NYHA) Class II-III heart failure; and
2. Member must be 18 years of age or older; and
3. Furoscix® must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of fluid overload; and
5. Member has been stable and refractory to at least 1 of the following loop diuretics, at maximally indicated doses:
    a. Bumetanide oral tablets; or
    b. Furosemide oral tablets; or
    c. Torsemide oral tablets; and
6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:
    a. Oxygen saturation ≥90% on exertion; and
    b. Respiratory rate <24 breaths per minute; and
    c. Resting heart rate <100 beats per minute; and
    d. Systolic blood pressure >100mmHg; and
8. Member must have an adequate environment for at-home administration and have been trained on the proper use of Furoscix®; and
9. Member must have a creatinine clearance (CrCl) >30mL/min or an estimated glomerular filtration rate (eGFR) >20mL/min/1.73m^2 and no evidence of acute renal failure; and
10. Member must not have any contraindications for use of Furoscix® including anuria, hepatic cirrhosis, or ascites; and
11. Member must not have acute pulmonary edema or other conditions that require immediate hospitalization; and
12. Approvals will be issued per incident of fluid overload; and

13. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of fluid overload.

Verquvo® (Vericiguat) Approval Criteria:

1. An FDA approved indication to reduce the risk of cardiovascular death and hospitalization for heart failure (HF) in adults with all of the following:
    a. Chronic symptomatic HF [New York Heart Association (NYHA) Class II, III, or IV]; and
    b. Reduced left ventricular ejection fraction (LVEF) <45%; and
    c. Already receiving guideline-directed medical therapy for HF, as documented in member's pharmacy claims history; and
2. Member has evidence of worsening HF (decompensation) demonstrated by at least 1 of the following:
    a. Hospitalization for HF within the past 6 months; or
    b. Received outpatient intravenous (IV) diuretics within the past 3 months; and
3. Member must be 18 years of age or older; and
4. Member must not be taking concomitant soluble guanylate cyclase (sGC) stimulators (e.g., riociguat); and
5. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation of therapy, and must agree to use effective contraception during treatment and for 1 month after the final dose of Verquvo®; and
6. Prescriber must agree to titrate to the target maintenance dose according to package labeling, as tolerated by the member; and
7. Initial approvals will be for the duration of 6 months. Compliance will be checked for continued approval every 6 months; and
8. A quantity limit of 30 tablets per 30 days will apply.

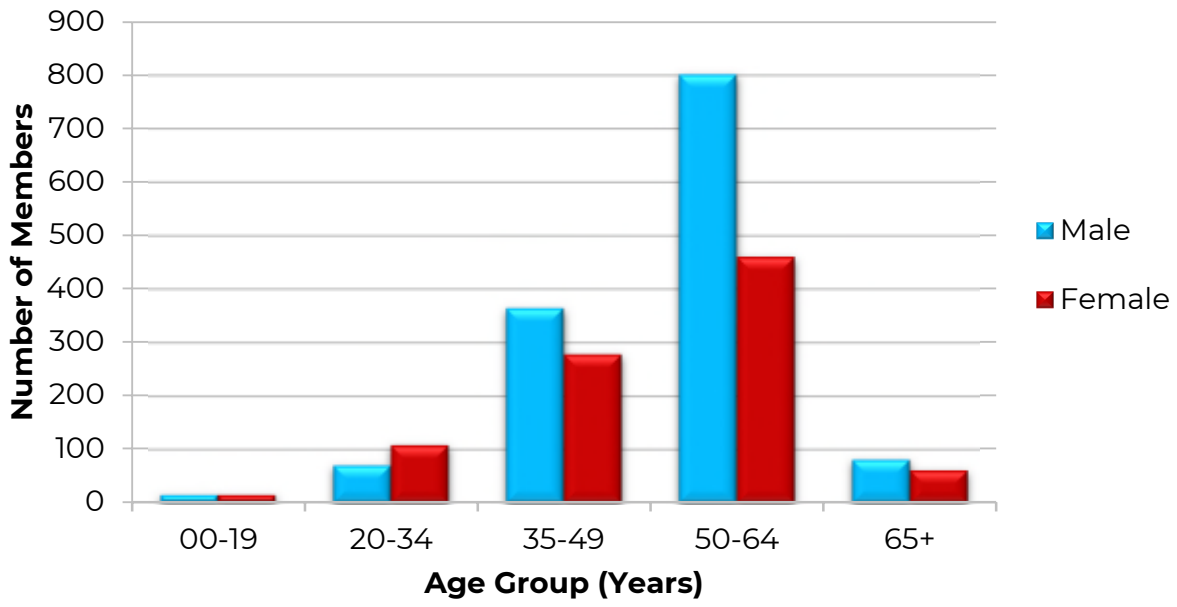
Utilization of HF Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

