OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
November 13, 2024
4:00pm

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

Viewing Access Only:
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The University of Oklahoma
Health Sciences Center
COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – November 13, 2024

DATE: November 6, 2024

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 November 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/Adherence to Asthma Maintenance Medications Prior to Adding on Biologic Therapy – Appendix B

Action Item – Approval of 2025 Drug Utilization Review (DUR) Board Meeting Dates – Appendix C

Action Item – Vote to Prior Authorize Bimzelx® (Bimekizumab-bkzx), Leqselvi™ (Deuruxolitinib), Omvoh™ (Mirikizumab-mrkz), Otulfi™ (Ustekinumab-aauz), Pyzchiva® (Ustekinumab-ttwe), Rinvoq® LQ (Upadacitinib Oral Solution), Selarsdi™ (Ustekinumab-aekn), Simlandi® (Adalimumab-ryvk), Tyenne® (Tocilizumab-aazg), Velsipity™ (Etrasimod), Wezlana™ (Ustekinumab-auub), and Zymfentra™ (Infliximab-dyyb) and Update the Approval Criteria for the Targeted Immunomodulator Agents – Appendix D

Action Item – Vote to Prior Authorize Rivfloza® (Nedosiran) – Appendix E

Action Item – Vote to Prior Authorize Casgevy™ (Exagamglogene Autotemcel), Lyfgenia® (Lovotibeglogene Autotemcel), Vafseo® (Vadadustat), and Xromi® (Hydroxyurea Oral Solution) and Update the Approval Criteria for the Anemia Medications – Appendix F

Action Item – Annual Review of Multiple Myeloma Medications – Appendix G

Action Item – Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications – Appendix H

Action Item – Annual Review of Hereditary Angioedema (HAE) Medications – Appendix I

30-Day Notice to Prior Authorize Nemluvio® (Nemolizumab-ilto) – Appendix J

Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Ohtuvayre™ (Ensifentrine) – Appendix K

Annual Review of Atopic Dermatitis Medications and 30-Day Notice to Prior Authorize Ebglyss™ (Lebrikizumab-lbkz) – Appendix L

Annual Review of Sohonos™ (Palovarotene) – Appendix M

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – November 13, 2024 @ 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. Muchmore, 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. John Muchmore –	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

Viewing Access Only via Zoom:

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https://oklahoma.zoom.us/webinar/register/WN_94lCoSe9Ty2msgsLMqg2Ww
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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. Muchmore, Chairman:

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

Items to be presented by Dr. Muchmore, Chairman:

3. **Action Item – Approval of DUR Board Meeting Minutes – See Appendix A**
   A. October 9, 2024 DUR Board Meeting Minutes
   B. October 9, 2024 DUR Board Recommendations Memorandum
   C. Correspondence

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

4. **Update on Medication Coverage Authorization Unit/Adherence to Asthma Maintenance Medications Prior to Adding on Biologic Therapy – See Appendix B**
   A. Pharmacy Help Desk Activity for October 2024
   B. Medication Coverage Activity for October 2024
   C. Adherence to Asthma Maintenance Medications Prior to Adding on Biologic Therapy

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

5. **Action Item – Approval of 2025 Drug Utilization Review (DUR) Board Meeting Dates – See Appendix C**
   A. 2025 DUR Board Meeting Dates

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

6. **Action Item – Vote to Prior Authorize Bimzelx® (Bimekizumab-bkzx), Leqselvi™ (Deuruxolitinib), Omvoh™ (Mirikizumab-mrkz), Otulfi™ (Ustekinumab-aauz), Pyzchiva® (Ustekinumab-ttwe), Rinvoq® LQ (Upadacitinib Oral Solution), Selarsdi™ (Ustekinumab-aekn), Simlandi® (Adalimumab-ryvk), Tyenne® (Tocilizumab-aazg), Velsipity™ (Etrasimod), Wezlana™ (Ustekinumab-auub), and Zymfentra™ (Infliximab-dyyb) and Update the Approval Criteria for the Targeted Immunomodulator Agents – See Appendix D**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

Items to be presented by Dr. Metts, Dr. Muchmore, Chairman:

7. **Action Item – Vote to Prior Authorize Rivfloza® (Nedosiran) – See Appendix E**
   A. Market News and Updates
   B. Rivfloza® (Nedosiran) Product Summary
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Casgevy™ (Exagamglogene Autotemcel), Lyfgenia® (Lovotibeglogene Autotemcel), Vafseo® (Vadadustat), and Xromi® (Hydroxyurea Oral Solution) and Update the Approval Criteria for the Anemia Medications – See Appendix F**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

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

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

10. **Action Item – Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications – See Appendix H**
   A. Current Prior Authorization Criteria
   B. Utilization of LEMS Medications
   C. Prior Authorization of LEMS Medications

D. Market News and Updates
E. College of Pharmacy Recommendation
F. Utilization Details of LEMS Medications

Items to be presented by Dr. Metts, Dr. Muchmore, Chairman:

11. Action Item – Annual Review of Hereditary Angioedema (HAE) Medications – See Appendix I

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

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

12. 30-Day Notice to Prior Authorize Nemluvio® (Nemolizumab-ilto) – See Appendix J

A. Introduction
B. Nemluvio® (Nemolizumab-ilto) Product Summary
C. College of Pharmacy Recommendations

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

13. Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Ohtuvayre™ (Ensifentrine) – See Appendix K

A. Current Prior Authorization Criteria
B. Utilization of Asthma and COPD Maintenance Medications
C. Prior Authorization of Asthma and COPD Maintenance Medications
D. Market News and Updates
E. Ohtuvayre™ (Ensifentrine) Product Summary
F. College of Pharmacy Recommendation
G. Utilization Details of Asthma and COPD Maintenance Medications

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

14. Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Ebglyss™ (Lebrikizumab-lbkz) – See Appendix L

A. Current Prior Authorization Criteria
B. Utilization of AD Medications
C. Prior Authorization of AD Medications
D. Market News and Updates
E. Ebglyss™ (Lebrikizumab-lbkz) Product Summary
F. Cost Comparisons
G. College of Pharmacy Recommendations
H. Utilization Details of AD Medications

Items to be presented by Dr. Metts, Dr. Muchmore, Chairman:

15. Annual Review of Sohonos™ (Palovarotene) – See Appendix M

A. Current Prior Authorization Criteria
B. Utilization of Sohonos™ (Palovarotene)
C. Prior Authorization of Sohonos™ (Palovarotene)
D. Market News and Updates
E. College of Pharmacy Recommendations

Items to be presented by Dr. Metts, Dr. Muchmore, Chairman:

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

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

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

A. Antidepressants
B. Complement Inhibitors and Miscellaneous Immunomodulatory Agents
C. Lysosomal Storage Disease Medications
D. Osteoporosis Medications

*Future product and class reviews subject to change.

18. 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 reported in this packet is based solely on the data provided by the SoonerSelect plans.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING OCTOBER 9, 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	
Cindy West, D.O., FAAP		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	
Josh Holloway, J.D.; Deputy General Counsel	X	
Conner Mulvaney, J.D.; Deputy General Counsel	X	
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	

Paula Root, M.D.; Senior Medical Director, Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist		X
Toney Welborn, M.D., MPH, MS; Medical Director	X	

OTHERS PRESENT:	
Taha Khan, Vertex Pharmaceuticals	Roberto Pedraza, Vertex Pharmaceuticals
Dawn Bey, Vertex Pharmaceuticals	Kristen Winters, Centene
Irene Chung, Aetna	Deidra Williams, Humana
David Prather, Novo Nordisk	Brent Young, Bristol Myers Squibb
Todd Ness, AbbVie	Rhonda Clark, Indivior
John Omick, Travere	Michael DeRemer
Raul Almanza	Frank Alvarado, Johnson & Johnson
Brent Fushimi, UCB	Tina Hartmann, Arcutis
Amanda Nowaskowski, ViiV Healthcare	Artia Solutions
Melissa Abbott, Eisai	Gary Parenteau, DexCom
Wendi Chandler	Brent Parker, Merck
Porscha Showers	

PRESENT FOR PUBLIC COMMENT:	
Taha Khan, Vertex Pharmaceuticals	

AGENDA ITEM NO. 1: **CALL TO ORDER**

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:00 pm. Roll call by Dr. Wilcox did not initially establish the presence of a quorum; however, a quorum was established prior to any action items being voted on.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: **PUBLIC COMMENT FORUM**

2A: AGENDA ITEM NO. 11 TAHA KHAN

ACTION: NONE REQUIRED

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

3A: SEPTEMBER 11, 2024 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore

Dr. Patatanian moved to approve; seconded by Dr. Walton

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/FALL 2024 PIPELINE UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR SEPTEMBER 2024

4B: MEDICATION COVERAGE ACTIVITY FOR SEPTEMBER 2024

4C: FALL 2024 PIPELINE UPDATE

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE WAINUA™ (EPLONTERSEN) AND UPDATE THE APPROVAL CRITERIA FOR AMYLOIDOSIS MEDICATIONS**

5A: MARKET NEWS AND UPDATES

5B: WAINUA™ (EPLONTERSEN) PRODUCT SUMMARY
5C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Metts
Dr. Haymore moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE HERCESSI™ (TRASTUZUMAB-STRF) AND TRUQAP™ (CAPIVASERTIB) AND UPDATE THE APPROVAL CRITERIA FOR THE BREAST CANCER MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARIES
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: ANNUAL REVIEW OF MYELOPROLIFERATIVE NEOPLASM (MPN) MEDICATIONS
7A: CURRENT PRIOR AUTHORIZATION CRITERIA
7B: UTILIZATION OF MPN MEDICATIONS
7C: PRIOR AUTHORIZATION OF MPN MEDICATIONS
7D: MARKET NEWS AND UPDATES
7E: COLLEGE OF PHARMACY RECOMMENDATIONS
7F: UTILIZATION DETAILS OF MPN MEDICATIONS
Materials included in agenda packet; presented by Dr. Sinko
Dr. Haymore moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: ANNUAL REVIEW OF HEPATITIS C MEDICATIONS
8A: CURRENT PRIOR AUTHORIZATION CRITERIA
8B: UTILIZATION OF HEPATITIS C MEDICATIONS
8C: PRIOR AUTHORIZATION OF HEPATITIS C MEDICATIONS
8D: MARKET NEWS AND UPDATES
8E: COLLEGE OF PHARMACY RECOMMENDATIONS
8F: UTILIZATION DETAILS OF HEPATITIS C MEDICATIONS
Materials included in agenda packet; presented by Dr. Metts
Dr. Patatanian moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: ANNUAL REVIEW OF TARGETED IMMUNOMODULATOR AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE BIMZELX® (BIMEKIZUMAB-BKZX), LEQSELVI™ (DEURUXOLITINIB), OMVOH™ (MIRIKIZUMAB-MRKZ), OTULFI™ (USTEKINUMAB-AAUZ), PYZCHIVA® (USTEKINUMAB-TTWE), RINVOQ® LQ (UPADACITINIB ORAL SOLUTION), SELARSDI™ (USTEKINUMAB-AEKN), SIMLANDI® (ADALIMUMAB-RYVK), TYENNE® (TOCILIZUMAB-AAZG), VELSIPITY™ (ETRASIMOD), WEZLANA™ (USTEKINUMAB-AUUB), AND ZYMFENTRA™ (INFLIXIMAB-DYYB)
9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF TARGETED IMMUNOMODULATOR AGENTS
9C: PRIOR AUTHORIZATION OF TARGETED IMMUNOMODULATOR AGENTS
9D: MARKET NEWS AND UPDATES
9E: PRODUCT SUMMARIES
9F: COLLEGE OF PHARMACY RECOMMENDATIONS
9G: UTILIZATION DETAILS OF TARGETED IMMUNOMODULATOR AGENTS

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

AGENDA ITEM NO. 10: ANNUAL REVIEW OF HYPEROXALURIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE RIVFLOZA® (NEDOSIRAN)
10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF HYPEROXALURIA MEDICATIONS
10C: PRIOR AUTHORIZATION OF HYPEROXALURIA MEDICATIONS
10D: MARKET NEWS AND UPDATES
10E: RIVFLOZA® (NEDOSIRAN) PRODUCT SUMMARY
10F: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Metts
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 11: ANNUAL REVIEW OF ANEMIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE CASGEVY™ (EXAGAMGLOGENE AUTOTEMCEL), LYFGENIA® (LOVOTIBEGLOGENE AUTOTEMCEL), VAFSEO® (VADADUSTAT), AND XROMI® (HYDROXYUREA ORAL SOLUTION)
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF ANEMIA MEDICATIONS
11C: PRIOR AUTHORIZATION OF ANEMIA MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: UTILIZATION DETAILS OF ANEMIA MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

AGENDA ITEM NO. 12: ANNUAL REVIEW OF SYNAGIS® (PALIVIZUMAB)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF SYNAGIS® (PALIVIZUMAB)
12C: PRIOR AUTHORIZATION OF SYNAGIS® (PALIVIZUMAB)
12D: RSV SEASON COMPARISON
12E: MARKET NEWS AND UPDATES
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF SYNAGIS® (PALIVIZUMAB)
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
14A: ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS
14B: ATOPIC DERMATITIS MEDICATIONS
14C: HEREDITARY ANGIOEDEMA (HAE) MEDICATIONS
14D: MULTIPLE MYELOMA MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 15: ADJOURNMENT

The meeting was adjourned at 5:35 pm.

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

Memorandum

Date: October 11, 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 October 9, 2024

Recommendation 1: Fall 2024 Pipeline Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Wainua™ (Eplontersen) and Update the Approval Criteria for Amyloidosis Medications

MOTION CARRIED by unanimous approval.

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

Wainua™ (Eplontersen) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by genetic testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by, or in consultation with, a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and

5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Wainua™; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. Wainua™ will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
9. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
10. A quantity limit of 0.8mL per 28 days will apply.

The College of Pharmacy also recommends updating the approval criteria for Amvuttra® (vutrisiran), Onpattro (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), and Vyndaqel® (tafamidis meglumine) to be more consistent with clinical practice (changes shown in red):

Amvuttra® (Vutrisiran) and Onpattro® (Patisiran) Approval Criteria:

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by ~~the following:~~
   ~~a. Tissue (fat pad) biopsy confirming amyloid deposits; or~~
   b. Genetic ~~confirmation of~~ testing identifying a transthyretin (*TTR*) gene mutation (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. For Onpattro®, prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and

9. Amvuttra® will not be approved for concomitant use with Onpattro® (patisiran), Tegsedi® (inotersen), Vyndaqel® (tafamidis meglumine), ~~or~~ Vyndamax® (tafamidis), or Wainua™ (eplontersen); and
10. Authorization for Amvuttra® will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and
11. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua™ (eplontersen); and
12. For Onpattro®, 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
13. For Amvuttra®, a quantity limit of 0.5mL per 90 days will apply; and
14. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

Tegsedi® (Inotersen) Approval Criteria:

1. An FDA approved indication for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by ~~the following:~~
   ~~a. Tissue (fat pad) biopsy confirming amyloid deposits; or~~
   b. Genetic ~~confirmation of~~ testing identifying a transthyretin (*TTR*) gene mutation (e.g., Val30Met) (results of genetic testing must be submitted); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Tegsedi® must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or Wainua™ (eplontersen); and

11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant; and
13. A quantity limit of 4 syringes per 28 days will apply.

Vyndamax® (Tafamidis) and Vyndaqel® (Tafamidis Meglumine) Approval Criteria:

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
    a. Genetic confirmation of transthyretin (*TTR*) mutation or wild-type amyloidosis (results of genetic testing must be submitted); and
    b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
    a. Nuclear scintigraphy; or
    b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and
5. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
6. Prescriber must confirm the member has not undergone a liver transplant; and
7. Vyndamax® or Vyndaqel® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Vyndamax® or Vyndaqel® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), ~~or~~ Tegsedi® (inotersen), or Wainua™ (eplontersen); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
10. A quantity limit of 1 Vyndamax® capsule or 4 Vyndaqel® capsules per day will apply.

Recommendation 3: Vote to Prior Authorize Hercessi™ (Trastuzumab-strf) and Truqap™ (Capivasertib) and Update the Approval Criteria for the Breast Cancer Medications

MOTION CARRIED by unanimous approval.

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

Truqap™ (Capivasertib) Approval Criteria [Breast Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic breast cancer; and
2. Hormone receptor (HR)-positive; and
3. Human epidermal growth factor receptor 2 (HER2)-negative; and
4. Used in combination with fulvestrant; and
5. Contains 1 or more *PIK3CA/AKT1/PTEN*-alterations as detected by an FDA-approved test; and
6. Member meets 1 of the following:
    a. Progressed following at least 1 endocrine-based regimen in the metastatic setting; or
    b. Progressed within 12 months of completing adjuvant therapy.

The College of Pharmacy also recommends updating the approval criteria for Enhertu® (fam-trastuzumab deruxtecan-nxki), Kisqali® (ribociclib), Kisqali® Femara® Co-Pack (ribociclib/letrozole), Piqray® (alpelisib), and Verzenio® (abemaciclib) based on recent FDA approvals (changes and new criteria noted in red):

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

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

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

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

~~ii. Must be used in postmenopausal women only.~~

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

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

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

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

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

1. Diagnosis of advanced or metastatic breast cancer; and
    a. Hormone receptor positive disease; and
    b. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in 1 of the following settings:
            1. In combination with an aromatase inhibitor as initial endocrine-based therapy ~~for postmenopausal women~~; or
            2. In combination with fulvestrant with disease progression following endocrine therapy; or
            3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy; or
2. Diagnosis of early-stage breast cancer; and
    a. Hormone receptor positive disease; and
    b. HER2-negative disease; and
    c. Node-positive disease high risk for recurrence; and
    d. Used as adjuvant treatment in combination with endocrine therapy.

Additionally, the College of Pharmacy recommends updating the Enhertu® (fam-trastuzumab deruxtecan-nxki), Halaven® (eribulin), Ixempra® (ixabepilone), and Orserdu® (elacestrant) approval criteria based on National Comprehensive Cancer Network (NCCN) recommendations (changes and new criteria noted in red):

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

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

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

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

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

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

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

1. Diagnosis of metastatic or locally advanced breast cancer; and
2. Used in combination with capecitabine; and
    a. After failure of an anthracycline and a taxane unless anthracycline contraindicated; or
3. Used as a single agent; and
    a. Used in 1 of the following settings:
        i. After failure of capecitabine, an anthracycline, and a taxane; or
        ii. In members with no response to preoperative systemic therapy; or

iii. After at least 1 line of therapy for recurrent unresectable (local or regional) disease; or
iv. Disease is human epidermal growth factor receptor 2 (HER2)-negative; or

4. Used in combination with trastuzumab; and
   a. Disease is HER2-positive; and
   b. ~~Third-line~~ Fourth-line or subsequent therapy.

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

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

Lastly, the College of Pharmacy recommends the prior authorization of Hercessi™ (trastuzumab-strf) and updating the approval criteria for the trastuzumab products based on net costs (changes and additions shown in red):

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive breast cancer; and
2. Preferred trastuzumab products include ~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Herceptin Hylecta™ (trastuzumab/hyaluronidase-oysk), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-pkrb), Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ or Trazimera® (trastuzumab-qyyp)]. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. Diagnosis of human epidermal receptor type 2 (HER2)-positive CRC; and
2. RAS and BRAF mutation negative; and
3. Used in combination with pertuzumab, lapatinib, or tucatinib; and
4. Used in 1 of the following settings:
    a. If first-line therapy, patient should not be a candidate for intensive therapy; or
    b. For the treatment of advanced or metastatic disease following disease progression; and
5. Preferred trastuzumab products include ~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-pkrb), Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ or Trazimera® (trastuzumab-qyyp)]. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

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

1. Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic gastric or gastroesophageal junction adenocarcinoma; and
2. Preferred trastuzumab products include ~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Hercessi™ (trastuzumab-strf), Herzuma® (trastuzumab-pkrb), Ogivri® (trastuzumab-dkst), or Ontruzant® (trastuzumab-dttb)] will also require a patient-specific, clinically significant reason why the member cannot use the preferred trastuzumab products [~~Herzuma® (trastuzumab-pkrb),~~ Kanjinti® (trastuzumab-anns)~~,~~ or Trazimera® (trastuzumab-qyyp)]. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in

comparison to the reference product and/or other available biosimilar products.

Recommendation 4: Annual Review of Myeloproliferative Neoplasm (MPN) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Inrebic® (fedratinib) based on the recent FDA label update with the following changes (shown in red):

Inrebic® (Fedratinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of MF in adult members; and
2. Intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia); and
3. In combination with prophylactic thiamine 100mg daily.

Recommendation 5: Annual Review of Hepatitis C Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to Hepatitis C Medication Approval Criteria based on clinical practice and to be consistent with requirements concerning substance use disorder (SUD) under the Americans with Disabilities Act (ADA) (changes shown in red):

Hepatitis C Medication Approval Criteria:

1. An FDA approved age appropriate to the requested medication; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) and an FDA-indicated genotype (GT) appropriate to the requested medication; and
3. Requested hepatitis C medication must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
4. Hepatitis C virus (HCV) GT testing must be confirmed and indicated on the prior authorization request; and
5. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent), then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent), then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or

ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

6. FDA approved regimens and requirements based on cirrhosis status, viral GT, treatment history, and viral load thresholds will apply; and
7. Member must sign and submit the Hepatitis C Intent to Treat Contract; and
8. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
9. Prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including sustained virologic response (SVR-12); and
10. Prescriber must agree to counsel members on the potential harms of illicit intravenous (IV) drug use or alcohol use ~~and member must agree to no illicit IV drug use or alcohol use while on treatment and post-therapy~~; and
11. Documentation of initiation of immunization with the hepatitis A and B vaccines must be provided; and
12. Decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C) restrictions based on FDA approvals and safety recommendations will apply; and
13. Member must not have a limited life expectancy (<12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
14. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy; and
15. Member must not be taking any medications not recommended for use with the requested hepatitis C medication; and
16. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight-management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and
17. Prescriber must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
18. Member must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and
19. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 16 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Recommendation 6: Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Bimzelx® (Bimekizumab-bkzx), Leqselvi™ (Deuruxolitinib), Omvoh™ (Mirikizumab-mrkz), Otulfi™ (Ustekinumab-aauz), Pyzchiva® (Ustekinumab-ttwe), Rinvoq® LQ (Upadacitinib Oral Solution), Selarsdi™ (Ustekinumab-aekn), Simlandi® (Adalimumab-ryvk), Tyenne® (Tocilizumab-aazg), Velsipity™ (Etrasimod), Wezlana™ (Ustekinumab-auub), and Zymfentra™ (Infliximab-dyyb

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER 2024.

Recommendation 7: Annual Review of Hyperoxaluria Medications and 30-Day Notice to Prior Authorize Rivfloza® (Nedosiran)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER 2024.

Recommendation 8: Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Casgevy™ (Exagamglogene Autotemcel), Lyfgenia® (Lovotibeglogene Autotemcel), Vafseo® (Vadadustat), and Xromi® (Hydroxyurea Oral Solution)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER 2024.

Recommendation 9: Annual Review of Synagis® (Palivizumab)

NO ACTION REQUIRED.

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

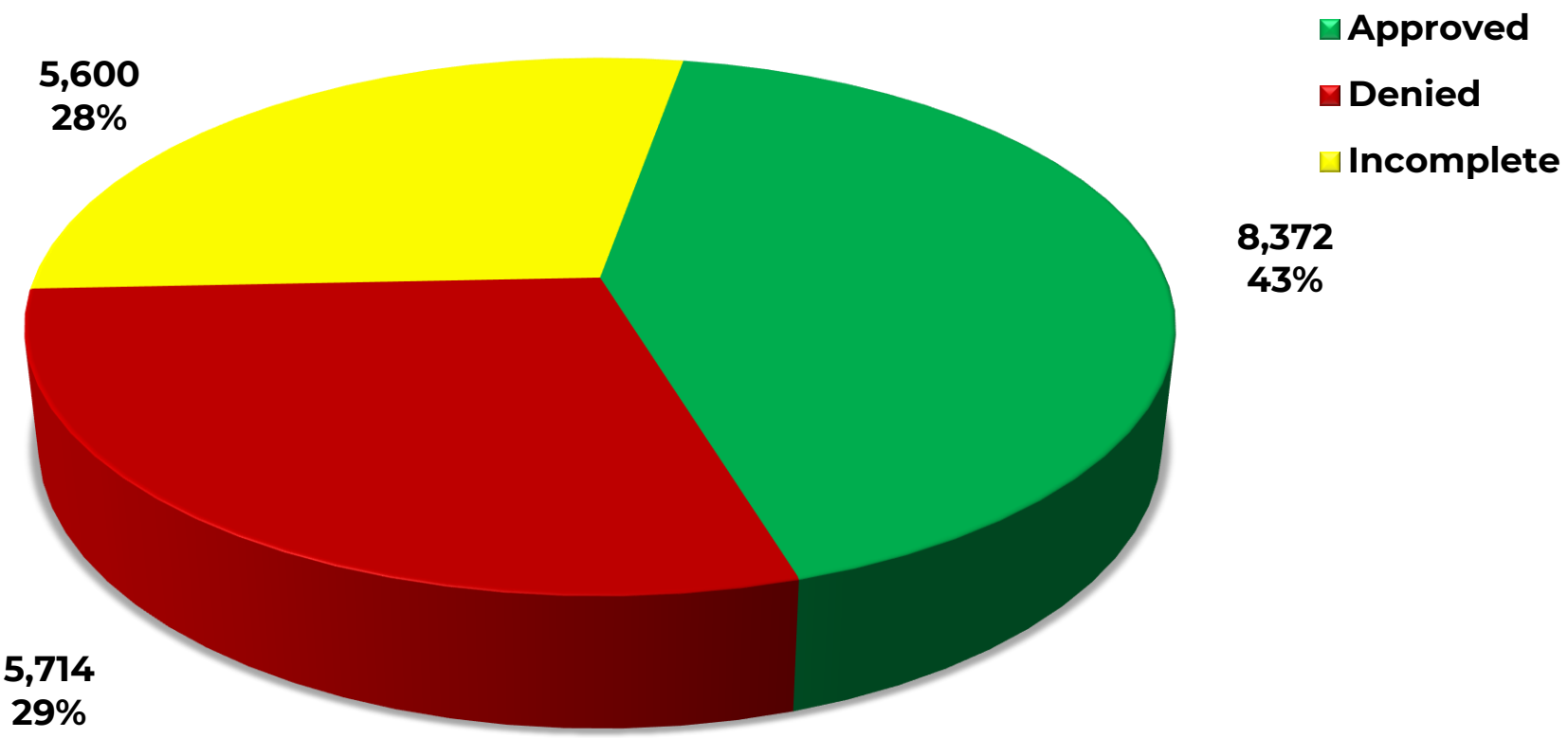
NO ACTION REQUIRED.

Recommendation 11: Future Business

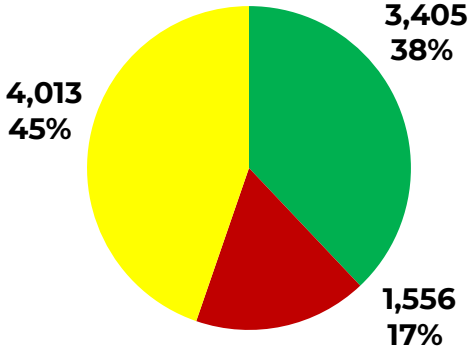
NO ACTION REQUIRED.

Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: OCTOBER 2024



SoonerCare FFS



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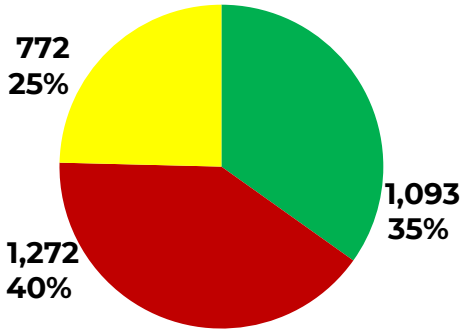
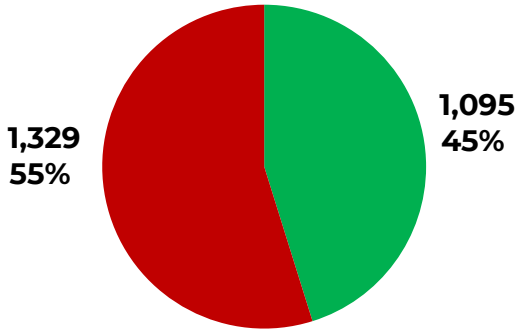
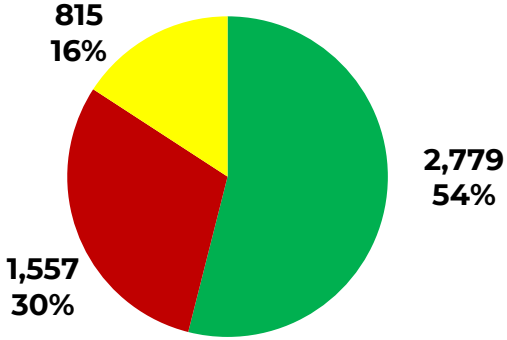


SoonerSelect Humana

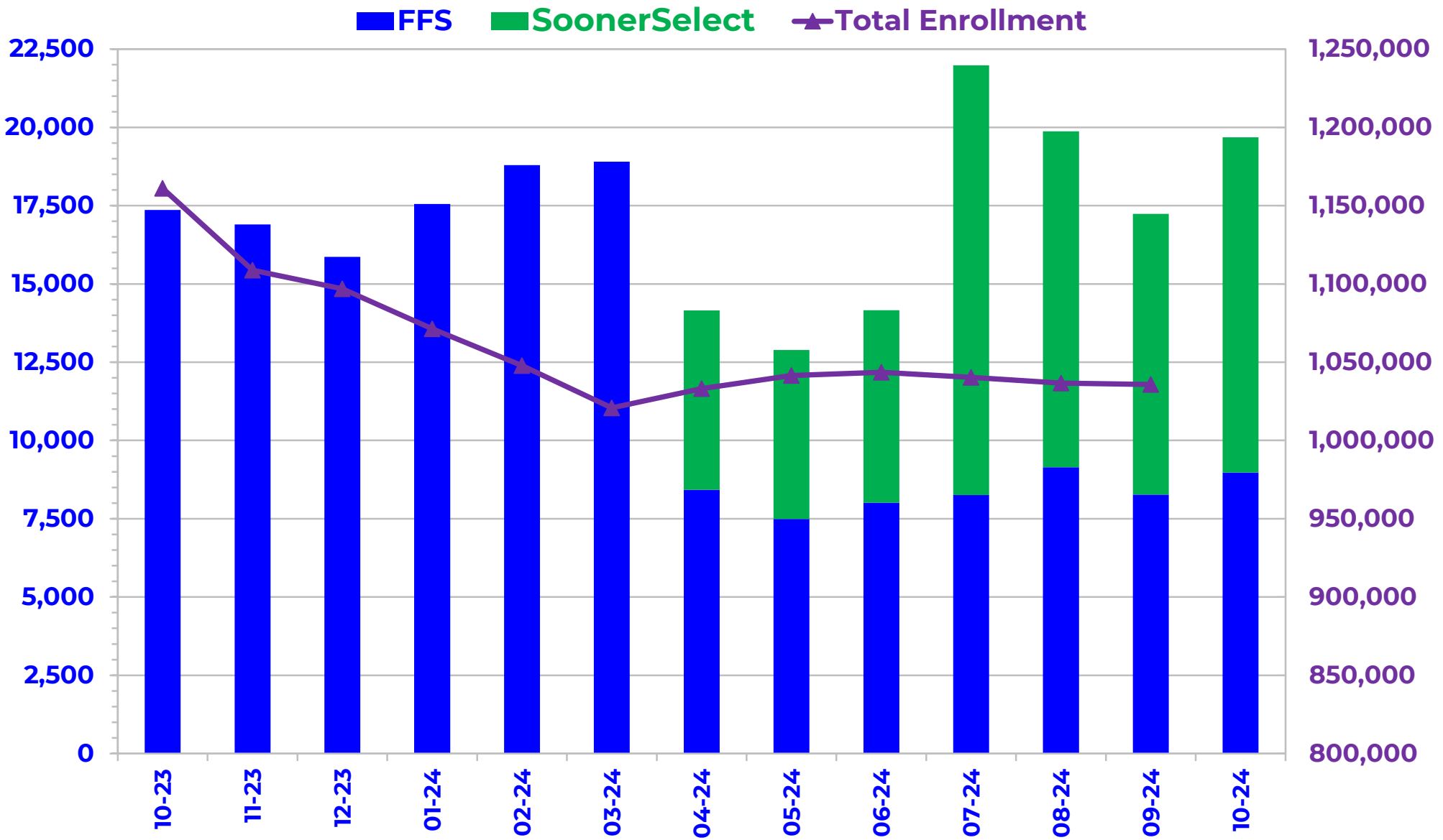


SoonerSelect OK Complete Health



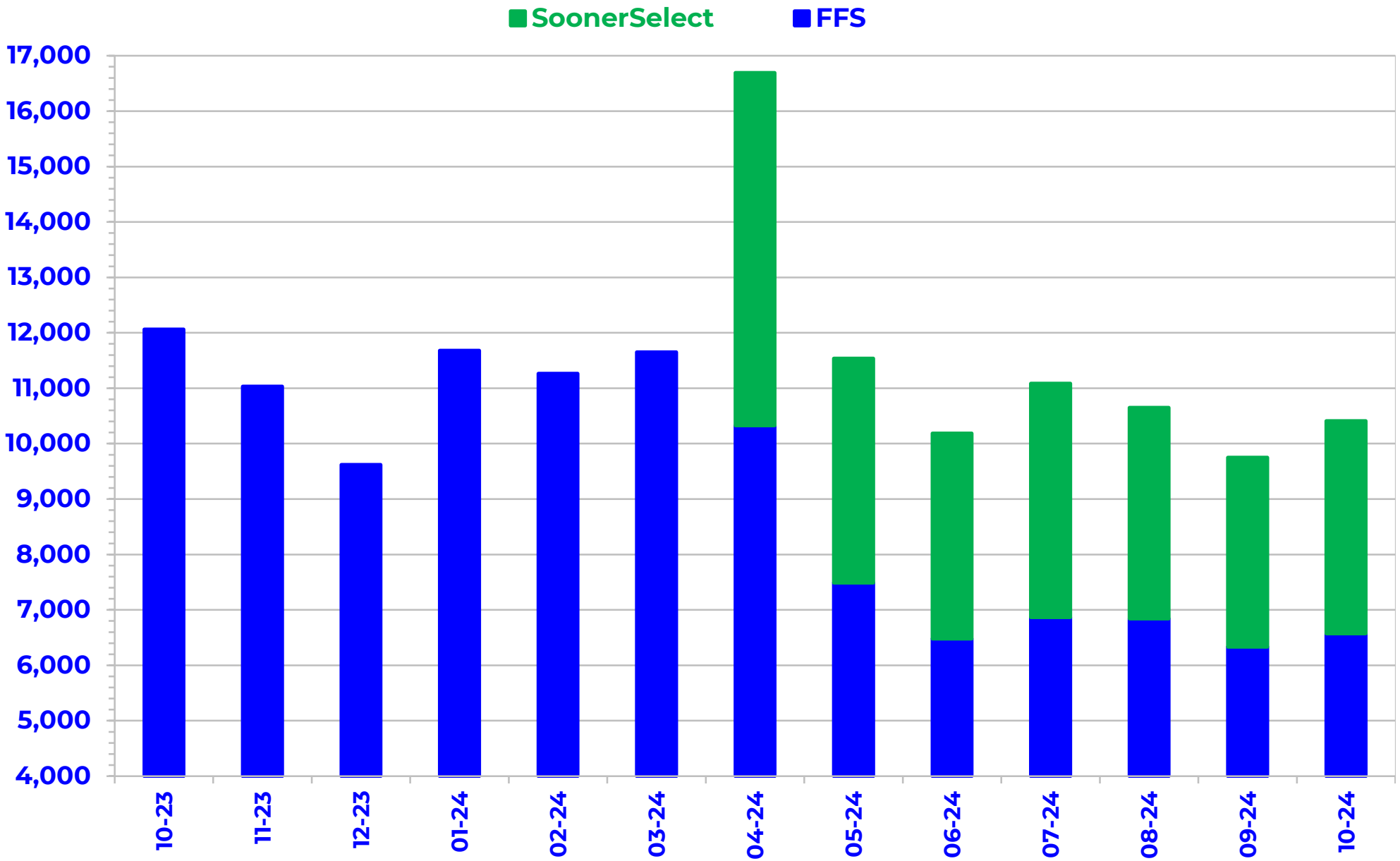
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: OCTOBER 2023 – OCTOBER 2024



SoonerCare FFS Prior Authorization Activity

10/1/2024 Through 10/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	634	390	9	235	353
Analgesics - Anti-Inflammatory	241	90	38	113	313
Analgesics - Nonnarcotic	17	0	3	14	0
Analgesics - Opioid	406	167	41	198	139
Androgens-Anabolic	87	16	18	53	359
Anorectal and Related Products	5	0	2	3	0
Anorexiants Non-Amphetamine	2	0	2	0	0
Anthelmintics	19	6	4	9	18
Anti-Infective Agents - Misc.	24	9	3	12	256
Anti-Obesity Agents	96	6	58	32	206
Antianginal Agents	2	2	0	0	359
Antianxiety Agents	25	5	4	16	188
Antiasthmatic and Bronchodilator Agents	509	94	97	318	323
Antibiotics	41	15	2	24	154
Anticoagulants	11	3	2	6	172
Anticonvulsants	226	107	16	103	332
Antidepressants	250	59	40	151	306
Antidiabetics	1,372	400	300	672	355
Antidiarrheal/Probiotic Agents	1	0	0	1	0
Antidotes and Specific Antagonists	5	2	1	2	181
Antiemetics	25	1	2	22	23
Antifungals	4	3	0	1	36
Antihistamines	34	6	14	14	303
Antihyperlipidemics	61	11	19	31	234
Antihypertensives	16	4	3	9	359
Antimalarials	6	3	1	2	191
Antineoplastics and Adjunctive Therapies	158	110	9	39	179
Antiparkinson and Related Therapy Agents	16	5	7	4	345
Antipsychotics/Antimanic Agents	333	115	42	176	347
Antivirals	25	13	2	10	40
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	238	162	18	58	349
Beta Blockers	13	0	1	12	0
Calcium Channel Blockers	10	2	1	7	197
Cardiovascular Agents - Misc.	86	40	16	30	329
Contraceptives	43	18	7	18	340
Corticosteroids	12	4	2	6	189
Dermatologicals	419	125	107	187	252
Diagnostic Products	47	19	2	26	147
Dietary Products/Dietary Management Products	2	0	2	0	0
Digestive Aids	13	5	2	6	360
Diuretics	7	3	1	3	359
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	1	0	1	360
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	185	98	20	67	209
Estrogens	8	2	2	4	253
Gastrointestinal Agents - Misc.	319	81	81	157	255
Genitourinary Agents - Misc.	7	2	0	5	360
Gout Agents	8	2	1	5	359

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hematological Agents - Misc.	16	11	1	4	280
Hematopoietic Agents	56	17	23	16	110
Hemostatics	4	0	1	3	0
Histamine H3-Receptor Antagonist/Inverse Agonists	4	2	0	2	183
Hypnotics/Sedatives/Sleep Disorder Agents	57	5	12	40	249
Laxatives	18	8	1	9	267
Medical Devices and Supplies	253	46	58	149	280
Migraine Products	312	70	112	130	303
Minerals and Electrolytes	4	0	2	2	0
Miscellaneous Therapeutic Classes	58	27	5	26	319
Multivitamins	9	3	0	6	197
Musculoskeletal Therapy Agents	58	9	10	39	178
Nasal Agents - Systemic and Topical	25	2	9	14	360
Neuromuscular Agents	119	37	60	22	328
Nutrients	1	1	0	0	118
Ophthalmic Agents	57	9	13	35	256
Other*	57	22	4	31	229
Otic Agents	30	0	4	26	0
Passive Immunizing and Treatment Agents	10	2	1	7	25
Progestins	6	0	2	4	0
Psychotherapeutic and Neurological Agents - Misc.	238	88	53	97	230
Respiratory Agents - Misc.	18	10	2	6	320
Stimulants - Misc.	209	75	18	116	353
Thyroid Agents	31	11	8	12	359
Ulcer Drugs/Antispasmodics/Anticholinergics	49	7	9	33	233
Urinary Antispasmodics	77	11	27	39	359
Vaccines	1	1	0	0	360
Vaginal and Related Products	2	0	1	1	0
Vasopressors	1	0	0	1	0
Vitamins	34	1	30	3	85
Total	**7,884**	**2,681**	**1,468**	**3,735**	
Overrides					
Brand	14	6	0	8	305
Compound	4	4	0	0	9
Diabetic Supplies	1	0	0	1	0
Dosage Change	194	174	2	18	13
High Dose	4	4	0	0	313
Ingredient Duplication	2	1	0	1	175
Lost/Broken Rx	45	40	0	5	28
MAT Override	18	14	2	2	111
NDC vs Age	213	130	39	44	292
NDC vs Sex	22	15	1	6	298
Nursing Home Issue	41	36	0	5	10
Opioid MME Limit	71	29	3	39	156
Opioid Quantity	26	12	5	9	162
Other	42	30	1	11	21
Quantity vs Days Supply	337	198	30	109	277
STBS/STBSM	14	7	3	4	67