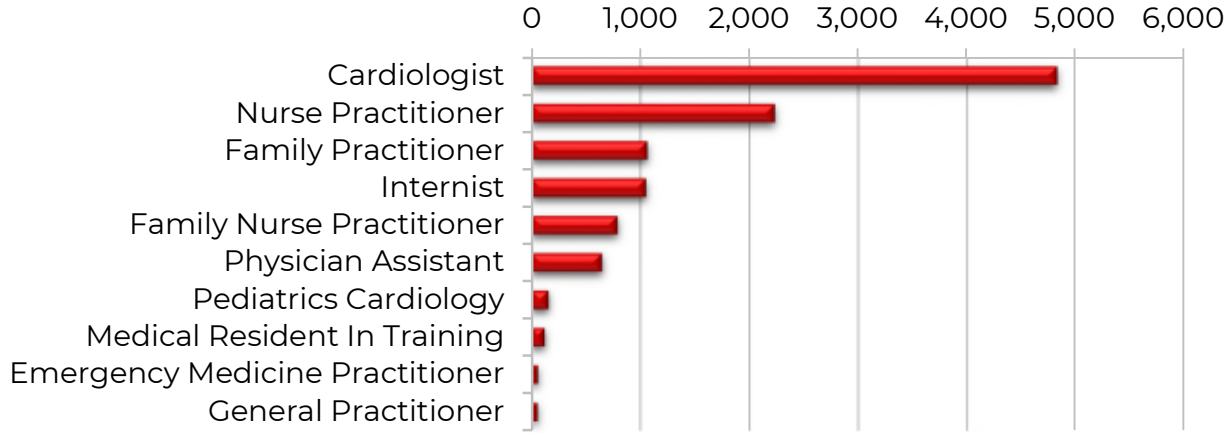
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	1,971	10,436	$6,283,561.35	$602.10	$19.96	617,839	314,865
2023 Total	**1,971**	**10,436**	**$6,283,561.35**	**$602.10**	**$19.96**	**617,839**	**314,865**
Fiscal Year 2024							
FFS	2,089	9,747	$6,014,777.65	$617.09	$20.67	574,063	291,027
Aetna	242	449	$291,943.61	$650.21	$22.27	27,238	13,109
Humana	299	625	$406,800.03	$650.88	$21.94	36,003	18,544
OCH	248	420	$266,886.53	$635.44	$21.27	23,956	12,549
2024 Total	**2,253**	**11,241**	**$6,980,407.82**	**$620.98**	**$20.82**	**661,260**	**335,229**
% Change	**14.30%**	**7.70%**	**11.10%**	**3.10%**	**4.30%**	**7.00%**	**6.50%**
Change	**282**	**805**	**$696,846.47**	**$18.88**	**$0.86**	**43,421**	**20,364**