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Step Therapy Exception	7	4	2	1	358
Stolen	2	2	0	0	17
Third Brand Request	33	18	0	15	37
Overrides Total	**1,090**	**724**	**88**	**278**	
Total Regular PAs + Overrides	**8,974**	**3,405**	**1,556**	**4,013**	

Denial Reasons	
Unable to verify required trials.	3,385
Does not meet established criteria.	1,586
Lack required information to process request.	682
Other PA Activity	
Duplicate Requests	943
Letters	34,905
No Process	0
Helpdesk Initiated Prior Authorizations	367
PAs Missing Information	428
Pharmacotherapy	98
Changes to Existing PAs	567

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

SoonerSelect Aetna Prior Authorization Activity

10/1/2024 Through 10/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	229	179	22	28	360
Analgesics - Anti-Inflammatory	119	74	24	21	345
Analgesics - Nonnarcotic	4	0	4	0	0
Analgesics - Opioid	181	79	63	39	233
Androgens-Anabolic	41	14	25	2	332
Anorexiants Non-Amphetamine	1	0	1	0	0
Anthelmintics	11	6	5	0	26
Antianxiety Agents	24	10	2	12	365
Antiasthmatic and Bronchodilator Agents	170	41	69	60	326
Antibiotics	27	8	7	12	75
Anticoagulants	8	3	1	4	213
Anticonvulsants	68	19	26	23	309
Antidepressants	194	50	65	79	322
Antidiabetics	477	122	268	87	328
Antiemetics	6	1	3	2	182
Antifungals	1	0	0	1	0
Antihistamines	20	3	16	1	365
Antihyperlipidemics	27	5	6	16	190
Antihypertensives	23	3	0	20	365
Anti-Infective Agents - Misc.	11	6	2	3	78
Antineoplastics and Adjunctive Therapies	29	11	2	16	254
Anti-Obesity Agents	45	7	35	3	365
Antiparkinson and Related Therapy Agents	11	1	1	9	365
Antipsychotics/Antimanic Agents	169	56	70	43	359
Antivirals	3	1	1	1	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	100	63	31	6	352
Beta Blockers	24	1	0	23	365
Calcium Channel Blockers	9	1	2	6	365
Cardiovascular Agents - Misc.	17	8	6	3	365
Chemicals	1	0	0	1	0
Contraceptives	10	0	8	2	0
Corticosteroids	2	1	1	0	365
Dermatologicals	238	93	110	35	216
Diagnostic Products	53	22	14	17	339
Dietary Products/Dietary Management Products	2	1	0	1	365
Digestive Aids	5	2	0	3	365
Diuretics	6	0	0	6	0
Endocrine and Metabolic Agents - Misc.	19	8	9	2	222
Estrogens	3	1	2	0	182
Gastrointestinal Agents - Misc.	66	20	42	4	262
Genitourinary Agents - Misc.	1	1	0	0	31
Gout Agents	6	3	2	1	365
Hematological Agents - Misc.	5	4	1	0	319
Hematopoietic Agents	7	3	3	1	274
Hypnotics/Sedatives/Sleep Disorder Agents	35	5	16	14	228
Laxatives	20	1	15	4	30

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Medical Devices and Supplies	92	26	41	25	335
Migraine Products	149	32	101	16	246
Minerals & Electrolytes	4	0	1	3	0
Miscellaneous Therapeutic Classes	10	4	3	3	365
Multivitamins	7	6	1	0	365
Musculoskeletal Therapy Agents	35	3	11	21	163
Nasal Agents - Systemic And Topical	21	0	9	12	0
Neuromuscular Agents	7	2	3	2	365
Ophthalmic Agents	12	3	4	5	285
Other	18	5	5	8	292
Otic Agents	19	3	15	1	56
Passive Immunizing and Treatment Agents	6	1	3	2	365
Progestins	2	1	0	1	365
Psychotherapeutic and Neurological Agents - Misc.	32	13	17	2	239
Respiratory Agents - Misc.	5	3	1	1	365
Stimulants - Misc.	79	44	25	10	355
Thyroid Agents	3	2	0	1	274
Ulcer Drugs/Antispasmodics/Anticholinergics	49	3	6	40	167
Urinary Antispasmodics	16	3	11	2	365
Vaccines	1	1	0	0	182
Vaginal and Related Products	4	0	1	3	0
Vasopressors	3	1	1	1	14
Vitamins	35	0	33	2	0
****Total**	**3,137**	**1,093**	**1,272**	**772**	

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

Overrides					
Brand	1	1	0	0	92
Other	777	5	0	772	365
Quantity Level Limit	37	37	0	0	321
Overrides Total	**815**	**43**	**0**	**772**	

Denial Reason	
Benefit	91
Experimental/Investigational	170
Lack Required Infomation to Process Request	69
Medical Necessity	941
Other	1

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

Other PA Activity	
Duplicate Requests	11
Letters	3721
No Process	296
Changes to existing PAs	1
Helpdesk initiated PA	4
PAs missing info	12

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

SoonerSelect Humana Prior Authorization Activity

10/1/2024 Through 10/31/2024

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	2	1	1	0	182
Amphetamines	9	1	8	0	730
Analgesics - Anti-Inflammatory	60	43	17	0	304
Analgesics - Nonnarcotic	3	1	2	0	365
Analgesics - Opioid	81	41	40	0	254
Androgens-Anabolic	37	11	26	0	309
Anthelmintics	5	3	2	0	219
Antiasthmatic and Bronchodilator Agents	146	34	112	0	259
Antibiotics	14	5	9	0	350
Anticonvulsants	10	6	4	0	437
Antidepressants	48	25	23	0	327
Antidiabetics	207	64	143	0	239
Antiemetics	2	1	1	0	365
Antifungals	2	1	1	0	365
Antihyperlipidemics	10	2	8	0	194
Anti-Infective Agents - Misc.	5	4	1	0	365
Antineoplastics and Adjunctive Therapies	28	28	0	0	263
Anti-Obesity Agents	41	4	37	0	189
Antipsychotics/Antimanic Agents	2	0	2	0	0
Antivirals	14	4	10	0	202
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	18	6	12	0	213
Beta Blockers	1	1	0	0	365
Calcium Channel Blockers	1	0	1	0	0
Cardiovascular Agents - Misc.	17	9	8	0	304
Contraceptives	14	6	8	0	284
Corticosteroids	2	1	1	0	84
Dermatologicals	114	62	52	0	242
Digestive Aids	3	1	2	0	365
Diuretics	1	1	0	0	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	0	2	0	0
Endocrine and Metabolic Agents - Misc.	20	13	7	0	263
Estrogens	7	5	2	0	261
Gastrointestinal Agents - Misc.	97	40	57	0	269
Gout Agents	3	2	1	0	274
Hematological Agents - Misc.	3	3	0	0	304
Hematopoietic Agents	11	5	6	0	148
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	1	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	14	1	13	0	91
Laxatives	7	0	7	0	0
Migraine Products	114	50	64	0	207
Miscellaneous Therapeutic Classes	10	6	4	0	228
Multivitamins	1	1	0	0	365
Musculoskeletal Therapy Agents	16	8	8	0	341
Nasal Agents - Systemic And Topical	2	0	2	0	0
Neuromuscular Agents	37	18	19	0	231
Ophthalmic Agents	15	7	8	0	338
Other	13	4	9	0	274
Otic Agents	4	1	3	0	183

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Passive Immunizing and Treatment Agents	1	1	0	0	31
Psychotherapeutic and Neurological Agents - Misc.	23	15	8	0	271
Respiratory Agents - Misc.	7	4	3	0	324
Stimulants - Misc.	13	7	6	0	341
Thyroid Agents	4	0	4	0	0
Ulcer Drugs/Antispasmodics/Anticholinergics	14	0	14	0	0
Urinary Antispasmodics	25	5	20	0	150
Vaginal and Related Products	2	0	2	0	0
Vitamins	23	8	15	0	400
Total	**1,386**	**570**	**816**	**0**	
Overrides					
Ingredient Duplication	107	45	62	0	221
MAT Override	5	3	2	0	292
NDC vs Age	250	177	73	0	271
NDC vs Sex	2	0	2	0	0
Opioid MME Edit	4	4	0	0	386
Opioid Quantity	6	5	1	0	426
Other	86	19	67	0	80
Quantity vs Days Supply	215	122	93	0	260
STBS/STBSM	94	30	64	0	134
Step Therapy Exception	269	120	149	0	179
Overrides Total	**1,038**	**525**	**513**	**0**	
Total Regular PAs + Overrides	**2,424**	**1,095**	**1,329**	**0**	
Denial Reasons					
Benefit					323
Medical Necessity					1,006

*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

10/1/2024 Through 10/31/2024

	Total	Approved	Denied	Incomplete	Average Length
Amebicides	1	1	0	0	365
Amphetamines	175	134	10	31	183
Analgesics - Anti-Inflammatory	94	54	29	11	352
Analgesics - Nonnarcotic	3	0	3	0	0
Analgesics - Opioid	247	77	134	36	218
Androgens - Anabolic	62	10	47	5	335
Anorectal and Related Products	2	0	2	0	0
Anorexiants Non-Amphetamine	1	0	1	0	0
Antacids	1	0	0	1	0
Anthelmintics	5	3	1	1	365
Antianginal Agents	6	5	0	1	71
Antianxiety Agents	105	65	17	23	108
Antiasthmatic and Bronchodilator Agents	399	201	143	55	220
Antibiotics	12	4	7	1	274
Anticoagulants	2	0	0	2	0
Anticonvulsants	308	226	29	53	149
Antidepressants	443	286	70	87	153
Antidiabetics	975	552	298	125	232
Antiemetics	7	1	4	2	89
Antifungals	5	1	1	3	91
Antihistamines	26	9	14	3	365
Antihyperlipidemics	45	27	11	7	144
Antihypertensives	95	70	1	24	114
Anti-Infective Agents - Misc.	11	7	3	1	250
Antimyasthenic/Cholinergic Agents	1	0	1	0	0
Antineoplastics and Adjunctive Therapies	12	7	2	3	286
Anti-Obesity Agents	53	3	48	2	114
Antiparkinson and Related Therapy Agents	6	5	0	1	192
Antipsychotics/Antimanic Agents	237	142	51	44	235
Antivirals	3	0	3	0	0
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	85	36	39	10	286
Beta Blockers	61	48	1	12	98
Calcium Channel Blockers	33	20	5	8	79
Cardiovascular Agents - Misc.	37	13	14	10	366
Contraceptives	17	4	11	2	218
Corticosteroids	6	1	2	3	56
Cough/Cold/Allergy	1	1	0	0	365
Dermatologicals	269	106	117	46	280
Diagnostic Products	40	18	13	9	291
Dietary Products/Dietary Management Products	2	0	2	0	0
Digestive Aids	1	1	0	0	365
Diuretics	30	24	0	6	90
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	1	0	0	365
Endocrine and Metabolic Agents - Misc.	63	40	16	7	298
Estrogens	3	2	1	0	221
Gastrointestinal Agents - Misc.	97	34	54	9	312
Genitourinary Agents - Misc.	7	7	0	0	82
Gout Agents	3	0	2	1	0
Hematological Agents - Misc.	6	3	1	2	170
Hematopoietic Agents	6	1	5	0	365

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	24	6	14	4	174
Laxatives	8	3	3	2	365
Medical Devices and Supplies	131	70	52	9	334
Migraine Products	134	34	88	12	284
Miscellaneous Therapeutic Classes	11	8	1	2	365
Multivitamins	13	8	5	0	365
Musculoskeletal Therapy Agents	22	5	13	4	298
Nasal Agents - Systemic and Topical	9	1	8	0	367
Neuromuscular Agents	14	2	9	3	273
Ophthalmic Agents	43	18	10	15	198
Other	47	12	8	27	221
Otic Agents	64	29	24	11	248
Passive Immunizing and Treatment Agents	1	0	1	0	0
Psychotherapeutic and Neurological Agents - Misc.	39	13	15	11	244
Respiratory Agents - Misc.	8	4	4	0	319
Stimulants - Misc.	287	192	56	39	257
Thyroid Agents	44	29	4	11	126
Ulcer Drugs/Antispasmodics/Anticholinergics	114	86	13	15	130
Urinary Antispasmodics	26	9	14	3	186
Vaccines	1	0	1	0	0
Vitamins	1	0	1	0	0
****Total**	**5,151**	**2,779**	**1,557**	**815**	

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

Denial Reasons	
Benefit	75
Medical Necessity	1,482

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

Adherence to Asthma Maintenance Medications Prior to Adding on Biologic Therapy

Oklahoma Health Care Authority
November 2024

Introduction[1,2]

In the United States, it is estimated that nearly 28 million people have a diagnosis of asthma, with 23 million being 18 years of age or older. The Global Initiative for Asthma (GINA) guidelines are published annually with the goal of asthma management to prevent asthma-related deaths and to minimize the burden of asthma. The treatment algorithms for asthma are broken down into different tracks based on patient age, symptoms, and severity, but at each track it is recommended that all patients should be initiated, as soon as possible, on an inhaled corticosteroid (ICS)-containing therapy when diagnosed with asthma for the best outcomes.

Some patients may continue to experience uncontrolled asthma symptoms even when adherent to maximally optimized therapy and when managing other contributing factors, and these patients are considered to have severe or severe refractory asthma. It is estimated that 3-10% of patients with asthma will have severe asthma. These patients are recommended to be referred to a specialist, if available, and be assessed for Type 2 (T2) inflammation that may require the addition of biologic treatment options. Depending on other clinical features and their T2 inflammation, these patients may also require other add-on treatments such as low-dose oral corticosteroids (OCS).

Currently, there are 6 U.S. Food and Drug Administration (FDA) approved asthma-indicated monoclonal antibodies (MAB): Cinqair® (reslizumab), Dupixent® (dupilumab), Fasenra® (benralizumab), Nucala (mepolizumab), Tezspire® (tezepelumab-ekko), and Xolair® (omalizumab). Each medication works by targeting specific T2 inflammation biomarkers, although Tezspire® targets thymic stromal lymphopoietin (TSLP) and does not require the patient to have elevated T2 markers.

Asthma-Indicated MAB Utilization in the SoonerCare Population

A claims analysis was performed to identify members who were newly initiated on asthma-indicated MAB therapy during fiscal year 2023 (07/01/2022 to 06/30/2023) and to assess those members' adherence to maintenance asthma inhaler therapy. Members were included if they had a reported diagnosis of asthma within 1 year prior to FY23 and were excluded if they had a reported diagnosis of chronic obstructive pulmonary disease

(COPD). Members were considered a new start if they had no paid claims for an asthma-indicated MAB during the 6 months prior to FY23. A total of 235 members were identified who met the aforementioned criteria.

The 235 members were evaluated for their adherence to maintenance inhaler therapy. Adherence was defined as having ≥80% proportion of days covered (PDC) 6 months prior and 6 months after starting MAB therapy. Additionally, the members were evaluated for frequent use of OCS, short-acting beta$_2$-agonist (SABA) use, and inpatient and/or emergency department (IP/ED) visits related to their asthma diagnosis 6 months prior to and 6 months after starting MAB therapy. Frequent OCS was defined as 2 or more claims in a 6-month period and frequent SABA use was defined as 1 or more claims in the 6-month period. The results of this analysis can be seen in Figure 1 below.

Figure 1: FY23 Results for Members with Asthma-Indicated MAB Utilization (N=235)

	Pre-MAB		Post-MAB		% Change
Members with:	**# of members**	**%**	**# of members**	**%**	
Maintenance inhaler claims	143	61%	132	56%	-8%
Adherence to maintenance inhaler	44	19%	29	12%	-34%
Frequent OCS use	68	29%	30	13%	-56%
Frequent SABA use	163	69%	136	58%	-17%
IP/ED visits related to asthma	57	24%	31	13%	-46%

FY23 = 07/01/2022 to 06/30/2023
Pre-MAB = 6 months prior to MAB start date; Post-MAB = 6 months after MAB start date
IP/ED = inpatient/emergency department; MAB = monoclonal antibody; OCS = oral corticosteroids; SABA = short-acting beta$_2$-agonist

The total cost for paid medical and pharmacy claims was also calculated for the 235 members, and the results are seen below in Figure 2.

Figure 2: FY23 Cost for Members with Asthma-Indicated MAB Utilization (N=235)

	Pre-MAB	Post-MAB	% Change
Pharmacy claims total cost*	$193,861.22	$154,752.06	-20%
IP/ED visit total cost	$149,250.08	$46,970.66	-69%
Total cost	**$343,111.30**	**$201,722.72**	**-41%**

FY23 = 07/01/2022-06/30/2023
Cost of MAB not included in the above table
*Includes cost for maintenance inhalers, OCS, and SABA
Cost of asthma-indicated MAB therapy is not included in the above table.
Pre-MAB = 6 months prior to MAB start date; Post-MAB = 6 months after MAB start date
IP/ED = inpatient/emergency department; MAB = monoclonal antibody; OCS = oral corticosteroids; SABA = short-acting beta$_2$-agonist

Conclusions

The purpose of this analysis was to assess adherence to maintenance inhaler therapy and the results showed that of the 235 members, only 143 members had claims for maintenance inhalers before starting a MAB and only 132 members had claims after starting the MAB therapy. This implied a minority of members were adherent to maintenance inhaler therapy prior to starting a MAB and declined even further after initiation of MAB therapy. The MAB therapies are FDA approved as an add-on treatment to the current maintenance regimen and the lack of adherence potentially could lead to worse outcomes for SoonerCare members, including more frequent OCS use, SABA use, and IP/ED visits. The results do show the benefit of adding MAB therapy, when warranted, as indicated by a significant decrease of 56% in OCS use and 46% in IP/ED visits. The total cost of pharmacy claims decreased by 20% and medical claims by 68%; however, this would have been expected to increase if patients were adherent to their maintenance asthma therapies. The total cost overall for prescription therapies and medical IP/ED visits decreased by 41%. It is important to note that the analysis is based on paid SoonerCare pharmacy claims and does not include whether a member received their medications through a non-SoonerCare source (i.e., Indian Health Services, private insurance, samples, free clinics) nor do we have access to evaluate if a member has other contributing factors that may lead to their uncontrolled asthma. These results indicate a need for provider and member education regarding the importance of adherence to maintenance inhaler therapy and their MAB therapy to ensure SoonerCare members with asthma have the best outcomes, to help prevent further exacerbations, and to improve their quality of life.

Recommendations

The College of Pharmacy recommends an educational provider mailing with the goal of improving the adherence to maintenance inhaler therapy for members who are currently initiated on asthma-indicated MAB therapy in the Oklahoma SoonerCare population. Future results will be shared with the Drug Utilization Review (DUR) Board when available.

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[1] Asthma and Allergy Foundation of America. Asthma Facts and Figures. Available online at: https://aafa.org/wp-content/uploads/2022/08/aafa-asthma-facts-and-figures.pdf. Last revised 09/2024. Last accessed 10/15/2024.

[2] Global Initiative for Asthma (GINA). 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 10/15/2024.

Appendix C

2025 Drug Utilization Review (DUR) Board Meeting Dates

Oklahoma Health Care Authority
November 2024

DUR Board meetings are held the second Wednesday of every month at 4:00pm at the Oklahoma Health Care Authority

January 8, 2025

February 12, 2025

March 12, 2025

April 9, 2025

May 14, 2025

June 11, 2025

July 9, 2025

August 13, 2025

September 10, 2025

October 8, 2025

November 12, 2025

December 10, 2025

Appendix D

Vote to Prior Authorize Bimzelx® (Bimekizumab-bkzx), Leqselvi™ (Deuruxolitinib), Omvoh™ (Mirikizumab-mrkz), Otulfi™ (Ustekinumab-aauz), Pyzchiva® (Ustekinumab-ttwe), Rinvoq® LQ (Upadacitinib Oral Solution), Selarsdi™ (Ustekinumab-aekn), Simlandi® (Adalimumab-ryvk), Tyenne® (Tocilizumab-aazg), Velsipity™ (Etrasimod), Wezlana™ (Ustekinumab-auub), and Zymfentra™ (Infliximab-dyyb) and Update the Approval Criteria for the Targeted Immunomodulator Agents

Oklahoma Health Care Authority
November 2024

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

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

- **October 2023:** The FDA approved Velsipity™ (etrasimod) for the treatment of moderately to severely active ulcerative colitis (UC) in adults.
- **October 2023:** The FDA approved Bimzelx® (bimekizumab-bkzx) for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
- **October 2023:** The FDA approved Zymfentra™ (infliximab-dyyb) for the maintenance treatment of adults with moderately to severely active Crohn's disease (CD) or UC following treatment with an infliximab product administered intravenously (IV). Zymfentra™ is the first subcutaneous (sub-Q) formulation of infliximab and is available as a 120mg/mL single-dose prefilled pen or syringe. The recommended maintenance dosing in CD or UC is 120mg sub-Q once every 2 weeks starting at week 10 and thereafter. Patients must first complete an induction regimen with an IV infliximab product prior to switching to Zymfentra™. For patients who are already responding to a maintenance regimen of an IV infliximab product, the first sub-Q dose of Zymfentra™ may be administered in place of the next scheduled IV dose and every 2 weeks thereafter.
- **October 2023:** The FDA approved Omvoh™ (mirikizumab-mrkz) for the treatment of moderately to severely active UC in adults.