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

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



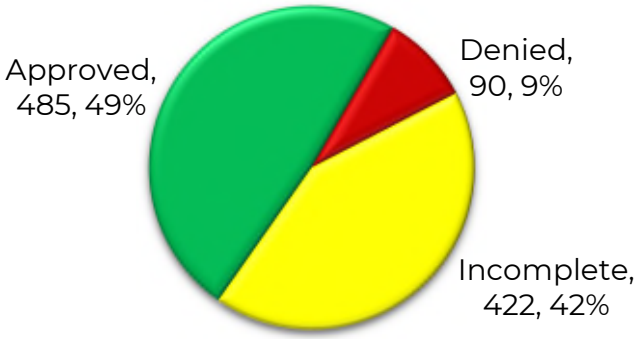
Top Prescriber Specialties of HF Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of HF Medications

There were 997 prior authorization requests submitted for HF medications during fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2024.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	419	47%	412	46%	65	7%	**896**
Aetna	14	54%	10	38%	2	8%	**26**
Humana	35	64%	0	0%	20	36%	**55**
OCH	17	85%	0	0%	3	15%	**20**
Total	**485**	**49%**	**422**	**42%**	**90**	**9%**	**997**

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

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

Anticipated Patent Expiration(s):

- Corlanor® (ivabradine oral solution): December 2026
- Corlanor® (ivabradine tablet): June 2027
- Verquvo® (vericiguat tablet): November 2032
- Furoscix® (furosemide on-body infusor): April 2034
- Entresto® (sacubitril/valsartan tablet): May 2036
- Entresto® Sprinkle (sacubitril/valsartan capsule, pellets): February 2037

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

- **April 2024:** The FDA approved Entresto® Sprinkle (sacubitril/valsartan), a new oral formulation available as 6mg/6mg and 15mg/16mg film-coated oral pellets within capsules. This formulation is approved for the same indications as the tablet formulations; however, the dosing recommendations in the package labeling suggest the oral pellets are intended for pediatric use. These oral pellets are to be administered by opening the capsule and sprinkling the full contents onto 1 to 2 teaspoons of soft food. The oral pellets cannot be administered via nasogastric, gastrostomy, or other enteral tubes because they may cause obstruction.
- **August 2024:** The FDA approved an expanded indication for Furoscix® (furosemide on-body infusor) to include treatment of congestion due to fluid overload in adult patients with chronic heart failure (CHF), regardless of New York Heart Association (NYHA) functional class. Previously, the indication limited use to patients with NYHA Class II and III CHF. The revised package labeling also removes "ascites" from the list of contraindications, removes the limitation of use in emergency situations or in patients with acute pulmonary edema, and adds a warning about the potential of incomplete dosing if patients cannot detect or respond to the device alarms. According to scPharma, current literature was utilized to request these changes, and no additional clinical trials were required.

News:

- **May 2024:** The FDA approved the first interchangeable generic versions of Entresto® (sacubitril/valsartan) tablets. There are no product launch dates announced at this time.
- **July 2024:** The first interchangeable generic versions of Corlanor® (ivabradine) tablets were launched. Corlanor® (ivabradine) oral solution is still only available as a branded product.

Pipeline:

- **Omecamtiv Mecarbil:** Cytokinetics is evaluating omecamtiv mecarbil, a selective small molecule cardiac myosin activator, for the treatment of symptomatic HF with severely reduced left ventricular ejection fraction (LVEF), which is defined as an LVEF <30%. This investigational medication is designed to directly target the contractile mechanism of the heart by stimulating cardiac myosin. Omecamtiv mecarbil is the subject of a confirmatory, multinational, double-blind, randomized, placebo-controlled Phase 3 clinical trial (COMET-HF) that was opened for patient enrollment on December 3, 2024.
- **Revascor® (Rexlemestrocel-L):** Mesoblast is evaluating Revascor® for the treatment of advanced and end-stage HF with reduced ejection fraction (HFrEF). Revascor® is a stem cell therapy consisting of 150 million mesenchymal precursor cells (MPCs) that are administered into the myocardium as a single, direct injection. MPCs are believed to release a variety of factors which may lead to cardiac recovery through induction of vascular network formulation, reduction in inflammation, reduction in cardiac scarring and fibrosis, and regeneration of myocardium. In December 2024, the results from the Phase 3 DREAM-HF trial indicated that patients with HFrEF at highest risk for cardiovascular (CV) death experienced a sustained reduction in CV mortality after a single intramyocardial injection of Revascor®. The reduction was 80% (P=0.003) when high-sensitivity C-reactive protein (hsCRP) was the measured biomarker or 60% (p=0.037) when plasma interleukin-6 (IL-6) was the measured biomarker. Previously, in March 2024, Mesoblast announced their plans to meet with the FDA to discuss the expectations for an accelerated approval for Revascor® in end-stage ischemic HFrEF patients with left ventricular assist device (LVAD) implantation. No updates regarding application status have been announced since the publication of the DREAM-HF trial results.
- **Ziltivekimab (NN6018):** Novo Nordisk is evaluating ziltivekimab for the treatment of HF. Ziltivekimab is a monoclonal antibody that inhibits IL-6 and is being studied in patients with HF and inflammation. The Phase 3 HERMES trial is currently recruiting patients with a diagnosis of NYHA Class II-IV HF and LVEF ≥40%. Patients will be randomized to receive ziltivekimab or placebo once monthly (in addition to standard of care) for up to 4 years. The primary efficacy outcome will be the time to first occurrence of a composite of CV death, HF hospitalization or urgent HF visit, non-fatal myocardial infarction (MI), or non-fatal stroke. The estimated completion of this study is July 2027.

Recommendations[12]

The College of Pharmacy recommends the prior authorization of Entresto® Sprinkle (sacubitril/valsartan) with the following criteria (shown in red):

Entresto® Sprinkle (Sacubitril/Valsartan) Approval Criteria:

1. An FDA approved diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction; and
2. Member must be 1 to 10 years of age; and
3. Member must weigh <50kg; and
4. A recent weight (within the last 3 months) must be provided on the prior authorization request to ensure proper weight-based dosing and to authorize the appropriate amount of drug required according to package labeling; and
5. A quantity limit of 240 capsules per 30 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Corlanor® (ivabradine) based on clinical practice and the American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society Clinical Practice Guidelines for the Management of Adult Patients with Supraventricular Tachycardia and recommends updating the approval criteria for Furoscix® (furosemide on-body infusor) based on the FDA-approved updates to the package labeling and clinical practice (changes shown in red):

Corlanor® (Ivabradine) Approval Criteria:

1. ~~An FDA approved indication~~ A diagnosis of 1 of the following:
    a. To reduce the risk of hospitalization for worsening heart failure (HF) in adult members with stable, symptomatic chronic HF with reduced left ventricular ejection fraction (LVEF); or
    b. For the treatment of stable, symptomatic HF due to dilated cardiomyopathy (DCM) in members 6 months of age and older; ~~and~~ or
    c. For the treatment of inappropriate sinus tachycardia (IST); and
2. For a diagnosis of worsening HF in adults:
    a. Prescriber must verify that the member has LVEF ≤35%; and
    b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate ≥70 beats per minute (bpm); and
    c. Member must be on maximal/maximally tolerated doses of beta blockers or have a contraindication to beta blockers; and
3. For a diagnosis of DCM in members 6 months of age or older:
    a. Prescriber must verify that the member has LVEF ≤45%; and
    b. Prescriber must verify that the member is in sinus rhythm with a resting heart rate (HR) as follows:
        i. Age 6 to 12 months, HR ≥105 bpm; or

ii. Age 1 to 3 years, HR ≥95 bpm; or
iii. Age 3 to 5 years, HR ≥75 bpm; or
iv. Age 5 to 18 years, HR ≥70 bpm; and

c. Prescriber must verify that dose titration will be followed according to package labeling; and
d. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and

4. Authorization of Corlanor® solution for members >40kg requires a patient-specific, clinically significant reason why Corlanor® tablets cannot be used; and
5. For Corlanor® tablets, a quantity limit of 60 tablets per 30 days will apply; and
6. For Corlanor® solution, a quantity limit of 280mL (56 ampules) per 28 days will apply.