- **October 2023:** The FDA approved Wezlana™ (ustekinumab-auub) as an interchangeable biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **October 2023:** The FDA approved Cosentyx® (secukinumab) for a new indication for the treatment of adults with moderate to severe hidradenitis suppurativa.
- **November 2023:** The FDA approved an unbranded formulation of Humira® (adalimumab) through a supplemental Biologics License Application (sBLA).
- **February 2024:** The FDA approved Simlandi® (adalimumab-ryvk) as a new interchangeable biosimilar to Humira® (adalimumab) for the treatment of 9 different Humira® indications.
- **March 2024:** The FDA approved Tyenne® (tocilizumab-aazg) as a biosimilar to Actemra® (tocilizumab) for the treatment of 4 different Actemra® indications.
- **March 2024:** The FDA approved Spevigo® (spesolimab-sbzo) for an age expansion and expanded indication for the treatment of generalized pustular psoriasis (GPP) in adult and pediatric patients 12 years of age and older weighing at least 40kg. Additionally, the FDA approved a new sub-Q formulation of Spevigo®, available as a 150mg/mL single-dose prefilled syringe, intended for ongoing maintenance treatment of GPP when the patient is not experiencing a GPP flare. The recommended sub-Q dosing is a loading dose of 600mg [(4) 150mg injections] followed by 300mg [(2) 150mg injections] 4 weeks later and every 4 weeks thereafter. Previously, Spevigo® was only FDA approved for the treatment of GPP flares in adults and was only available as an IV formulation used during treatment of a GPP flare.
- **April 2024:** The FDA approved Selarsdi™ (ustekinumab-aekn) as a biosimilar to Stelara® (ustekinumab) for the treatment of 4 different Stelara® indications.
- **April 2024:** The FDA approved the sub-Q formulation of Entyvio® (vedolizumab) for a new indication for the maintenance treatment of moderate to severely active CD after at least 2 IV doses of vedolizumab. The sub-Q formulation is available as a 108mg/0.68mL prefilled syringe or pen and the recommended dosing is 108mg every 2 weeks.
- **April 2024:** The FDA approved Rinvoq® (upadacitinib) for an age expansion for pediatric patients 2 years of age and older with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to 1 or more tumor necrosis factor (TNF) blockers. Additionally, the FDA approved a new indication for Rinvoq® for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to 1 or more TNF blockers. Along with these approvals, Rinvoq® LQ (upadacitinib oral solution) was approved for use

in patients with these indications. Rinvoq® LQ is available as a 1mg/mL oral solution in a 180mL bottle.

- **April 2024:** The FDA approved Lupkynis® (voclosporin) for an updated label to include new efficacy and safety data supporting a longer duration of treatment beyond 1 year. Previously, the FDA approved labeling for Lupkynis® stated that the safety and efficacy of the medication had not been established beyond 1 year.
- **June 2024:** The FDA approved Pyzchiva® (ustekinumab-ttwe) as a biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **July 2024:** The FDA approved Leqselvi™ (deuruxolitinib) for the treatment of adults with severe alopecia areata.
- **September 2024:** The FDA approved Bimzelx® (bimekizumab-bkzx) for 3 new indications: treatment of adults with active PsA, treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and treatment of adults with active ankylosing spondylitis.
- **September 2024:** The FDA approved Otulfi™ (ustekinumab-aauz) as a biosimilar to Stelara® (ustekinumab) for the treatment of all 6 different Stelara® indications.
- **October 2024:** The FDA approved Bimzelx® (bimekizumab-bkzx) for new dosage formulations, including a 320mg/2mL prefilled autoinjector and a 320mg/2mL prefilled syringe.

News:

- **April 2024:** The National Psoriasis Foundation (NPF) published a new set of consensus statements regarding GPP. In consideration of the potential life-threatening nature of acute GPP flares, the NPF strongly advocates for timely access to FDA approved therapies for GPP and discourages relying solely on the European Rare and Severe Psoriasis Expert Network (ERASPEN) consensus definitions for diagnosing GPP prior to initiating treatment for GPP.
- **July 2024:** The Internation Psoriasis Council (IPC) published a new consensus definition and diagnostic criteria for GPP. Consensus was achieved through the modified Delphi method involving an international panel of 33 GPP experts, including representatives from the United States. The IPC advocates for timely access to treatment and allows for diagnosis of GPP at the time of the first flare. Based on expert consensus, the essential component of the new diagnostic criteria for GPP requires macroscopically visible sterile pustules on an erythematous base that is not restricted to the acral region or within psoriatic plaques. Additional clinical features which can support the diagnosis and which achieved consensus were: lakes of pus, painful skin, fatigue, fever, history of recurrent flares, positive personal or family

history of psoriasis, elevated C-reactive protein, leukocytosis, neutrophilia, abnormal laboratory tests (e.g., hypocalcemia, hypoproteinemia, hypoalbuminemia, abnormal liver or renal function), biopsy confirmation with the presence of spongiform pustules of Kogoj, or any positive genetic finding suggestive of GPP.

Bimzelx® (Bimekizumab-bkzx) Product Summary[22]

Therapeutic Class: Humanized interleukin (IL)-17A and F antagonist

Indication(s):
- Treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- Treatment of adults with active PsA
- Treatment of adults with active nr-axSpA with objective signs of inflammation
- Treatment of adults with active ankylosing spondylitis

How Supplied:
- 160mg/mL as a single-dose prefilled syringe or single-dose prefilled autoinjector
- 320mg/2mL as a single-dose prefilled syringe or single-dose prefilled autoinjector

Dosing and Administration:
- Plaque Psoriasis:
  - 320mg by sub-Q administration at weeks 0, 4, 8, 12, and 16, followed by 320mg every 8 weeks thereafter
  - For patients weighing ≥120kg, a dose of 320mg every 4 weeks should be considered after week 16
- PsA, Nr-axSpA, and Ankylosing Spondylitis:
  - 160mg by sub-Q administration every 4 weeks
  - Patients with PsA with coexisting moderate to severe plaque psoriasis should use the recommended dosage and administration for plaque psoriasis.

Efficacy: The efficacy of Bimzelx® was based primarily on 2 Phase 3, placebo-controlled studies (Trial-Ps-1 and Trial-Ps-2) for the plaque psoriasis indication, 2 Phase 3, placebo-controlled studies (Trial PsA-1 and Trial PsA-2) for the PsA indication, 1 Phase 3, placebo-controlled study (Trial nr-axSpA) for the nr-axSpA indication, and 1 Phase 3, placebo-controlled study (Trial AS-1) for the ankylosing spondylitis indication. These studies all enrolled adult patients 18 years of age or older.
- **Plaque Psoriasis Indication:**
  - Key Inclusion Criteria:
    - Psoriasis Area and Severity Index (PASI) score ≥12

        - Body surface area (BSA) involvement ≥10%
        - Investigator's Global Assessment (IGA) score ≥3 ("moderate")
    - Primary Endpoint(s):
        - Proportion of patients with an IGA score of 0 ("clear") or 1 ("almost clear") and at least a 2-grade improvement from baseline at week 16
        - Proportion of patients who achieve at least 90% reduction from baseline in PASI score (PASI 90) at week 16
    - Results:
        - IGA score of 0 or 1:
            - Trial-Ps-1: Achieved by 84% of patients who received bimekizumab vs. 5% of patients who received placebo [treatment difference: 79%; 95% confidence interval (CI): 73%, 85%]
            - Trial-Ps-2: Achieved by 93% of patients who received bimekizumab vs. 1% of patients who received placebo (treatment difference: 91%; 95% CI: 88%, 95%)
        - PASI 90:
            - Trial-Ps-1: Achieved by 85% of patients who received bimekizumab vs. 5% of patients who received placebo (treatment difference: 80%; 95% CI: 74%, 86%)
            - Trial-Ps-2: Achieved by 91% of patients who received bimekizumab vs. 1% of patients who received placebo (treatment difference: 90%; 95% CI: 86%, 93%)
- **PsA Indication:**
    - Key Inclusion Criteria:
        - Active PsA with baseline tender joint count ≥3 and swollen joint count ≥3
        - Trial PsA-1: No current or prior exposure to any biologics for the treatment of PsA or plaque psoriasis
        - Trial PsA-2: History of inadequate response or intolerance to treatment with 1 or 2 TNFα inhibitors
    - Primary Endpoint(s):
        - Proportion of patients achieving an American College of Rheumatology 50% (ACR50) response at week 16
    - Results:
        - ACR50 response:
            - Trial PsA-1: Achieved by 43.9% of patients who received bimekizumab vs. 10% of patients who received placebo (treatment difference: 33.9%; 95% CI: 28%, 39.7%)
            - Trial PsA-2: Achieved by 43.4% of patients who received bimekizumab vs. 6.8% of patients who received placebo (treatment difference: 36.7%; 95% CI: 29.4%, 44%)

- **Nr-axSpA Indication:**
  - Key Inclusion Criteria:
    - Active disease defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score ≥4 and spinal pain ≥4 on a 0-10 numerical rating scale (NRS)
    - Objective signs of inflammation with elevated C-reactive protein (CRP) and/or evidence of sacroiliitis on magnetic resonance imaging (MRI)
    - No definitive radiographic evidence of structural damage in the sacroiliac joints
    - History of failure to respond to 2 different nonsteroid anti-inflammatory drugs (NSAIDs) or intolerance or a contraindication to NSAID therapy
  - Primary Endpoint(s):
    - Proportion of patients achieving at least a 40% improvement in Assessment of Spondyloarthritis International Society score (ASAS40) at week 16
  - Results:
    - ASAS40:
      - Trial nr-axSpA-1: Achieved by 47.7% of patients who received bimekizumab vs. 21.4% of patients who received placebo (treatment difference: 26.2%; 95% CI: 15%, 37.5%)
- **Ankylosing Spondylitis Indication:**
  - Key Inclusion Criteria:
    - Documented radiologic (x-ray) evidence fulfilling the modified New York (mNY) criteria for ankylosing spondylitis
    - Moderate to severe active disease defined by BASDAI score ≥4 and spinal pain ≥4 on a 0-10 NRS
    - History of failure to respond to 2 different NSAIDs or intolerance or a contraindication to NSAID therapy
  - Primary Endpoint(s):
    - Proportion of patients achieving ASAS40 at week 16
  - Results:
    - ASAS40:
      - Trial AS-1: Achieved by 44.8% of patients who received bimekizumab vs. 22.5% of patients who received placebo (treatment difference: 22.3%; 95% CI: 12.1%, 32.4%)

Cost: The Wholesale Acquisition Cost (WAC) of Bimzelx® is $7,552.80 per milliliter, resulting in a cost of $15,105.60 per 320mg dose or $7,552.80 per 160mg dose. For a member with plaque psoriasis weighing <120kg, this would result in an estimated cost of $135,950.40 for the first year of treatment. For a member with plaque psoriasis weighing ≥120kg using 320mg every 4 weeks,

this would result in an estimated cost of $196,372.80 per year. For a member with PsA, nr-axSpA, or ankylosing spondylitis, the estimated cost would be $7,552.80 per 28 days or $98,186.40 per year based on recommended dosing.

Leqselvi™ (Deuruxolitinib) Product Summary[23]

Therapeutic Class: Janus kinase (JAK) inhibitor

Indication(s): Treatment of severe alopecia areata in adults

- **Limitation(s) of Use:** Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

How Supplied: 8mg oral tablet

Dosing and Administration: 8mg orally twice daily

Efficacy: The efficacy of Leqselvi™ was based primarily on 2 Phase 3, placebo-controlled studies (AA-1 and AA-2).

- Key Inclusion Criteria:
  - 18 years of age or older
  - At least 50% scalp hair loss, as defined by a Severity of Alopecia Tool (SALT) score ≥50
  - Current alopecia areata episode lasting at least 6 months and not exceeding 10 years
- Primary Endpoint(s):
  - Proportion of patients achieving at least 80% scalp hair coverage (a SALT score ≤20) at week 24
- Results:
  - SALT score ≤20:
    - AA-1: Achieved by 29% of patients who received deuruxolitinib vs. 1% of patients who received placebo (treatment difference: 28%; 95% CI: 23%, 33%)
    - AA-2: Achieved by 32% of patients who received deuruxolitinib vs. 1% of patients who received placebo (treatment difference: 31%; 95% CI: 25%, 37%)

Cost: The Wholesale Acquisition Cost (WAC) of Leqselvi™ is not yet available.

Omvoh™ (Mirikizumab-mrkz) Product Summary[24]

Therapeutic Class: IL-23 antagonist

Indication(s): Treatment of moderately-to-severely active UC in adults

How Supplied:

- 300mg/15mL solution in a single-dose vial for IV infusion

- 100mg/mL solution in a single-dose prefilled pen or syringe for sub-Q injection

Dosing and Administration:

- Induction Dosing: 300mg by IV infusion over at least 30 minutes at weeks 0, 4, and 8
- Maintenance Dosing: 200mg [(2) 100mg injections] sub-Q at week 12 and every 4 weeks thereafter

Efficacy: The efficacy of Omvoh™ was based primarily on 2 Phase 3, placebo-controlled studies (UC-1 and UC-2). UC-1 was a 12-week IV induction study and UC-2 was a 40-week sub-Q maintenance study.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Moderately to severely active UC
  - Inadequate response, loss of response, or intolerance to any of the following: corticosteroids, 6-mercaptopurine, azathioprine, biologic therapy (TNF blocker, vedolizumab), or tofacitinib
- Primary Endpoint(s):
  - Clinical remission, defined as a modified Mayo score (mMS) stool frequency subscore of 0 or 1, rectal bleeding score of 0, and centrally read endoscopy subscore of 0 or 1 (excluding friability) at week 12 (for UC-1) or week 40 (for UC-2)
- Results:
  - Clinical remission:
    - UC-1: Achieved by 24% of patients who received mirikizumab vs. 15% of patients who received placebo (treatment difference: 10%; 95% CI: 5%, 15%)
    - UC-2: Achieved by 51% of patients who received mirikizumab vs. 27% of patients who received placebo (treatment difference: 22%; 95% CI: 14%, 31%)

Cost: The Specialty Pharmaceutical Acquisition Cost (SPAC) of Omvoh™ is $694.86 per milliliter for the IV formulation and $3,474.30 per milliliter for the sub-Q formulation. This results in a cost of $10,422.90 per dose for the IV formulation and $6,948.60 per dose for the sub-Q formulation. This would result in an estimated cost of $100,754.70 for the first year of treatment.

Velsipity™ (Etrasimod) Product Summary[25]

Therapeutic Class: Sphingosine 1-phosphate (S1P) receptor modulator

Indication(s): Treatment of moderately-to-severely active UC in adults

How Supplied: 2mg oral tablet

Dosing and Administration: 2mg orally once daily

Efficacy: The efficacy of Velsipity™ was based primarily on 2 Phase 3, placebo-controlled studies (UC-1 and UC-2).

- Key Inclusion Criteria:
  - 16 years of age or older
  - Moderately to severely active UC
  - Inadequate response, loss of response, or intolerance to 1 or more of the following: oral aminosalicylates, corticosteroids, thiopurines, JAK inhibitors, biologic therapies (e.g., TNF blocker, anti-integrin, anti-IL 12/23).
- Primary Endpoint(s):
  - Clinical remission, defined as a mMS stool frequency subscore of 0 or 1, rectal bleeding score of 0, and centrally read endoscopy subscore of ≤1 (excluding friability) at weeks 12 and 52 (for UC-1) or at week 12 (for UC-2)
- Results:
  - Clinical remission at week 12:
    - UC-1: Achieved by 27% of patients who received etrasimod vs. 7% of patients who received placebo (treatment difference: 20%; 95% CI: 13%, 27%)
    - UC-2: Achieved by 26% of patients who received etrasimod vs. 15% of patients who received placebo (treatment difference: 11%; 95% CI: 3%, 20%)
  - Clinical remission at week 52:
    - UC-1: Achieved by 32% of patients who received etrasimod vs. 7% of patients who received placebo (treatment difference: 26%; 95% CI: 19%, 33%)

Cost: The WAC of Velsipity™ is $205.48 per tablet, resulting in an estimated cost of $6,164.40 per 30 days and $73,972.80 per year based on recommended dosing.

Recommendations

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

1. Adding topical corticosteroids as a Tier-1 option for appropriate indications (e.g., plaque psoriasis); and
2. Updating the Special Prior Authorization (PA) approval criteria for clarity to list all the required lower-tiered trials prior to Special PA Tier approval; and
3. Making Humira® (adalimumab) brand preferred; and

4. Moving Hadlima™ (adalimumab-bwwd) and Yusimry™ (adalimumab-aqvh) to Tier-2, and updating the adalimumab approval criteria based on net cost; and
5. Prior authorization and placement of Tyenne® (tocilizumab-aazg) into Tier-3, and updating the tocilizumab approval criteria based on net cost; and
6. Moving Sotyktu™ (deucravacitinib) from the Special PA Tier to Tier-3 based on net cost; and
7. Prior authorization and placement of Bimzelx® (bimekizumab-bkzx), Omvoh™ (mirikizumab-mrkz), Velsipity™ (etrasimod), and Zymfentra™ (infliximab-dyyb) into the Special PA Tier based on net cost; and
8. Moving Siliq® (brodalumab) from Tier-3 to the Special PA Tier based on net cost; and
9. Prior authorization and placement of Leqselvi™ (deuruxolitinib) into the Special PA Tier with additional approval criteria for the diagnosis of alopecia areata; and
10. Prior authorization and placement of Otulfi™ (ustekinumab-auz), Pyzchiva® (ustekinumab-ttwe), Selarsdi™ (ustekinumab-aekn), Simlandi® (adalimumab-ryvk), and Wezlana™ (ustekinumab-auub) into the Special PA Tier with additional criteria for use of a biosimilar product; and
11. Prior authorization and placement of Rinvoq® LQ (upadacitinib oral solution) into the Special PA Tier, based on net cost, with additional criteria for use of a special formulation; and
12. Adding new approval criteria for Cosentyx® (secukinumab) for the diagnosis of hidradenitis suppurativa; and
13. Updating the approval criteria for Entyvio® (vedolizumab) based on the recent FDA approval for CD and moving the sub-Q formulation of Entyvio® to the Special PA Tier based on net cost; and
14. Updating the approval criteria for Lupkynis® (voclosporin) and Spevigo® (spesolimab-sbzo) based on recent FDA approvals and expert consensus recommendations.

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
6-mercaptopurine	adalimumab (Humira®)+± **- Brand Preferred**	abatacept (Orencia®, Orencia® ClickJect™)¤	adalimumab-aacf (Idacio®)±
azathioprine	**adalimumab-aqvh (Yusimry™)+±**	~~**brodalumab (Siliq®)****~~	adalimumab-aaty (Yuflyma®)±
hydroxychloroquine	**adalimumab-bwwd (Hadlima™)+±**	certolizumab pegol (Cimzia®)	adalimumab-adaz (Hyrimoz®)±

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
leflunomide	anakinra (Kineret®)	**deucravacitinib (Sotyktu™)**	adalimumab-adbm (Cyltezo®)±
mesalamine	apremilast (Otezla®)ß	golimumab (Simponi®, Simponi Aria®)	adalimumab-afzb (Abrilada™)±
methotrexate	etanercept (Enbrel®)±	infliximab (Remicade®)±	~~**adalimumab-aqvh (Yusimry™)±**~~
minocycline	infliximab-dyyb (Inflectra®)±	infliximab-abda (Renflexis®)±	adalimumab-atto (Amjevita™)±
NSAIDs	rituximab (Rituxan®)~±	infliximab-axxq (Avsola®)±	~~**adalimumab-bwwd (Hadlima™)±**~~
oral corticosteroids	rituximab-abbs (Truxima®)±	sarilumab (Kevzara®)§	adalimumab-fkjp (Hulio®)±
sulfasalazine	rituximab-arrx (Riabni®)±	**tocilizumab-aazg (Tyenne®)±**	**adalimumab-ryvk (Simlandi®)±**
topical corticosteroids	rituximab-pvvr (Ruxience®)±	tofacitinib (Xeljanz®, Xeljanz® XR, Xeljanz® oral solution)**	anifrolumab-fnia (Saphnelo®)**
		vedolizumab **intravenous (IV)** (Entyvio®)**	avacopan (Tavneos®)**
			baricitinib (Olumiant®)€
			belimumab (Benlysta®)**
			bimekizumab-bkzx (Bimzelx®)
			brodalumab (Siliq®)**
			canakinumab (Ilaris®)¥
			~~**deucravacitinib (Sotyktu™)**~~
			deuruxolitinib (Leqselvi™)€
			etanercept-szzs (Erelzi®)±
			etanercept-ykro (Eticovo®)±
			etrasimod (Velsipity™)
			guselkumab (Tremfya®)
			infliximab-dyyb (Zymfentra®)±
			ixekizumab (Taltz®)
			mirikizumab-mrkz (Omvoh™)
			rilonacept (Arcalyst®)**
			risankizumab-rzaa (Skyrizi®)
			ritlecitinib (Litfulo™)€
			secukinumab (Cosentyx®)Δ

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
			spesolimab-sbzo (Spevigo®)**
			tildrakizumab-asmn (Ilumya®)
			tocilizumab (Actemra®)[π±]
			tocilizumab-bavi (Tofidence™)[±]
			upadacitinib (Rinvoq®, **Rinvoq® LQ**)[#]
			ustekinumab (Stelara®)[±]
			ustekinumab-aauz (Otulfi™)[±]
			ustekinumab-aekn (Selarsdi™)[±]
			ustekinumab-auub (Wezlana™)[±]
			ustekinumab-ttwe (Pyzchiva®)[±]
			vedolizumab subcutaneous (sub-Q) (Entyvio®)[**]
			voclosporin (Lupkynis®)**

DMARDs = disease modifying anti-rheumatic drugs; NSAIDs = nonsteroidal anti-inflammatory drugs
*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). Products may be moved to a higher tier based on net cost if the manufacturer chooses not to participate in supplemental rebates.
[±]Biosimilars or reference products preferred based on lowest net cost product. Authorization of higher net cost biosimilars or reference products requires a patient-specific, clinically significant reason why the member could not use the preferred formulation.
[+]Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS) and noninfectious intermediate and posterior uveitis and panuveitis.
[β]Unique criteria applies for a diagnosis of Behçet's disease (BD).
[¥]Unique criteria applies for a diagnosis of cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor-associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), familial Mediterranean fever (FMF), systemic juvenile idiopathic arthritis (SJIA), adult-onset Still's disease (AOSD), or gout flare.
~Unique criteria applies for a diagnosis of pemphigus vulgaris (PV). Unique criteria applies for a diagnosis of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA).
[π]Unique criteria applies for a diagnosis of giant cell arteritis (GCA), chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS), and systemic sclerosis-associated interstitial lung disease (SSc-ILD).
[¤]Unique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.
[#]Unique criteria applies for a diagnosis of atopic dermatitis (AD).
[€]Unique criteria applies for a diagnosis of alopecia areata.
[§]Unique criteria applies for a diagnosis of polymyalgia rheumatica (PMR).
[Δ]Unique criteria applies for a diagnosis of hidradenitis suppurativa (HS).
[**]Unique criteria applies to this medication for approval.

Targeted Immunomodulator Agents Special Prior Authorization (PA) Approval Criteria:

1. An FDA approved diagnosis; and
2. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
3. ~~A~~ Recent trials (within the last 360 days) of 1 Tier-1 medication (appropriate to the member's disease state), at least 2 Tier-2 medications (appropriate to the member's disease state), and 1 Tier-3 medication (appropriate to the member's disease state) that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Special PA medication documented within the last 100 days; or
5. A unique FDA-approved indication not covered by lower-tiered medications (unique approval criteria may apply).

Abrilada™ (Adalimumab-afzb), Amjevita™ (Adalimumab-atto), Cyltezo® (Adalimumab-adbm), ~~Hadlima™ (Adalimumab-bwwd)~~, Hulio® (Adalimumab-fkjp), Hyrimoz® (Adalimumab-adaz), Idacio® (Adalimumab-aacf), Simlandi® (Adalimumab-ryvk), Yuflyma® (Adalimumab-aaty), and ~~Yusimry™ (Adalimumab-aqvh)~~ Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry™ (adalimumab-aqvh) 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.

Actemra® (Tocilizumab) and Tofidence™ (Tocilizumab-bavi) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use ~~Actemra® (tocilizumab)~~ Tyenne® (tocilizumab-aazg) 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.

Actemra® (Tocilizumab), Tofidence™ (Tocilizumab-bavi), and Tyenne® (Tocilizumab-aazg) Approval Criteria [Giant Cell Arteritis (GCA) Diagnosis]:

1. An FDA approved diagnosis of GCA; and
2. Member must be 50 years of age or older; and
3. History of erythrocyte sedimentation rate (ESR) of ≥30mm/hr or a history of C-reactive protein (CRP) ≥1mg/dL; and
4. Member should have a trial of corticosteroids for a minimum of 4 weeks or a reason why this is not appropriate must be provided; and
5. ~~Actemra®~~ Must be taken in combination with a tapering course of corticosteroids upon initiation; and
6. Member must have baseline liver enzymes, absolute neutrophil count (ANC), lipid panel, and platelet count and verification that they are acceptable to prescriber; and
7. Member must not have severe hepatic impairment; and
8. ~~Actemra®~~ Should not be initiated in members with active or chronic infection including hepatitis B, hepatitis C, human immunodeficiency virus, or tuberculosis; and
9. Requests for Actemra® or Tofidence™ will require a patient-specific, clinically significant reason why the member cannot use Tyenne®. 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. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Cosentyx® (Secukinumab) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. A diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 5 abscesses or inflammatory nodules; and
4. Previous failure of at least 2 of the following categories:
    a. Topical or systemic antibiotics; or
    b. Oral or intralesional corticosteroids; or
    c. Dapsone; or
    d. Cyclosporine; or
    e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
    f. Finasteride; or
    g. Surgery; and
5. Previous failure of Hadlima™ (adalimumab-bwwd), Humira® (adalimumab), or Yusimry™ (adalimumab-aqvh) for at least 12 weeks at recommended dosing (or documented intolerance).

Entyvio® (Vedolizumab) Approval Criteria:

1. An FDA approved diagnosis of moderately-to-severely active Crohn's disease (CD) or moderately-to-severely active ulcerative colitis (UC); and
   ~~a. For intravenous (IV) administration: Moderately-to-severely active Crohn's disease (CD) or moderately-to-severely active ulcerative colitis (UC); or~~
   ~~b. For subcutaneous (sub-Q) administration: Moderately-to-severely active UC; and~~
2. Member must be 18 years of age or older; and
3. A minimum of a 4 week trial of a Tier-2 tumor necrosis factor (TNF) blocker indicated for the treatment of CD or UC that did not yield adequate relief of symptoms or resulted in intolerable adverse effects. Current Tier-2 medications include the following:
   a. CD: Humira® (adalimumab), Inflectra® (infliximab-dyyb); or
   b. UC: Humira® (adalimumab), Inflectra® (infliximab-dyyb); or
4. Prior stabilization on the medication documented within the last 100 days; and
5. For Entyvio® subcutaneous (sub-Q) administration, member must have received at least 2 initial intravenous (IV) doses of Entyvio®; and
   a. A patient-specific, clinically significant reason (beyond convenience) why the member cannot continue to use the IV formulation must be provided; and
6. A quantity limit of 300mg every 8 weeks will apply for the IV formulation and 108mg every 2 weeks will apply for the sub-Q formulation. Approvals will be granted for titration quantities required for initial dosing; and
7. Initial approvals will be for the duration of 14 weeks as Entyvio® should be discontinued in patients who do not show evidence of therapeutic benefit by week 14.

Hadlima™ (Adalimumab-bwwd), Humira® (Adalimumab), or Yusimry™ (Adalimumab-aqvh) Approval Criteria [Hidradenitis Suppurativa (HS) Diagnosis]:

1. Diagnosis of moderate-to-severe HS; and
2. Hurley Stage II or III disease; and
3. Member must have at least 3 abscesses or inflammatory nodules; and
4. Previous failure of at least 2 of the following categories:
   a. Topical or systemic antibiotics; or
   b. Oral or intralesional corticosteroids; or
   c. Dapsone; or
   d. Cyclosporine; or
   e. Antiandrogens (e.g., spironolactone, oral contraceptives); or
   f. Finasteride; or
   g. Surgery.

Hadlima™ (Adalimumab-bwwd), Humira® (Adalimumab), or Yusimry™ (Adalimumab-aqvh) Approval Criteria [Noninfectious Intermediate and Posterior Uveitis or Panuveitis Diagnosis]:

1. Diagnosis of noninfectious intermediate uveitis, posterior uveitis, or panuveitis in members 2 years of age and older; and
2. A failed trial with a corticosteroid injection or systemic corticosteroid in which member has had an inadequate response; or
3. A patient-specific, clinically significant reason why a trial of corticosteroid treatment is inappropriate for the member must be provided.

Leqselvi™ (Deuruxolitinib), Litfulo™ (Ritlecitinib), and Olumiant® (Baricitinib) Approval Criteria [Alopecia Areata Diagnosis]:

1. An FDA approved diagnosis of severe alopecia areata; and
2. For Litfulo™, member must be 12 to 20 years of age; or
3. For Leqselvi™ or Olumiant®, member must be 18 to 20 years of age; and
4. Prescriber must confirm the member or caregiver has been counseled regarding the covered age range for the requested product and that the medication will no longer be covered once the member turns 21 years of age; and
5. Member's baseline Severity of Alopecia Tool (SALT) score must be provided and must be ≥50; and
6. Must be prescribed by a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
7. Prescriber must agree to screen for tuberculosis and viral hepatitis prior to initiating treatment; and
8. ~~Prescriber must agree to evaluate lymphocyte and platelet counts at baseline, 4 weeks after initiation, and as clinically indicated thereafter; and~~
9. Prescriber must confirm that all baseline assessments and follow-up monitoring (e.g., laboratory assessment, infectious disease screening) will be performed as recommended in the package labeling for the requested product; and
10. Prescriber must provide documentation of patient-specific, clinically significant information (e.g., impacting member's mental health or ability to function in day-to-day living, reason why no treatment or cosmetic solutions are not appropriate) to demonstrate the medical necessity of this medication for this member; and
11. Member must have documented trials within the last 6 months that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance to all alternatives):
    a. Medium potency to very-high potency Tier-1 topical corticosteroid used for at least 12 weeks; or
    b. Oral corticosteroid used for at least 6 weeks; or

    c. Cyclosporine; or
    d. Methotrexate; or
    e. Contact immunotherapy (e.g., diphenylcyclopropenone, squaric acid dibutyl ester); and
12. Concurrent use with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants will not be approved; and
13. Prescriber must verify female members are not breastfeeding; and
14. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the pregnancy registry; and
15. Initial approvals will be for a duration of 24 weeks of treatment; and
16. Reauthorization may be considered if the prescriber documents the member is responding well to treatment as indicated by a reduction in the member's SALT score (current SALT score must be provided).

Lupkynis® (Voclosporin) Approval Criteria:

1. An FDA approved indication for the treatment of adults with active lupus nephritis (LN) in combination with a background immunosuppressive therapy regimen; and
    a. Lupkynis® must be used in combination with mycophenolate mofetil and low dose oral corticosteroids; and
2. Member must be 18 years of age or older; and
3. Lupkynis® must be prescribed by a nephrologist, rheumatologist, or other specialist with expertise in the treatment of LN; and
4. Member's current urine protein-to-creatinine ratio (UPCR) must be provided and must be ≥1.5mg/mg; and
5. Member's current estimated glomerular filtration rate (eGFR) must be provided and must be >45mL/min/1.73m^2 prior to initiating treatment with Lupkynis®; and
    a. Prescriber must agree to monitor renal function regularly during treatment with Lupkynis® and modify the dose as needed in accordance with the package labeling; and
6. Member's current blood pressure (BP) must be ≤165/105mmHg prior to initiating treatment with Lupkynis®; and
    a. Prescriber must agree to monitor BP regularly during treatment with Lupkynis® and agree to discontinue treatment if BP is >165/105mmHg or member experiences a hypertensive emergency; and
7. Member must not be taking strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) concomitantly with Lupkynis®; and

8. Prescriber must verify member has been counseled on proper administration of Lupkynis® including taking it on an empty stomach every 12 hours; and
9. Lupkynis® will not be approved in combination with biologic therapies or cyclophosphamide; and
10. A quantity limit of 180 capsules per 30 days will apply; and
11. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in the member's UPCR. If the member does not experience therapeutic benefit by 6 months, discontinuation of Lupkynis® should be considered.~~; and~~
12. ~~The safety and efficacy of Lupkynis® have not been established beyond 1 year of treatment. For continued authorization consideration after 1 year of treatment, a patient-specific, clinically significant reason why a longer treatment duration is appropriate for the member must be provided.~~

Otulfi™ (Ustekinumab-aauz), Pyzchiva® (Ustekinumab-ttwe), Selarsdi™ (Ustekinumab-aekn), and Wezlana™ (Ustekinumab-auub) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use Stelara® (ustekinumab) 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.

Rinvoq® LQ (Upadacitinib Oral Solution) Approval Criteria:

1. Member must meet Special Prior Authorization (PA) approval criteria; and
2. An age restriction of 2 years of age to 10 years of age will apply. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.

Siliq® (Brodalumab) Approval Criteria:

1. Member must meet ~~Tier 3~~ Special Prior Authorization (PA) approval criteria; and
2. Members must also be enrolled in the Siliq® Risk Evaluation and Mitigation Strategy (REMS) program for approval; and
3. Members with a concomitant diagnosis of Crohn's disease will not be approved; and

4. Initial authorizations of Siliq® (brodalumab) will be for the duration of 12 weeks at which time the prescriber must verify the member is responding to treatment. If an adequate response has not been achieved after 12 to 16 weeks of treatment with brodalumab, consideration should be given to discontinuing therapy.

Spevigo® (Spesolimab-sbzo) Approval Criteria [Intravenous (IV) Flare Dosing]:

1. An FDA approved indication for the treatment of generalized pustular psoriasis (GPP) flares ~~(GPP diagnosis should be verifiable in the member's diagnosis history)~~; and
2. Prescriber must verify ~~at least 1 of the following:~~ the member has presence of macroscopically visible sterile pustules on an erythematous base that is not restricted to the acral region or within psoriatic plaques; and
   ~~a. Member has experienced >1 flare (relapsing GPP); or~~
   ~~b. Member has symptoms persisting for >3 months (persistent GPP); and~~
3. Member must be currently experiencing a moderate-to-severe GPP flare meeting all the following criteria:
   a. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score must be provided and must be ≥3; and
   b. Presence of fresh pustules (new appearance or worsening of pustules); and
   c. GPPPGA pustulation sub-score must be provided and must be ≥2; and
   d. ≥5% of body surface area (BSA) covered with erythema and the presence of pustules; and
4. Member must be ~~21~~ 12 years of age or older; and
5. Must be prescribed by a dermatologist or other specialist with expertise in the treatment of GPP (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of GPP); and
6. Prescriber must submit documentation of negative tuberculosis (TB) test or initiation of anti-TB therapy for latent TB prior to initiation of therapy with Spevigo®; and
7. Prescriber must verify the member does not have any clinically significant active infections and the member will be monitored for active infections prior to each dose of Spevigo®; and
8. Approvals will be for 1 dose of Spevigo®. A second dose of Spevigo® may be approved 1 week after the first dose if the prescriber submits documentation that the member has been evaluated and continues to experience GPP flare symptoms; and

9. A quantity limit of 2 doses per year will apply (the safety and efficacy of additional doses of Spevigo® have not been assessed); and
    a. Requests for additional doses of Spevigo® to treat new GPP flares occurring within 1 year (after successful resolution of the previous flare) will be reviewed on a case-by-case basis and will require the prescriber to submit patient-specific, clinically significant information documenting the clinical necessity of additional treatment despite the lack of adequate safety and efficacy data; and
10. Subsequent requests for new GPP flares (after 1 year) will require the member to meet all initial approval criteria, and information regarding the member's response to previous treatment with Spevigo® must be submitted. Members who did not experience resolution of pustules after previous treatment will not be approved for additional use of Spevigo®.

Spevigo® (Spesolimab-sbzo) Approval Criteria [Subcutaneous (Sub-Q) Non-Flare Dosing]:

1. An FDA approved indication for the treatment of generalized pustular psoriasis (GPP); and
2. Prescriber must verify the member has presence of macroscopically visible sterile pustules on an erythematous base that is not restricted to the acral region or within psoriatic plaques; and
3. Member must be 12 years of age or older; and
4. Must be prescribed by a dermatologist or other specialist with expertise in the treatment of GPP (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of GPP); and
5. Prescriber must submit documentation of negative tuberculosis (TB) test or initiation of anti-TB therapy for latent TB prior to initiation of therapy with Spevigo®; and
6. Prescriber must verify the member does not have any clinically significant active infections and the member will be monitored for active infections during treatment with Spevigo®; and
7. Initial approvals will be for the duration of 6 months. Subsequent approvals (for the duration of 1 year) may be approved if the prescriber documents the member is responding well to the medication.

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Appendix E

Vote to Prior Authorize Rivfloza® (Nedosiran) and Update the Approval Criteria for the Hyperoxaluria Medications

Oklahoma Health Care Authority
November 2024

Market News and Updates[1]

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

- **October 2023:** The FDA approved Rivfloza® (nedosiran), a once monthly subcutaneous (sub-Q) injection, to lower urinary oxalate levels in adults and children 9 years of age and older with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function.

Rivfloza® (Nedosiran) Product Summary[2,3]

Therapeutic Class: Lactate dehydrogenase A (LDHA)-directed small interfering ribonucleic acid (siRNA)

Indication(s): To lower urinary oxalate levels in children 9 years of age and older and adults with PH1 and relatively preserved kidney function [e.g., estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2]

How Supplied: Rivfloza® is a 160mg/mL solution available as follows:

- 80mg (0.5mL) single dose vial (SDV)
- 128mg (0.8mL) single dose prefilled syringe
- 160mg (1mL) single dose prefilled syringe

Dosing and Administration: Administered as a sub-Q injection to the abdomen or upper thigh once monthly, with dosing based on age and actual body weight:

Age	Weight	Dosing Regimen
9 to 11 years of age	<50kg	3.3mg/kg, not to exceed 128mg, once monthly (0.5mL SDV)
	≥50kg	160mg once monthly (1mL prefilled syringe)
12 years of age and older	<50kg	128mg once monthly (0.8mL prefilled syringe)
	≥50kg	160mg once monthly (1mL prefilled syringe)

- SDVs are intended for use under the supervision of a health care professional. Caregivers for pediatric patients may administer vials after proper training or if a health care professional determines it is appropriate.

- In pediatric patients 9 to 11 years of age who weigh ≥50kg, a health care professional or caregiver may inject Rivfloza® using the 1mL prefilled syringe.

Efficacy: The safety and efficacy of Rivfloza® were studied in a multicenter, randomized, double-blind, placebo-controlled trial over a 6-month treatment period.

- Key Inclusion Criteria:
  - 6 years of age or older with PH1 or primary hyperoxaluria type 2 (PH2) and an eGFR ≥30mL/min/1.73m^2
  - 24-hour urinary oxalate excretion ≥0.7mmol/1.73m^2 collected during screening period
- Key Exclusion Criteria:
  - Prior renal or hepatic transplant
  - Plasma oxalate >30micromol/L
  - Documented evidence of clinical manifestation of systemic oxalosis
  - Currently on dialysis or anticipated requirement for dialysis during study period
  - Use of an RNA interference (RNAi) drug during the last 6 months
- Primary Endpoint(s):
  - The area under curve (AUC) from days 90 to 180 of the percent change from baseline in 24-hour urinary oxalate excretion
- Results:
  - Mean percent change from baseline in 24-hour urinary oxalate excretion was 35% in the nedosiran group and 12% in the placebo group
  - Too few patients with PH2 were enrolled to evaluate efficacy in the PH2 population

Cost Comparison:

Product	Cost Per mL	Cost Per Dose	Cost Per Year
Rivfloza® (nedosiran 160mg/mL)	**$62,880**	**$62,880***	**$754,560***
Oxlumo® (lumasiran 94.5mg/0.5mL)	$116,698	$175,047	$700,188⁺

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost is based on the FDA approved maximum dose of 160mg once monthly.
⁺Cost is based on the FDA approved maintenance dose of 3mg/kg every 3 months for a member weighing 80kg.