Furoscix® (Furosemide On-Body Infusor) Approval Criteria:

1. An FDA approved indication for the treatment of congestion due to fluid overload in members with ~~New York Heart Association (NYHA) Class II-III~~ chronic heart failure; and
2. Member must be 18 years of age or older; and
3. Furoscix® must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of fluid overload; and
5. Member has been ~~stable~~ established on maintenance therapy with and is refractory to a dose escalation with at least 1 of the following loop diuretics, at maximally tolerated ~~indicated~~ doses:
   a. Bumetanide oral tablets; or
   b. Furosemide oral tablets; or
   c. Torsemide oral tablets; and
6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:
   a. Oxygen saturation ≥90% on exertion; and
   b. Respiratory rate <24 breaths per minute; and
   c. Resting heart rate <100 beats per minute; and
   d. Systolic blood pressure >100mmHg; and
8. Member must have an adequate environment for at-home administration, ~~and~~ have been trained on the proper use of Furoscix®, and be able to detect and respond to the device alarms; and

9. Member must have a creatinine clearance (CrCl) >30mL/min or an estimated glomerular filtration rate (eGFR) >20mL/min/1.73m^2 and no evidence of acute renal failure; and
10. Member must not have any contraindications for use of Furoscix® including anuria~~, or~~ hepatic cirrhosis~~, or ascites~~; and
11. Member must not have ~~acute pulmonary edema or other~~ conditions that require immediate hospitalization; and
12. Approvals will be issued per incident of fluid overload; and
13. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of fluid overload.