Recommendations

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

Rivfloza® (Nedosiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels. Diagnosis of PH1 must be confirmed by:
   a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene (results of genetic testing must be submitted); or
   b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic (results of liver biopsy must be submitted); and
2. Member must be 9 years of age or older; and
3. Rivfloza® must be prescribed by a geneticist, nephrologist, urologist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a geneticist, nephrologist, urologist, or other specialist with expertise in the treatment of PH1); and
4. Prescriber must verify the member has an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2 prior to starting Rivfloza® and must agree to monitor renal function regularly during treatment; and
5. Prescriber must confirm the member has not undergone a liver or kidney transplant; and
6. Member must not have evidence of systemic oxalosis; and
7. Prescriber must verify that Rivfloza® will be administered by a health care professional or, if appropriate, the member or caregiver have been trained on the subcutaneous administration and proper storage of Rivfloza®; and
8. Rivfloza® will not be approved for concomitant use with Oxlumo® (lumasiran); and
9. 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
10. 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 reduction in urinary oxalate excretion.

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

Oxlumo® (Lumasiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels. Diagnosis of PH1 must be confirmed by:

   a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene (results of genetic testing must be submitted); or
   b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic (results of liver biopsy must be submitted); and
2. Oxlumo® must be prescribed by a nephrologist, geneticist, urologist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a nephrologist, geneticist, urologist, or other specialist with expertise in the treatment of PH1); and
3. Member must not have a history of liver transplant; and
4. Prescriber must verify that Oxlumo® will be administered by a health care professional; and
5. For members 9 years of age or older, a patient-specific, clinically significant reason why the member cannot use Rivfloza® (nedosiran) must be provided; and
6. Oxlumo® will not be approved for concomitant use with Rivfloza® (nedosiran); 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 reduction in urinary oxalate excretion or plasma oxalate levels.

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[1] Novo Nordisk. FDA Approves Rivfloza™ for Children ≥9 Years Old and Adults Living with Primary Hyperoxaluria Type 1 (PH1), A Rare Genetic Condition. *PR Newswire.* Available online at: https://www.prnewswire.com/news-releases/fda-approves-rivfloza-for-children-9-years-old-and-adults-living-with-primary-hyperoxaluria-type-1-ph1-a-rare-genetic-condition-301944564.html. Last revised 10/02/2023. Last accessed 10/24/2024.

[2] Baum MA, Langman C, Cochat P, et al. PHYOX2: a Pivotal Randomized Study of Nedosiran in Primary Hyperoxaluria Type 1 or 2. *Kidney Int* 2023; 103(1):207-217. doi:10.1016/j.kint.2022.07.025.

[3] Rivfloza® (Nedosiran) Prescribing Information. NovoNordisk, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215842s000lbl.pdf. Last revised 09/2023. Last accessed 10/11/2024.

Appendix F

Vote to Prior Authorize Casgevy™ (Exagamglogene Autotemcel), Lyfgenia® (Lovotibeglogene Autotemcel), Vafseo® (Vadadustat), and Xromi® (Hydroxyurea Oral Solution) and Update the Approval Criteria for the Anemia Medications

Oklahoma Health Care Authority
November 2024

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

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

- **December 2023:** The FDA approved Casgevy™ (exagamglogene autotemcel) and Lyfgenia® (lovotibeglogene autotemcel) for the treatment of sickle cell disease (SCD) in patients 12 years of age or older. The 2 approvals represent the first cell-based gene therapies for the treatment of SCD. Casgevy™ is the first FDA approved therapy that will utilize the CRISPR/Cas9 technology. Lyfgenia® uses a lentiviral vector (LVV) for genetic modification. Both products are made from the patients' own stem cells, which are modified and given back as a one-time, single-dose infusion as part of a hematopoietic stem cell transplant (HSCT).
- **January 2024:** The FDA approved a new indication for Casgevy™ to treat patients 12 years of age and older with transfusion-dependent beta thalassemia (TDT). This approval follows the first FDA approved gene therapy for TDT, Zynteglo™ (betibeglogene autotemcel), which was FDA approved in August 2022.
- **March 2024:** Akebia Therapeutics announced the FDA approval of Vafseo® (vadadustat) oral tablets for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been on dialysis for at least 3 months.
- **April 2024:** The FDA approved Xromi® (hydroxyurea) oral solution to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients 6 months to younger than 2 years of age with sickle cell anemia with recurrent moderate to severe painful crises. Xromi® will be available in a 100mg/mL oral solution.
- **July 2024:** Ani Pharmaceuticals announced the FDA approval and launch of L-glutamine oral powder, a generic version of Endari®. L-glutamine was approved through an Abbreviated New Drug Application (ANDA).

News:

- **September 2024:** Pfizer announced the voluntary withdrawal of all lots of Oxbryta® (voxelotor) from the market and the discontinuation of all active voxelotor clinical trials and expanded access programs worldwide. The decision is based on clinical data that now indicates the overall benefits of Oxbryta® no longer outweigh the risks in the SCD population, as the data suggests an imbalance in vaso-occlusive crises (VOCs) and fatal events.

Casgevy™ (Exagamglogene Autotemcel) Product Summary[8]

Therapeutic Class: Autologous genome-edited hematopoietic stem cell (HSC)-based gene therapy

Indication(s): Treatment of patients 12 years of age or older with:

- SCD with recurrent VOCs; or
- TDT

How Supplied: A cell suspension for intravenous (IV) infusion

- Casgevy™ is supplied in 1 or more vials containing a frozen suspension of genome edited autologous CD34+ cells

Dosing and Administration:

- Patients are required to undergo HSC mobilization followed by apheresis to obtain CD34+ cells for Casgevy™ manufacturing.
- Dosing of Casgevy™ is based on body weight and the minimum recommended dose is 3×10^6 CD34+ cells/kg.
- Full myeloablative conditioning must be administered between 48 hours and 7 days before infusion of Casgevy™.
- Prophylaxis for seizures should be considered prior to initiating myeloablative conditioning.
- Patient's identity should be verified to match the unique patient identification information on the product labels and Lot Information Sheet prior to thaw and infusion.
- Casgevy™ should not be sampled, altered, or irradiated.
- Each vial of Casgevy™ should be administered via IV infusion within 20 minutes of thawing.

Mechanism of Action: After Casgevy™ infusion, the edited CD34+ cells engraft in the bone marrow and differentiate to erythroid lineage cells with reduced *BCL11A* gene expression. Reduced *BCL11A* gene expression results in an increase in γ-globin expression and fetal hemoglobin (HgbF) protein production in erythroid cells.

Efficacy: The safety and efficacy of Casgevy™ were evaluated in single-arm, open-label, multi-center trials for each indication in patients 12 to 35 years of

age. All eligible patients underwent mobilization and apheresis to collect CD34+ stem cells for the manufacturing of Casgevy™ followed by myeloablative conditioning and infusion of Casgevy™.

- **SCD Indication:**
  - Key Inclusion Criteria:
    - History of ≥2 protocol-defined severe VOC events during each of the 2 years prior to screening defined as: acute pain event requiring a visit to a medical facility and administration of pain medications or red blood cell (RBC) transfusions, acute chest syndrome, priapism lasting >2 hours and requiring a visit to a medical facility, or splenic sequestration
  - Key Exclusion Criteria:
    - Available 10/10 human leukocyte antigen (HLA)-matched related HSC donor
    - More than 10 unplanned hospitalizations or emergency department (ED) visits related to chronic pain rather than SCD-related acute pain crises in the year before screening
  - Intervention(s):
    - At the time of the interim analysis, a total of 63 patients enrolled in the trial, of which 58 (92%) patients started mobilization. A total of 44 (76%) patients received Casgevy™ infusion and formed the full analysis set (FAS).
  - Primary Endpoint(s):
    - Freedom from severe VOC episodes ≥12 consecutive months during the 24-month follow-up period (VF12)
    - Freedom from hospitalization for severe VOCs ≥12 consecutive months within the 24-month evaluation period (HF12)
  - Results:
    - The VF12 response rate was 29 of 31 patients [93.5%; 98% one-sided confidence interval (CI): 77.9%, 100.0%]. The 29 VF12 responders did not experience protocol-defined severe VOCs during the evaluation period with a median duration of 22.2 months at the time of the interim analysis.
    - One VF12 responder, after initially achieving a VF12 response, experienced an acute pain episode meeting the definition of a severe VOC at month 22.8 requiring a 5-day hospitalization; this patient was reported to have a parvovirus B19 infection at the time.
    - Of the 31 patients evaluable for VF12 response, 1 patient was not evaluable for HF12 response; the remaining 30 patients (100%; 98% one-sided CI: 87.8%, 100.0%) achieved the endpoint of HF12.

        - There were no reported cases of graft failure or graft rejection
- **<u>TDT Indication:</u>**
    - <u>Key Inclusion Criteria:</u>
        - History of requiring ≥100mL/kg/year or 10 units/year of RBC transfusions 2 years prior to enrollment
    - <u>Key Exclusion Criteria:</u>
        - Available 10/10 HLA-matched related donor
        - Prior allogeneic HSCT
    - <u>Intervention(s):</u>
        - At the time of the interim analysis, a total of 59 patients enrolled in the trial, of which 59 (100%) started mobilization. A total of 52 (88%) patients received Casgevy™ infusion and formed the FAS.
        - 35 patients from the FAS (67%) had adequate follow-up to allow evaluation of the primary efficacy endpoint and formed the primary efficacy set (PES).
    - <u>Primary Endpoint(s):</u>
        - Proportion of patients achieving transfusion independence for ≥12 consecutive months (TI12)
    - <u>Results:</u>
        - The TI12 responder rate was 32 of 35 patients (91.4%; 98.3% one-sided CI: 75.7%, 100%).
        - All patients who achieved TI12 remained transfusion-independent, with a median duration of transfusion-independence of 20.8 months and normal mean weighted average total hemoglobin (Hgb) levels.
        - The median time to last RBC transfusion for patients who achieved TI12 was 30 days following Casgevy™ infusion.
        - Three patients did not achieve TI12. These patients had reductions in annualized RBC transfusion volume requirements of 79.8%, 83.9%, and 97.9%, and reductions in annualized transfusion frequency of 78.6%, 67.4%, and 94.6%, respectively, compared to baseline requirements.
        - There were no reported cases of graft failure or graft rejection.

Cost: The Wholesale Acquistion Cost (WAC) of Casgevy™ is $2.2 million per 1-time treatment, regardless of indication.

Lyfgenia® (Lovotibeglogene Autotemcel) Product Summary[9]

Therapeutic Class: Autologous HSC-based gene therapy

Indication(s): Treatment of SCD and a history of vaso-occlusive events (VOEs) in patients 12 years of age or older

- **Limitation(s) of Use:** Following treatment with Lyfgenia®, patients with an α-thalassemia trait (-α3.7/-α3.7) may experience anemia with erythroid dysplasia that may require chronic RBC transfusions. Lyfgenia® has not been studied in patients with more than 2 α-globin gene deletions.

How Supplied: A cell suspension for IV infusion

- A single dose of Lyfgenia® contains a minimum of 3 x10^6 CD34+ cells/kg of body weight, in 1-4 infusion bags.

Dosing and Administration:

- Patients are required to undergo HSC mobilization followed by apheresis to obtain CD34+ cells for Lyfgenia® manufacturing.
- Dosing of Lyfgenia® is based on the number of CD34+ cells in the infusion bag(s) per kg of body weight. The minimum recommended dose is 3×10^6 CD34+ cells/kg.
- Myeloablative conditioning must be administered before infusion of Lyfgenia®. Following myeloablative conditioning, a minimum of 48 hours of washout before Lyfgenia® infusion should be allowed.
- Patient's identity should be verified to match the unique patient identification information on the Lyfgenia® infusion bag(s) prior to infusion.
- Lyfgenia® should not be sampled, altered, irradiated or refrozen.
- Lyfgenia® should be administered within 4 hours after thawing.

Mechanism of Action: Lyfgenia® adds functional copies of a modified β^A-globin gene into patients' HSCs through transduction of autologous CD34+ cells with BB305 LVV. After Lyfgenia® infusion, the transduced CD34+ HSCs engraft in the bone marrow and differentiate to produce RBCs containing biologically active β^A-T87Q-globin that will combine with α-globin to produce functional Hgb containing adult hemoglobin (HgbA).

Efficacy: The safety and efficacy of Lyfgenia® were evaluated in single-arm, 24-month, open-label, multi-center Phase 1/2 trial in patients 12 to 50 years of age.

- <u>Key Inclusion Criteria:</u>
  - Diagnosis of SCD with either βS/βS or βS/β0 or βS/β+ genotype
  - ≥4 severe VOEs in the 24 months prior to informed consent
  - Hydroxyurea failure or intolerance
- <u>Key Exclusion Criteria:</u>

    - Prior recipient of an allogeneic transplant or gene therapy
    - Unable to receive RBC transfusion
    - Availability of a willing, matched HLA–identical sibling hematopoietic cell donor
    - Presence of 2 α-globin gene deletions
- Intervention(s):
    - 43 patients underwent apheresis after mobilization with plerixafor, of which 36 patients received myeloablative busulfan conditioning.
    - 7 patients did not proceed to conditioning; 2 patients discontinued due to apheresis-related issues, and 5 discontinued at patient and/or physician discretion.
    - 36 patients received the IV infusion of Lyfgenia® with a median dose of $6.4x10^6$ CD34+ cells/kg (48 hours after the last dose of busulfan).
- Primary Endpoint(s):
    - VOE complete resolution between 6 months and 18 months after infusion
    - Severe VOE complete resolution between 6 months and 18 months after infusion
- Results:
    - VOE complete resolution was seen in 28 of 32 patients (88.2%; 95% CI: 71%, 97%).
    - Severe VOE complete resolution was seen in 30 of 32 patients (94%; 95% CI: 79%, 99%).
    - No patients experienced graft failure or graft rejection.
    - A median of 2 mobilization cycles were required in order to obtain an adequate cell count from apheresis.
    - All 36 patients infused in HGB-206 Group C were evaluated for globin response (GR). In Group C, 31 of 36 patients (86%) achieved GR. All patients maintained GR once it was achieved.

Cost: The WAC of Lyfgenia® is $3.1 million per 1-time treatment.

Vafseo® (Vadadustat) Product Summary[10]

Therapeutic Class: Hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor

Indication(s): Treatment of anemia due to CKD in adults who have been receiving dialysis for at least 3 months

- **Limitation(s) of Use:**
    - Not shown to improve quality of life, fatigue, or patient well-being
    - Not indicated for use:

- As a substitute for transfusion in patients requiring immediate correction of anemia
- In patients with anemia due to CKD not on dialysis

How Supplied: 150mg, 300mg, and 450mg tablets

Dosing and Administration:

- The recommended starting dose is 300mg orally once daily, with or without food.
- The maximum recommended dose is 600mg once daily.
- Hgb levels should be monitored when initiating or adjusting the dose and then monthly.
- The dose should be increased no more frequently than once every 4 weeks. Decreases in dose can occur more frequently.
- The dose should be adjusted in increments of 150mg to achieve or maintain Hgb levels of 10g/dL to 11g/dL.
- Refer to the full *Prescribing Information* for the recommended starting dose, titration, and monitoring recommendations.

Efficacy: The safety and efficacy of Vafseo® were studied in 2 Phase 3 randomized noninferiority open-label trials, INNO$_2$VATE-1 and INNO$_2$VATE-2. For INNO$_2$VATE-1 patients were included that had initiated dialysis <16 weeks prior to trial participation and were erythropoietin stimulating agent (ESA)-naïve, had limited ESA use, or were maintained on an ESA. For INNO$_2$VATE-2 patients were included who were on chronic maintenance dialysis for >12 weeks and who converted from prior ESA therapy.

- Key Inclusion Criteria:
  - 18 years of age or older
  - Serum ferritin ≥100ng/mL and transferrin saturations ≥20%
  - Hgb concentration between 8 and <11g/dL
- Key Exclusion Criteria:
  - Anemia due to causes other than CKD
  - Received RBC transfusion within 8 weeks prior to randomization
  - Uncontrolled hypertension or recent cardiovascular (CV) event
- Intervention(s):
  - Patients were randomized 1:1 to 1 of the following for 52 weeks:
    - Vafseo® 300mg once daily; and
      - Vafseo® was titrated in increments of 160mg up to 600mg to achieve the target Hgb range of 10-11g/dL.
    - Darbepoetin alfa as per the *Prescribing Information*
- Primary Endpoint(s):
  - Efficacy: Mean change in Hgb levels from baseline to weeks 24-36
    - A key secondary endpoint was the mean change in Hgb levels from baseline to weeks 40-52.

- Safety: Median time to the first major adverse CV event (MACE)

- Results:
  - Vafseo® was found to be noninferior in both trials to darbepoetin alfa with a treatment difference of -0.3 (95% CI: -0.5, -0.1) and -0.2 (95% CI: -0.2, -0.1) at weeks 24-36, and for weeks 40-52, the treatment difference was -0.1 (95% CI: -0.3, -0.2) and -0.2 (95% CI: -0.3, -0.1).

Cost Comparison: HIF PH Inhibitor Products

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
Vafseo® (vadadustat) 300mg tablet	**$42.60**	**$2,556.00***	**$30,672.00***
Jesduvroq® (daprodustat) 8mg tablet	$31.28	$2,815.20⁺	$33,782.40⁺

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Vafseo® cost is based on the maximum FDA approved dose of 600mg once daily.
⁺Jesduvroq® cost is based on the maximum FDA approved dose of 24mg once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Casgevy™ (exagamglogene autotemcel), Lyfgenia® (lovotibeglogene autotemcel), Vafseo® (vadadustat), and Xromi® (hydroxyurea solution) with the following criteria (shown in red):

Casgevy™ (Exagamglogene Autotemcel) Approval Criteria [Sickle Cell Disease (SCD) Diagnosis]:

1. An FDA approved diagnosis of SCD with recurrent vaso-occlusive crises (VOCs); and
2. Member must be 12 years of age or older; and
3. Member must have evidence of severe disease as demonstrated by ≥2 severe vaso-occlusive events (VOEs) per year in the last 2 years; and
4. Casgevy™ must be prescribed by a hematologist with expertise in the treatment of SCD and the administration of Casgevy™; and
5. Member has a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca); and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Lyfgenia™ (lovotibeglogene autotemcel); and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and

10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Casgevy™); and
11. Prescriber must verify the member has discontinued disease modifying therapies 8 weeks prior to mobilization and conditioning; and
12. Prescriber must verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization; and
13. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy™ administration; and
14. 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 Casgevy™; and
15. 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; and
16. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy™; and
17. Casgevy™ must be administered at a Casgevy™ authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy™ dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Casgevy™ (Exagamglogene Autotemcel) Approval Criteria [Transfusion-Dependent Beta Thalassemia (TDT) Diagnosis]:

1. An FDA approved diagnosis of TDT; and
2. Member must be 12 years of age or older; and
3. Member must require regular red blood cell (RBC) transfusions as demonstrated by the following:
    a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
    b. 10 units of packed RBCs per year in the last 2 years; and
4. Casgevy™ must be prescribed by a hematologist with expertise in the treatment of TDT and the administration of Casgevy™; and
5. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
6. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
7. Member must not have previously received treatment with Zynteglo™ (betibeglogene autotemcel); and

8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
9. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Casgevy™); and
10. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Casgevy™ administration; and
11. 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 Casgevy™; and
12. 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; and
13. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Casgevy™; and
14. Member will not be approved for treatment with Reblozyl® (luspatercept-aamt) following Casgevy™ infusion (current authorizations for luspatercept-aamt will be discontinued upon Casgevy™ approval); and
15. Casgevy™ must be administered at a Casgevy™ authorized treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Casgevy™ dose from receipt to storage to administration; and
16. Approvals will be for 1 dose per member per lifetime.

Lyfgenia® (Lovotibeglogene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of sickle cell disease (SCD) with a history of vaso-occlusive events (VOEs); and
2. Member must be 12 years of age or older; and
3. Member must have evidence of severe disease as demonstrated by ≥4 severe VOEs in the last 2 years; and
4. Member must not have >2 α-globin gene deletions; and
5. Lyfgenia® must be prescribed by a hematologist with expertise in the treatment of SCD and the administration of Lyfgenia®; and
6. Member has a trial with at least 1 pharmacological treatment option for SCD (i.e., hydroxyurea, L-glutamine, crizanlizumab-tmca); and
7. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
8. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and

9. Member must not have previously received treatment with Casgevy™ (exagamglogene autotemcel); and
10. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to package labeling; and
11. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Lyfgenia®); and
12. Prescriber must verify the member has discontinued disease modifying therapies 8 weeks prior to mobilization and conditioning; and
13. Prescriber must verify that granulocyte-colony stimulating factor (G-CSF) will not be used for the CD34+ HSC mobilization; and
14. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Lyfgenia® administration; and
15. 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 Lyfgenia®; and
16. 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; and
17. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Lyfgenia®; and
18. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Lyfgenia®, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
19. Lyfgenia® must be administered at a Lyfgenia® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Lyfgenia® dose from receipt to storage to administration; and
20. A patient-specific, clinically significant reason why the member cannot use Casgevy™ (exagamglogene autotemcel) must be provided; and
21. Approvals will be for 1 dose per member per lifetime.

Vafseo® (Vadadustat) Approval Criteria:

1. An FDA approved indication for the treatment of anemia due to chronic kidney disease (CKD) in adults; and
2. Member must currently be on dialysis and must have been receiving dialysis for ≥3 months; and
3. Prescriber must verify that member does not have uncontrolled hypertension; and

4. Prescriber must verify that member does not have an active malignancy; and
5. Prescriber must verify that liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to initiation of Vafseo® treatment, every month for the first 3 months of treatment, and periodically thereafter or as clinically indicated; and
6. Member's pre-treatment hemoglobin (Hgb) must be <11g/dL. Recent Hgb levels must be provided; and
7. Member must be hyporesponsive to an erythropoiesis-stimulating agent (ESA) (or have a contraindication to use), defined as:
    a. No increase in Hgb after 1 month of weight-based dosing; or
    b. 2 increases in ESA dose up to 50% more than previous dose to maintain current Hgb level; and
8. Prescriber must verify that member will not use Vafseo® concomitantly with an ESA or another hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor; and
9. Initial and subsequent approvals will be for the duration of 12 weeks of treatment. Subsequent approvals will be granted if the member meets 1 of the following:
    a. Member has achieved or maintained a clinically meaningful increase in Hgb of ≥1g/dL and the member's Hgb level is <12g/dL; or
    b. If the member has not achieved or maintained a clinically meaningful increase in Hgb of ≥1g/dL, then all of the following will be required:
        i. The dose will be increased as tolerated to a maximum of 600mg per day; and
        ii. The member has not received 600mg per day for >12 weeks without achieving a clinically meaningful increase in hemoglobin of ≥1g/dL; and
        iii. The member's Hgb is <12g/dL; and
10. Vafseo® should be discontinued in members who do not show evidence of a clinically meaningful increase in Hgb by 24 weeks.

Xromi® (Hydroxyurea Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of sickle cell anemia; and
2. Xromi® will not require a prior authorization for members 6 years of age and younger. For members 7 years of age and older, a patient-specific, clinically significant reason why the member cannot use hydroxyurea capsules or tablets must be provided; and
3. Member must have a history of moderate-to-severe, painful crises; and
4. Prescriber must agree to monitor blood counts every 2 weeks throughout therapy; and
5. Prescriber must agree to monitor the member for the development of secondary malignancies; and

6. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
7. Male and female members of reproductive potential must be willing to use effective contraception during and after treatment with Xromi® for at least 6 months after therapy; and
8. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Additionally, the College of Pharmacy recommends the following changes to the Reblozyl® (luspatercept-aamt) and Zynteglo™ (betibeglogene autotemcel) criteria based on the FDA approval of Casgevy™ (changes shown in red):

Reblozyl® (Luspatercept-aamt) Approval Criteria [Beta Thalassemia Diagnosis]:

1. An FDA approved indication for the treatment of adult members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must require regular RBC transfusions (no transfusion-free period >35 days during the prior 6 month period); and
3. Member must not have previously received treatment with Zynteglo™ (betibeglogene autotemcel) or Casgevy™ (exagamglogene autotemcel); and
4. Reblozyl® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of beta thalassemia (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating beta thalassemia); and
5. The prescriber must verify the member's hemoglobin will be monitored prior to each Reblozyl® administration; and
6. Prescriber must verify Reblozyl® will be administered by a trained health care provider; and
7. A recent (within the last 3 months) 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. Approval quantities will be dependent on member weight and every 3 week dosing in accordance with package labeling; and
9. Initial approvals will be for the duration of 4 months. Further approvals will not be granted if the member does not experience a decrease in transfusion burden after 9 weeks of treatment (administration of 3 doses) at the maximum dose of 1.25mg/kg (allows for initial dosing of 6 weeks at 1mg/kg). Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

Zynteglo™ (Betibeglogene Autotemcel) Approval Criteria:

1. An FDA approved indication for the treatment of adult and pediatric members with beta thalassemia who require regular red blood cell (RBC) transfusions; and
2. Member must be 4 years of age or older; and
3. Member must weigh ≥6kg; and
4. Member must require regular RBC transfusions as demonstrated by the following:
   a. History of ≥100mL/kg/year transfusions of packed RBCs in the last 2 years; or
   b. ≥8 transfusions of packed RBCs per year in the last 2 years; and
5. Zynteglo™ must be prescribed by a hematologist with expertise in the treatment of beta thalassemia and the administration of Zynteglo™; and
6. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
7. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
8. Member must not have previously received treatment with Casgevy™ (exagamglogene autotemcel) for the transfusion-dependent beta thalassemia (TDT) indication; and
9. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis; and
10. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Zynteglo™); and
11. Female members must not be pregnant and must have a negative pregnancy test prior to the start of mobilization, prior to conditioning procedures, and prior to Zynteglo™ administration; and
12. Male and female members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6months after administration of Zynteglo™; and
13. 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; and
14. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Zynteglo™; and
15. Member will not be approved for treatment with Reblozyl® (luspatercept-aamt) following Zynteglo™ infusion (current authorizations for luspatercept-aamt will be discontinued upon Zynteglo™ approval); and
16. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential)

performed at month 6 and month 12 after treatment with Zynteglo™, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
17. Zynteglo™ must be administered at a Zynteglo™ qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Zynteglo™ dose from receipt to storage to administration; and
18. Approvals will be for 1 dose per member per lifetime.

Next, the College of Pharmacy recommends the following changes to the Jesduvroq® (daprodustat) criteria based on the FDA approval of Vafseo® (vadadustat) (changes shown in red):

Jesduvroq® (Daprodustat) Approval Criteria:

1. An FDA approved indication for the treatment of anemia due to chronic kidney disease (CKD) in adults; and
2. Member must currently be on dialysis and must have been receiving dialysis for ≥4 months; and
3. Prescriber must verify that member does not have uncontrolled hypertension; and
4. Prescriber must verify that member does not have an active malignancy; and
5. Member must not be concurrently taking strong CYP2C8 inhibitors (i.e., gemfibrozil); and
6. Member's pre-treatment hemoglobin (Hgb) must be <11g/dL. Recent Hgb levels must be provided; and
7. Member must be hyporesponsive to an erythropoiesis-stimulating agent (ESA) (or have a contraindication to use), defined as:
    a. No increase in Hgb after 1 month of weight-based dosing; or
    b. 2 increases in ESA dose up to 50% more than previous dose to maintain current Hgb level; and
8. Prescriber must verify that member will not use Jesduvroq® concomitantly with an ESA or another hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor; and
9. Initial and subsequent approvals will be for the duration of 12 weeks of treatment. Subsequent approvals will granted if the member meets 1 of the following:
    a. Member has achieved or maintained a clinically meaningful increase in Hgb of ≥1g/dL and the member's Hgb level is <12g/dL; or
    b. If the member has not achieved or maintained a clinically meaningful increase in Hgb of ≥1g/dL, then all of the following will be required:
        i. The dose will be increased as tolerated to a maximum of 24mg per day; and

ii. The member has not received 24mg per day for >12 weeks without achieving a clinically meaningful increase in hemoglobin of ≥1g/dL; and
iii. The member's Hgb is <12g/dL; and

10. Jesduvroq® should be discontinued in members who do not show evidence of a clinically meaningful increase in Hgb by 24 weeks.

Next, the College of Pharmacy recommends the prior authorization of generic Endari® (L-glutamine) based on net costs with the following criteria (shown in red):

Endari® (L-Glutamine) Approval Criteria:

1. An FDA approved diagnosis of sickle cell disease (SCD); and
2. Member must be 5 years of age or older; and
3. A trial of hydroxyurea or documentation why hydroxyurea is not appropriate for the member must be provided; and
4. Endari® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of SCD (or in consultation with an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating SCD); and
5. Endari® (L-glutamine) is brand preferred. Use of generic L-glutamine will require a patient specific, clinically significant reason why the member cannot use the brand formulation; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
7. Initial approvals will be for a duration of 6months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment

Finally, the College of Pharmacy recommends removal of SoonerCare coverage and of the prior authorization criteria for Oxbryta® (voxelotor) based on the withdrawal of the medication from the market (changes noted in red):

~~**Oxbryta® (Voxelotor) Approval Criteria:**~~

~~1. An FDA approved indication for the treatment of sickle cell disease (SCD) in members 4 years of age and older; and~~
~~2. Member must have baseline hemoglobin ≤10.5g/dL; and~~
~~3. Oxbryta® must be prescribed by, or in consultation with, a hematologist or a specialist with expertise in treatment of SCD (or an advanced care practitioner with a supervising physician who is a hematologist or specialist with expertise in treating SCD); and~~
~~4. Member must not be taking concomitant strong or moderate CYP3A4 inducers (e.g., rifampin) or the prescriber must verify the dose of~~

~~Oxbryta® will be adjusted during concomitant use according to package labeling; and~~

5. ~~Prescriber must verify that the dose of Oxbryta® will be reduced in accordance with package labeling for members with severe hepatic impairment; and~~
6. ~~For members younger than 12 years of age, the member's recent weight (kg)must be provided on the prior authorization request to ensure accurate dosing in accordance with package labeling; and~~
7. ~~Oxbryta® tablets for oral suspension will have an age restriction of 4 to 10 years of age; and~~
    a. ~~Members older than 10 years of age requesting Oxbryta® tablets for oral suspension will require a patient-specific, clinically significant reason why the member cannot use Oxbryta® oral tablets; and~~
8. ~~The following quantity limits will apply:~~
    a. ~~(3) 500mg tablets per day; and~~
    b. ~~(5) 300mg tablets for oral suspension per day; and~~
9. ~~Initial approvals will be for the duration of 6months. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.~~

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Appendix G

Fiscal Year 2024 Annual Review of Multiple Myeloma Medications

Oklahoma Health Care Authority
November 2024

Current Prior Authorization Criteria

Abecma® (Idecabtagene Vicleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥4 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody; and
        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma; and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

Carvykti® (Ciltacabtagene Autoleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ≥4 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody; and

        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and
    c. Member must not have any central nervous system involvement with multiple myeloma; and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Light Chain Amyloidosis Diagnosis]:

1. Relapsed/refractory light chain amyloidosis as a single agent; or
2. Newly diagnosed light chain amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone.

Darzalex® (Daratumumab) and Darzalex Faspro® (Daratumumab/ Hyaluronidase-fihj) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
2. Used in 1 of the following settings:
    a. In combination with lenalidomide and dexamethasone as primary therapy in members who are ineligible for autologous stem cell transplant (ASCT) or in members who have received at least 1 prior therapy; or
    b. In combination with bortezomib, melphalan, and prednisone as primary therapy in members who are ineligible for ASCT; or
    c. In combination with bortezomib, thalidomide, and dexamethasone or bortezomib, lenalidomide, and dexamethasone as primary therapy in members who are eligible for ASCT; or
    d. After at least 1 prior therapy, in combination with 1 of the following:
        i. Dexamethasone and bortezomib; or

ii. Carfilzomib and dexamethasone; or
iii. Dexamethasone and lenalidomide; or
iv. Cyclophosphamide, bortezomib, and dexamethasone; or
v. Pomalidomide and dexamethasone* [*previous therapy for this combination must include lenalidomide and a proteasome inhibitor (PI)]; or
vi. Selinexor and dexamethasone; or

e. In combination with lenalidomide and dexamethasone for members who are ineligible for ASCT or with cyclophosphamide, bortezomib, and dexamethasone as primary therapy or for disease relapse after 6 months following primary induction therapy with the same regimen; or
f. As a single-agent in members who have received ≥3 prior therapies, including a PI and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.

Elrexfio™ (Elranatamab-bcmm) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member has received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; and
3. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Empliciti® (Elotuzumab) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of previously treated multiple myeloma with relapsed or progressive disease; and
2. Used in combination with 1 of the following regimens:
   a. Lenalidomide and dexamethasone in members who have received 1 to 3 prior therapies; or
   b. Bortezomib and dexamethasone; or
   c. Pomalidomide and dexamethasone in members who have received ≥2 prior therapies, including an immunomodulatory agent and a proteasome inhibitor (PI).

Hemady® (Dexamethasone 20mg Tablet) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use dexamethasone 4mg tablets to achieve the required dose in place of Hemady® must be provided.

Ninlaro® (Ixazomib) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of symptomatic multiple myeloma; and
2. Used in 1 of the following settings:
    a. As primary therapy; or
    b. Following disease relapse after 6 months following primary induction therapy with the same regimen, used in combination with 1 of the following regimens:
        i. Lenalidomide and dexamethasone; or
        ii. Cyclophosphamide and dexamethasone for transplant candidates only; or
        iii. Pomalidomide and dexamethasone if member has failed ≥2 prior therapies and demonstrated disease progression within 60 days; or
    c. As a single-agent for the maintenance treatment of disease.

Sarclisa® (Isatuximab-irfc) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
2. Used in 1 of the following settings:
    a. Used in combination with pomalidomide and dexamethasone after ≥2 prior therapies [previous treatment must have included lenalidomide and a proteasome inhibitor (PI)]; or
    b. Used in combination with carfilzomib and dexamethasone after 1 to 3 prior therapies.

Talvey® (Talquetamab-tgvs) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member has received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody; and
3. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Tecvayli® (Teclistamab-cqyv) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma; and
2. Member has received ≥4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody; and
3. Health care facilities must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements.

Xpovio® (Selinexor) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. Diagnosis of relapsed/refractory DLBCL, not otherwise specified, including DLBCL arising from follicular lymphoma; and
2. Member has received ≥2 prior lines of systemic therapy.

Xpovio® (Selinexor) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
2. Used in 1 of the following settings:
    a. In combination with dexamethasone in members who have received ≥4 prior therapies including refractory disease to ≥2 proteasome inhibitors (PIs), ≥2 immunomodulatory agents, and an anti-CD38 monoclonal antibody; or
    b. Used in combination with bortezomib and dexamethasone in members who have failed at least 1 prior therapy.

Oncology Medications Additional Criteria:

1. Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and
    a. Unless otherwise specified in a medication's approval criteria, continuation requests will be approved for the duration of 6 months if there is no evidence of disease progression or adverse drug reactions; and
2. The following situations require the request to be reviewed by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician:
    a. Any request for an oncology medication which does not meet approval criteria; or
    b. Any continuation request if the member has evidence of disease progression or adverse drug reactions while on the requested medication; or
    c. Any level-1 appeal request for an oncology medication; or
    d. Any peer-to-peer request for an oncology medication.

Utilization of Multiple Myeloma 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	4	15	$177,311.05	$11,820.74	$422.17	45	420
2023 Total	**4**	**15**	**$177,311.05**	**$11,820.74**	**$422.17**	**45**	**420**
Fiscal Year 2024							
FFS	3	6	$73,496.46	$12,249.41	$437.48	18	168
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**3**	**6**	**$73,496.46**	**$12,249.41**	**$437.48**	**18**	**168**
% Change	**-25.0%**	**-60.0%**	**-58.5%**	**3.6%**	**3.6%**	**-60.0%**	**-60.0%**
Change	**-1**	**-9**	**-$103,814.59**	**$428.67**	**$15.31**	**-27**	**-252**

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	28	227	$2,213,181.10	$9,749.70	8.11
2023 Total	**28**	**227**	**$2,213,181.10**	**$9,749.70**	**8.11**
Fiscal Year 2024					
FFS	32	228	$2,011,924.80	$8,824.23	7.13
Aetna	0	0	$0.00	$0.00	0
Humana	2	2	$17,613.00	$8,806.50	1
OCH	3	5	$44,055.00	$8,811.00	1.67
2024 Total	**33**	**235**	**$2,073,412.80**	**$8,823.03**	**7.12**
% Change	**17.86%**	**3.52%**	**-6.32%**	**-9.50%**	**-12.21%**
Change	**5**	**8**	**-$139,768.30**	**-$926.67**	**-0.99**

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

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

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

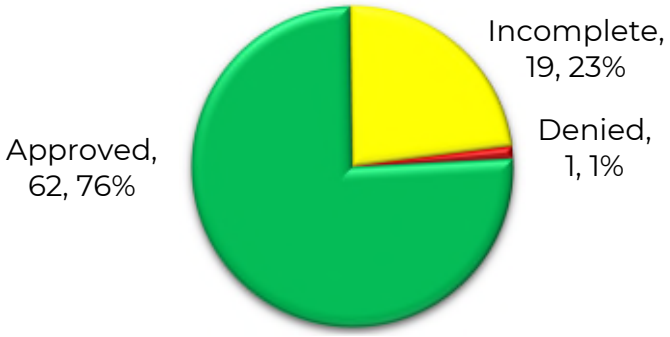
Top Prescriber Specialties of Multiple Myeloma Medications by Number of Claims: Pharmacy Claims (All Plans)

- The only prescriber specialty listed on paid pharmacy claims for multiple myeloma medications during fiscal year 2024 was hematology/oncology.

Prior Authorization of Multiple Myeloma Medications

There were 82 prior authorization requests submitted for multiple myeloma 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	56	74%	19	25%	1	1%	**76**
Aetna	0	0%	0	0%	0	0%	**0**
Humana	6	100%	0	0%	0	0%	**6**
OCH	0	0%	0	0%	0	0%	**0**
Total	**62**	**76%**	**19**	**23%**	**1**	**1%**	**82**

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]

Anticipated Patent Expiration(s):

- Ninlaro® (ixazomib): November 2029
- Xpovio® (selinexor): August 2035
- Hemady® (dexamethasone): December 2037

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

- **April 2024:** The FDA approved Abecma® (idecabtagene vicleucel) for an updated indication for the treatment of adult patients with relapsed or refractory multiple myeloma after 2 or more prior lines of therapy

including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

- **April 2024:** The FDA approved Carvykti® (ciltacabtagene autoleucel) for an updated indication for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and who are refractory to lenalidomide.
- **July 2024:** The FDA approved Darzalex Faspro® (daratumumab/hyaluronidase-fihj) for a new indication, in combination with bortezomib, lenalidomide, and dexamethasone, for induction and consolidation in patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT).
- **September 2024:** The FDA approved Sarclisa® (isatuximab-irfc) for a new indication, in combination with bortezomib, lenalidomide, and dexamethasone, for adults with newly diagnosed multiple myeloma who are not eligible for ASCT.

Recommendations

The College of Pharmacy recommends updating the approval criteria for Abecma® (idecabtagene vicleucel), Carvykti® (ciltacabtagene autoleucel), and Sarclisa® (isatuximab-irfc) based on recent FDA approvals (changes shown in red):

Abecma® (Idecabtagene Vicleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
    a. Member has received ~~≥4~~ ≥2 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody; and
        i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and
        ii. Must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
    b. Member must have measurable disease, including at least 1 of the following:
        i. Serum M-protein ≥0.5g/dL; or
        ii. Urine M-protein ≥200mg/24hr; or
        iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
        iv. Bone marrow plasma cells >30% of total bone marrow cells; and

c. Member must not have any central nervous system involvement with multiple myeloma; and

2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

Carvykti® (Ciltacabtagene Autoleucel) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM):
   ~~a. Member has received ≥4 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody; and~~
      ~~i. Induction with or without autologous hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen; and~~
      ~~ii. Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and~~
   b. Member has received ≥1 prior line of therapy, including an immunomodulatory agent and a proteasome inhibitor; and
      i. Member must be refractory to lenalidomide; and
      ii. Member must have undergone ≥2 consecutive cycles of treatment for each regimen unless progressive disease was seen after 1 cycle; and
   c. Member must have measurable disease, including at least 1 of the following:
      i. Serum M-protein ≥0.5g/dL; or
      ii. Urine M-protein ≥200mg/24hr; or
      iii. Serum free light chain (FLC) assay: involved FLC ≥10mg/dL (100mg/L); or
      iv. Bone marrow plasma cells >30% of total bone marrow cells; and
   d. Member must not have any central nervous system involvement with multiple myeloma; and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

Sarclisa® (Isatuximab-irfc) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of multiple myeloma; and
   a. Used in the first line setting; and
   b. Used in combination with bortezomib, lenalidomide, and dexamethasone; and
   c. Member is considered ineligible for autologous stem cell transplantation; or
2. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
   a. Used in 1 of the following settings:
      i. Used in combination with pomalidomide and dexamethasone after ≥2 prior therapies [previous treatment must have included lenalidomide and a proteasome inhibitor (PI)]; or
      ii. Used in combination with carfilzomib and dexamethasone after 1 to 3 prior therapies.