Utilization Details of HF Medications: Fiscal Year 2024

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SACUBITRIL/VALSARTAN PRODUCTS						
ENTRESTO TAB 24/26MG	5,563	1,344	$3,424,966.20	$615.67	4.14	49.07%
ENTRESTO TAB 49/51MG	3,126	718	$1,969,661.71	$630.09	4.35	28.22%
ENTRESTO TAB 97/103MG	2,111	424	$1,349,367.69	$639.21	4.98	19.33%
SUBTOTAL	**10,800**	**2,486**	**$6,743,995.60**	**$624.44**	**4.34**	**96.61%**
IVABRADINE PRODUCTS						
CORLANOR TAB 5MG	268	78	$124,872.16	$465.94	3.44	1.79%
CORLANOR TAB 7.5MG	86	22	$46,504.04	$540.74	3.91	0.67%
CORLANOR SOL 5MG/5ML	18	4	$11,574.20	$643.01	4.5	0.17%
SUBTOTAL	**372**	**104**	**$182,950.40**	**$491.80**	**3.58**	**2.62%**
VERICIGUAT PRODUCTS						
VERQUVO TAB 5MG	26	4	$13,376.15	$514.47	6.5	0.19%
VERQUVO TAB 10MG	25	6	$16,037.59	$641.50	4.17	0.23%
VERQUVO TAB 2.5MG	13	6	$7,688.67	$591.44	2.17	0.11%
SUBTOTAL	**64**	**16**	**$37,102.41**	**$579.73**	**4**	**0.53%**
SUBCUTANEOUS FUROSEMIDE PRODUCTS						
FUROSCIX KIT 80MG/10ML	5	5	$16,359.41	$3,271.88	1	0.23%
SUBTOTAL	**5**	**5**	**$16,359.41**	**$3,271.88**	**1**	**0.23%**
TOTAL	**11,241**	**2,253***	**$6,980,407.82**	**$620.98**	**4.99**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 01/2025. Last Accessed 01/15/2025.
[2] Entresto® Sprinkle (Sacubitril/Valsartan) – New Formulation Approval. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-approvals/drugapproval_entresto_2024-0417.pdf. Issued 04/12/2024. Last accessed 01/15/2025.
[3] Entresto® Sprinkle (Sacubitril/Valsartan) Prescribing Information. Novartis. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/207620s025,218591s000lbl.pdf. Last revised 04/12/2024. Last accessed 01/15/2025.
[4] Furoscix® (Furosemide Injection), for Subcutaneous Use Prescribing Information. scPharmaceuticals, Inc. Available online: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/209988s001lbl.pdf. Last revised 08/09/2024. Last accessed 01/15/2025.
[5] scPharmaceuticals, Inc. ScPharmaceuticals Announces FDA Approval of Supplemental New Drug Application Expanding the Furoscix® Indication in Heart Failure. *GlobeNewswire*. Available online at: https://www.globenewswire.com/en/news-release/2024/08/12/2928205/0/en/scPharmaceuticals-Announces-FDA-Approval-of-Supplemental-New-Drug-Application-Expanding-the-FUROSCIX-Indication-in-Heart-Failure.html#xd_co_f=YzRlMTljYzQtYzIwNy00MDQ1LTllZWEtYTZiNDc5NTdlM2Zm~. Issued 08/12/2024. Last accessed 01/15/2025.
[6] Corlanor® (Ivabradine) – First-time Generic. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/new-generics/newgenerics_corlanor_2024-0801.pdf. Issued 07/15/2024. Last accessed 01/15/2025.
[7] U.S. FDA. FDA Roundup: May 31, 2024. Available online at: https://www.fda.gov/news-events/press-announcements/fda-roundup-may-31-2024. Issued 05/31/2024. Last accessed 01/15/2025.
[8] Cytokinetics. Cytokinetics Announces Start of COMET-HF, a Confirmatory Phase 3 Clinical Trial of Omecamtiv Mecarbil in Patients with Symptomatic Heart Failure with Severely Reduced Ejection Fraction. Available online at: https://ir.cytokinetics.com/news-releases/news-release-details/cytokinetics-announces-start-comet-hf-confirmatory-phase-3. Issued 12/03/2024. Last accessed 01/15/2025.
[9] Mesoblast Limited. Revascor Improves Survival and Reduces Major Morbidity in High-Risk Ischemic Heart Failure Patients With Inflammation. *GlobeNewswire*. Available online at: https://www.globenewswire.com/news-release/2024/12/02/2990209/0/en/Revascor-Improves-Survival-and-Reduces-Major-Morbidity-in-High-Risk-Ischemic-Heart-Failure-Patients-With-Inflammation.html. Issued 12/02/2024. Last accessed 01/15/2025.
[10] Novo Nordisk. R&D Pipeline. Available online at: https://www.novonordisk.com/science-and-technology/r-d-pipeline.html. Last accessed 01/15/2025.
[11] A Research Study to Look at How Ziltivekimab Works Compared to Placebo in People with Heart Failure and Inflammation (HERMES). *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/ct2/show/NCT05636176. Last revised 10/15/2024. Last accessed 01/15/2025.
[12] Page RL, Joglar, JA, Caldwell MA, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *JACC* 2016; 67(13):e27-e115. doi: 10.1016/j.jacc2015.08.856.

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: February 5, 2025

FDA Alerts Patients of Potential to Miss Critical Safety Alerts Due to Phone Settings When Using Smartphone—Compatible Diabetes Devices

The FDA is alerting patients of a safety concern regarding diabetes devices, such as continuous glucose monitors (CGMs), insulin pumps and automated insulin dosing systems, that rely on a smartphone to deliver critical safety alerts. Users of these smartphone-compatible diabetes devices can configure alert settings, such as which alerts to receive, how often and how the alerts are delivered (e.g., audible, vibration, text only) through the app on their phone.

The FDA has received medical device reports in which users report that these alerts are not being delivered or not being heard, in cases where the users thought they had configured the alerts to be delivered. In some cases, missing these alerts may have contributed to serious harm, including severe hypoglycemia, severe hyperglycemia, diabetic ketoacidosis, and death.

The FDA has identified, among others, the following hardware and software changes, updates and configurations that may lead to critical alerts not being received as expected:

- software configuration issues, such as app notification permissions, using “do not disturb” or “focus mode” or the app entering “deep sleep” after a period of not being used; and
- connecting new hardware to the smartphone, such as connecting to car audio or using wireless earphones, that can change the default volume of alerts or prevent delivery of alerts; and
- smartphone operating system updates that are not supported by the medical device application.

The FDA’s safety communication provides recommendations, such as the following, for users of these devices:

- Carefully follow the instructions provided by diabetes device manufacturers when installing, setting up or updating mobile medical apps on the smartphone; and
- turn off automatic operating system (OS) updates to the smartphone and do not update the phone’s OS until confirming the diabetes device app is compatible with the new OS version; and
- after updating the phone’s OS or adding a new accessory, such as wireless headphones, confirm alert settings then carefully monitor the

medical device app to make sure alerts are received and can be heard as expected; and
- at least once a month, check that the smartphone alerts are configured as expected; and
- if alerts are not being received as expected from the mobile medical app, or cannot be heard, call the technical support number for the medical device for assistance; and
- report any problems with the diabetes device to the FDA.

The FDA is working with diabetes-related medical device manufacturers to ensure that smartphone alert configurations of their devices are carefully evaluated prior to use by patients. The agency is also working with manufacturers to ensure that settings in smartphones and mobile medical apps that may impact safety alerts are continuously tested and any updates to recommended configurations are communicated quickly and clearly to users.

FDA NEWS RELEASE

For Immediate Release: January 30, 2025

FDA Approves Novel Non-Opioid Treatment for Moderate to Severe Acute Pain

The FDA approved Journavx™ (suzetrigine) 50mg oral tablets, a first-in-class non-opioid analgesic, to treat moderate to severe acute pain in adults. Journavx™ reduces pain by targeting a pain-signaling pathway involving sodium channels in the peripheral nervous system, before pain signals reach the brain. Journavx™ is the first drug to be approved in this new class of pain management medicines.

Pain is a common medical problem and relief of pain is an important therapeutic goal. Acute pain is short-term pain that is typically in response to some form of tissue injury, such as trauma or surgery. Acute pain is often treated with analgesics that may or may not contain opioids.

The FDA has long supported the development of non-opioid pain treatment. As part of the FDA Overdose Prevention Framework, the agency has issued draft guidance aimed at encouraging development of non-opioid analgesics for acute pain and awarded cooperative grants to support the development and dissemination of clinical practice guidelines for the management of acute pain conditions.

The efficacy of Journavx™ was evaluated in two randomized, double-blind, placebo- and active-controlled trials of acute surgical pain, one following abdominoplasty and the other following bunionectomy. In addition to receiving the randomized treatment, all participants in the trials with inadequate pain control were permitted to use ibuprofen as needed for “rescue” pain medication. Both trials demonstrated a statistically significant superior reduction in pain with Journavx™ compared to placebo.

The safety profile of Journavx™ is primarily based on data from the pooled, double-blind, placebo- and active-controlled trials in 874 participants with moderate to severe acute pain following abdominoplasty and bunionectomy, with supportive safety data from one single-arm, open-label study in 256 participants with moderate to severe acute pain in a range of acute pain conditions.

The most common adverse reactions in study participants who received Journavx™ were itching, muscle spasms, increased blood level of creatine phosphokinase, and rash. Journavx™ is contraindicated for concomitant use with strong CYP3A inhibitors. Additionally, patients should avoid food or drink containing grapefruit when taking Journavx™.

Current Drug Shortages Index (as of January 31, 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***
Amifostine Injection	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***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***
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***
Chloroprocaine Hydrochloride Injection	***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***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***

Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Indocyanine Green Injection	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lactated Ringers Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Mefloquine Hydrochloride Tablet	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Naltrexone Hydrochloride Tablet	***Currently in Shortage***

Nitroglycerin Injection	***Currently in Shortage***
Oxazepam Capsule	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Peritoneal Dialysis Solution	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection	***Currently in Shortage***
Sodium Chloride 0.9% Irrigation	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium Tc-99m Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***