Utilization Details of Multiple Myeloma Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IXAZOMIB PRODUCTS						
NINLARO CAP 4MG	3	2	$36,750.23	$12,250.08	1.5	50.00%
NINLARO CAP 3MG	3	1	$36,746.23	$12,248.74	3	50.00%
TOTAL	**6**	**3***	**$73,496.46**	**$12,249.41**	**2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Fee-For-Service Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9144 DARATUM/HYALURON INJ	220	31	$1,942,662.60	$8,830.28	7.1
J9145 DARATUMUMAB INJ	8	1	$69,262.20	$8,657.78	8
TOTAL	**228**	**32**	**$2,011,924.80**	**$8,824.23**	**7.13**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated members.
DARATUM/HYALURON = daratumumab/hyaluronidase; INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Humana Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9144 DARATUM/HYALURON INJ	2	2	$17,613.00	$8,806.50	1
TOTAL	**2**	**2**	**$17,613.00**	**$8,806.50**	**1**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated members.
DARATUM/HYALURON = daratumumab/hyaluronidase; 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.

OK Complete Health Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9144 DARATUM/HYALURON INJ	5	3	$44,055.00	$8,811.00	1.67
TOTAL	**5**	**3**	**$44,055.00**	**$8,811.00**	**1.67**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated members.
DARATUM/HYALURON = daratumumab/hyaluronidase; 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 10/2024. Last accessed 10/10/2024.

[2] Bristol Myers Squibb. U.S. FDA Approves Bristol Myers Squibb and 2seventy Bio's Abecma® for Triple-Class Exposed Relapsed or Refractory Multiple Myeloma After Two Prior Lines of Therapy. Available online at: https://news.bms.com/news/details/2024/U.S.-FDA-Approves-Bristol-Myers-Squibb-and-2seventy-bios-Abecma-for-Triple-Class-Exposed-Relapsed-or-Refractory-Multiple-Myeloma-After-Two-Prior-Lines-of-Therapy/default.aspx. Issued 04/05/2024. Last accessed 10/10/2024.

[3] Johnson & Johnson. Carvykti® is the First and Only BCMA-Targeted Treatment Approved by the U.S. FDA for Patients with Relapsed or Refractory Multiple Myeloma Who Have Received At Least One Prior Line of Therapy. Available online at: https://www.jnj.com/media-center/press-releases/carvykti-is-the-first-and-only-bcma-targeted-treatment-approved-by-the-u-s-fda-for-patients-with-relapsed-or-refractory-multiple-myeloma-who-have-received-at-least-one-prior-line-of-therapy. Issued 04/06/2024. Last accessed 10/10/2024.

[4] U.S. FDA. FDA Approves Daratumumab and Hyaluronidase-fihj with Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-daratumumab-and-hyaluronidase-fihj-bortezomib-lenalidomide-and-dexamethasone-multiple. Issued 07/30/2024. Last accessed 10/10/2024.

[5] U.S. FDA. FDA Approves Isatuximab-irfc with Bortezomib, Lenalidomide, and Dexamethasone for Newly Diagnosed Multiple Myeloma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-isatuximab-irfc-bortezomib-lenalidomide-and-dexamethasone-newly-diagnosed-multiple. Issued 09/20/2024. Last accessed 10/10/2024.

Appendix H

Fiscal Year 2024 Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications

Oklahoma Health Care Authority
November 2024

Current Prior Authorization Criteria

Firdapse® (Amifampridine) Approval Criteria:

1. An FDA approved diagnosis of Lambert-Eaton myasthenic syndrome (LEMS); and
2. LEMS diagnosis must be confirmed by 1 of the following:
    a. A high titer anti-P/Q-type voltage-gated calcium channel (VGCC) antibody assay; or
    b. A confirmatory electrodiagnostic study [e.g., repetitive nerve stimulation (RNS), needle electromyography (EMG), single-fiber electromyography (SFEMG)]; and
3. The requested medication must be prescribed by, or in consultation with, a neurologist or oncologist; and
4. Member must not have a history of seizures or be taking medications that lower the seizure threshold (e.g., bupropion, tramadol, amphetamines, theophylline); and
5. A quantity limit of 240 tablets per 30 days will apply; and
6. Initial approvals will be for 6 months. Continued authorization will require the prescriber to indicate that the member is responding well to treatment and continues to require treatment with the requested medication.

Utilization of LEMS Medications: Fiscal Year 2024

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

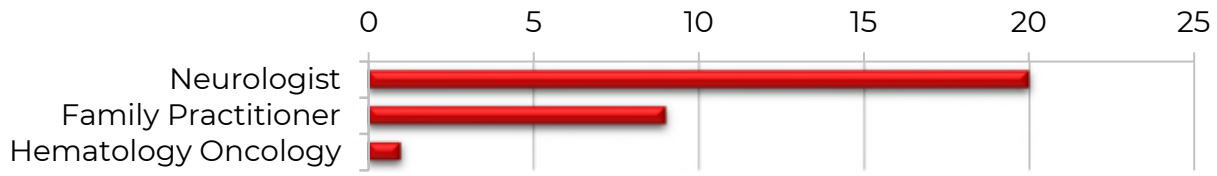
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	2	21	$785,924.96	$37,425.00	$1,247.50	3,684	630
2023 Total	**2**	**21**	**$785,924.96**	**$37,425.00**	**$1,247.50**	**3,684**	**630**
Fiscal Year 2024							
FFS	3	26	$983,966.32	$37,844.86	$1,261.50	4,380	780
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	1	2	$55,652.42	$27,826.21	$927.54	240	60
OCH	1	2	$83,467.22	$41,733.61	$1,391.12	360	60
2024 Total	**3**	**30**	**$1,123,085.96**	**$37,436.20**	**$1,247.87**	**4,980**	**900**
% Change	**50.00%**	**42.90%**	**42.90%**	**0.00%**	**0.00%**	**35.20%**	**42.90%**
Change	**1**	**9**	**$337,161.00**	**$11.20**	**$0.37**	**1,296**	**270**

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 LEMS Medications

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

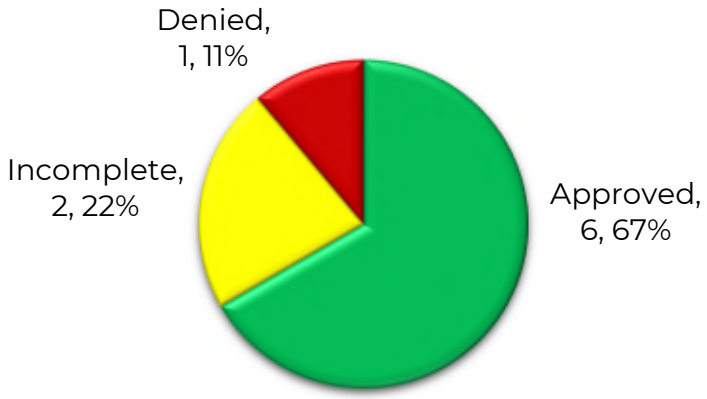
Top Prescriber Specialties of LEMS Medications by Number of Claims (All Plans)



Prior Authorization of LEMS Medications

There were 9 prior authorization requests submitted for Firdapse® (amifampridine) 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	2	50%	2	50%	0	0%	**4**
Aetna	0	0%	0	0%	0	0%	**0**
Humana	3	100%	0	0%	0	0%	**3**
OCH	1	50%	0	0%	1	50%	**2**
Total	**6**	**67%**	**2**	**22%**	**1**	**11%**	**9**

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 and/or Exclusivity Expiration(s):

- Firdapse® (amifampridine): February 2037

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

- **May 2024:** The FDA approved Firdapse® (amifampridine) for an updated label, increasing the maximum daily dose from 80mg per day to 100mg per day for adults and pediatric patients weighing ≥45kg. Firdapse® is administered orally in 3 to 4 divided doses daily and is available as a 10mg oral tablet.

Recommendations

The College of Pharmacy recommends updating the Firdapse® (amifampridine) approval criteria to be consistent with the recent FDA approval to increase the maximum daily dose (changes shown in red):

Firdapse® (Amifampridine) Approval Criteria:

1. An FDA approved diagnosis of Lambert-Eaton myasthenic syndrome (LEMS); and
2. LEMS diagnosis must be confirmed by 1 of the following:
   a. A high titer anti-P/Q-type voltage-gated calcium channel (VGCC) antibody assay; or
   b. A confirmatory electrodiagnostic study [e.g., repetitive nerve stimulation (RNS), needle electromyography (EMG), single-fiber electromyography (SFEMG)]; and
3. The requested medication must be prescribed by, or in consultation with, a neurologist or oncologist; and
4. Member must not have a history of seizures or be taking medications that lower the seizure threshold (e.g., bupropion, tramadol, amphetamines, theophylline); and
5. A quantity limit of ~~240~~ 300 tablets per 30 days will apply; and
6. Initial approvals will be for 6 months. Continued authorization will require the prescriber to indicate that the member is responding well to treatment and continues to require treatment with the requested medication.

Utilization Details of LEMS Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMIFAMPRIDINE PRODUCTS						
FIRDAPSE TAB 10MG	26	3	$983,966.32	$37,844.86	8.67	100%
TOTAL	**26**	**3***	**$983,966.32**	**$37,844.86**	**8.67**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMIFAMPRIDINE PRODUCTS						
FIRDAPSE TAB 10MG	2	1	$55,652.42	$27,826.21	2	100%
TOTAL	**2**	**1***	**$55,652.42**	**$27,826.21**	**2**	**100%**

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

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AMIFAMPRIDINE PRODUCTS						
FIRDAPSE TAB 10MG	2	1	$83,467.22	$41,733.61	2	100%
TOTAL	**2**	**1***	**$83,467.22**	**$41,733.61**	**2**	**100%**

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

[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.cf. Last revised 11/2024. Last accessed 11/01/2024.
[2] Catalyst Pharmaceuticals, Inc. Catalyst Pharmaceuticals Receives U.S. FDA Approval for Increased Maximum Daily Dose for Firdapse®. Available online at: https://ir.catalystpharma.com/news-releases/news-release-details/catalyst-pharmaceuticals-receives-us-fda-approval-increased. Issued 05/30/2024. Last accessed 11/01/2024.
[3] Firdapse® (Amifampridine) Prescribing Information. Catalyst Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/208078s012lbl.pdf. Last revised 05/2024. Last accessed 11/04/2024.

Appendix I

Fiscal Year 2024 Annual Review of Hereditary Angioedema (HAE) Medications

Oklahoma Health Care Authority
November 2024

Current Prior Authorization Criteria

Berinert® (C1 Esterase Inhibitor), Firazyr® (Icatibant), Kalbitor® (Ecallantide), and Ruconest® (C1 Esterase Inhibitor) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for the treatment of acute attacks of HAE; and
3. For authorization consideration of Firazyr® (icatibant) or Kalbitor® (ecallantide), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor) must be provided; or
4. For authorization consideration of Ruconest® (C1 esterase inhibitor), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor), Firazyr® (icatibant), or Kalbitor® (ecallantide) must be provided.

Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), Orladeyo® (Berotralstat), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Authorization of Cinryze® or Haegarda® will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo®; and
7. Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, or Orladeyo®; and
8. Cinryze® Dosing:

a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
b. Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and
c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); or

9. Haegarda® Dosing:
    a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
    b. 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
    c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or
10. Orladeyo® Dosing:
    a. The recommended dose of Orladeyo® is 150mg by mouth once daily; and
    b. A quantity limit of 28 capsules per 28 days will apply; or
11. Takhzyro® Dosing:
    a. For members 12 years of age of older: The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    b. For members 6-11 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    c. For members 2 to 5 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 4 weeks; and
    d. Prescriber must verify member or caregiver has been trained by a health professional on proper storage and sub-Q administration of Takhzyro®; and
    e. A quantity limit of (2) vials per 28 days will apply.

Utilization of HAE 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	9	$89,768.48	$9,974.28	$356.22	88	252
2023 Total	**3**	**9**	**$89,768.48**	**$9,974.28**	**$356.22**	**88**	**252**
Fiscal Year 2024							
FFS	3	21	$643,617.53	$30,648.45	$1,079.90	410	596
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**3**	**21**	**$ 643,617.53**	**$30,648.45**	**$1,079.90**	**410**	**596**
% Change	**0.00%**	**133.33%**	**616.97%**	**207.27%**	**203.15%**	**365.91%**	**136.51%**
Change	**0**	**12**	**$553,849.05**	**$20,674.17**	**$723.68**	**322**	**344**

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.

Fiscal Year 2024 Utilization: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	1	1	$15,921.60	$15,921.60	1
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**1**	**1**	**$15,921.60**	**$15,921.60**	**1**

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

Demographics of Members Utilizing HAE Medications (All Plans)

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

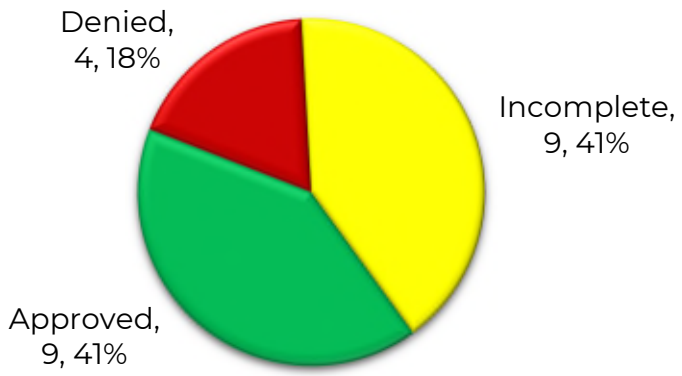
Top Prescriber Specialties of HAE Medications by Number of Claims (All Plans)

- There were 21 pharmacy claims for HAE medications during fiscal year 2024, all of which were prescribed by allergists.

Prior Authorization of HAE Medications

There were 22 prior authorization requests submitted for HAE medications for 3 unique members 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	9	41%	9	41%	4	18%	**22**
Aetna	0	0%	0	0%	0	0%	**0**
Humana	0	0%	0	0%	0	0%	**0**
OCH	0	0%	0	0%	0	0%	**0**
Total	**9**	**41%**	**9**	**41%**	**4**	**18%**	**22**

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

Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

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

Anticipated Patent Expiration(s):

- Orladeyo® (berotralstat): November 2039

News:

- **July 2020:** The U.S. Food and Drug Administration (FDA) approved an icatibant 30mg/3mL therapeutic equivalent to Firazyr® (icatibant) under

an Abbreviated New Drug Application (ANDA). In June 2021, the FDA approved a proprietary name change to the labeling and Cycle Pharmaceuticals launched the product as Sajazir™ (icatibant).

Pipeline:

- **Donidalorsen:** Donidalorsen is an investigational ligand-conjugated antisense (LICA) medicine designed to target the prekallikrein (PKK) pathway. PKK plays an important role in the activation of inflammatory mediators associated with acute attacks of HAE. A press release from January 2024 reported that results from a Phase 3 trial indicated a statistically significant reduction in the rate of angioedema attacks when participants with HAE were treated with donidalorsen subcutaneous (sub-Q) injection every 4 weeks ($P<0.001$) or every 8 weeks ($P=0.004$) compared to placebo.
- **Garadacimab:** In December 2023, CSL announced that the company's Biologics License Application (BLA) for the investigational product, garadacimab, was accepted by the FDA for review. Garadacimab is a monoclonal antibody that targets activated Factor XII (FXIIa) and was studied to be administered sub-Q once monthly for HAE prophylaxis. In a Phase 3, randomized, placebo-controlled trial, participants who received garadacimab experienced a mean HAE monthly attack rate of 0.27 compared to 2.01 for those who received placebo ($P<0.0001$).
- **NTLA-2002:** In October 2024, Intellia Therapeutics announced positive results from a Phase 2 trial evaluating NTLA-2002, an investigational gene therapy for HAE. Compared to placebo, one-time intravenous infusions of 25mg or 50mg of NTLA-2002 reduced HAE attack rates by 75% and 77% during weeks 1 to 16 and by 80% and 85% during weeks 5 to 16, respectively. The trial also reported that NTLA-2002 was well-tolerated with the most reported adverse effects being headache, fatigue, and nasopharyngitis. The safety and efficacy of the NLTA-2002 50mg dose will be evaluated in a global, Phase 3 trial, which is currently enrolling participants.
- **Sebetralstat:** In October 2024, KalVista announced that the FDA accepted their New Drug Application (NDA) for sebetralstat, an investigational oral treatment for HAE. Sebetralstat is a kallikrein inhibitor being studied for on-demand treatment of HAE attacks in adults and pediatric patients 12 years of age and older. The safety and efficacy of sebetralstat were evaluated in a Phase 3 clinical trial. Compared to placebo, sebetralstat significantly reduced the time to beginning of symptom relief with a safety profile similar to placebo. The Prescription Drug User Fee Act (PDUFA) date for sebetralstat has been set as June 17, 2025.

Cost Comparison: Icatibant Products

Product	Cost Per mL	Cost Per Day*
Sajazir™ (icatibant) 30mg/3mL syringe (branded generic)	**$3,715.83**	**$33,442.47**
Firazyr® (icatibant) 30mg/3mL syringe	$3,715.83	$33,442.47
icatibant acetate 30mg/3mL syringe (generic)	$1,694.42⁺	$15,249.78

Costs do not reflect rebated prices or net costs. Costs based on Wholesale Acquisition Costs (WAC).
*Cost per day based on the FDA approved maximum dosing of 90mg (9mL) per 24 hours.
⁺Cost per mL varies per NDC.

Recommendations

The College of Pharmacy recommends updating the icatibant approval criteria based on net costs (changes shown in red):

Berinert® (C1 Esterase Inhibitor), Firazyr® (Icatibant), Kalbitor® (Ecallantide), Ruconest® (C1 Esterase Inhibitor), and Sajazir™ (Icatibant) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for the treatment of acute attacks of HAE; and
3. For authorization consideration of Firazyr® (icatibant) or Kalbitor® (ecallantide), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor) must be provided; or
4. For authorization consideration of Ruconest® (C1 esterase inhibitor) or Sajazir™ (icatibant), a patient-specific, clinically significant reason why the member cannot use Berinert® (C1 esterase inhibitor), Firazyr® (icatibant), or Kalbitor® (ecallantide) must be provided.

The College of Pharmacy recommends updating the Cinryze® (C1 esterase inhibitor) approval criteria to be consistent with clinical practice (changes shown in red):

Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), Orladeyo® (Berotralstat), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or

5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Authorization of Cinryze® or Haegarda® will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo®; and
7. Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, or Orladeyo®; and
8. Cinryze® Dosing:
    a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
    b. Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and
    c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); ~~or~~ and
        i. For requests exceeding the quantity limit, clinical documentation supporting the need for the dose increase (i.e., up to a maximum of 16,000 units per month) must be provided for a quantity limit override; or
9. Haegarda® Dosing:
    a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
    b. 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
    c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or
10. Orladeyo® Dosing:
    a. The recommended dose of Orladeyo® is 150mg by mouth once daily; and
    b. A quantity limit of 28 capsules per 28 days will apply; or
11. Takhzyro® Dosing:
    a. For members 12 years of age of older: The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    b. For members 6-11 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
    c. For members 2 to 5 years of age: The recommended dose of Takhzyro® is 150mg sub-Q every 4 weeks; and

d. Prescriber must verify member or caregiver has been trained by a health professional on proper storage and sub-Q administration of Takhzyro®; and
e. A quantity limit of (2) vials per 28 days will apply.

Utilization Details of HAE Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORLADEYO CAP 150MG	11	1	$455,920.99	$41,447.36	11	70.84%
ICATIBANT INJ 30MG/3ML	5	2	$91,555.85	$18,311.17	2.5	14.23%
TAKHZYRO INJ 150MG/ML	3	1	$76,789.77	$25,596.59	3	11.93%
BERINERT INJ 500 UNIT	2	1	$19,350.92	$9,675.46	2	3.00%
TOTAL	**21**	**3***	**$643,617.53**	**$30,648.45**	**7**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Fee-For-Service Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
J1290 ECALLANTIDE INJ 1MG	1	1	$15,921.60	$15,921.60	1	100.00%
TOTAL	**1**	**1**	**$15,921.60**	**$15,921.60**	**1**	**100%**

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

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Appendix J

30-Day Notice to Prior Authorize Nemluvio® (Nemolizumab-ilto)

Oklahoma Health Care Authority
November 2024

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

Prurigo nodularis (PN) is a chronic skin disorder characterized by the presence of multiple, firm, pruritic, nodular lesions. The prevalence of PN has been estimated at approximately 40-72 per 100,000 people in the United States, although the true prevalence has been difficult to determine. PN usually affects older adults, with a mean age of approximately 50-60 years. In one estimate, 47.5% of patients with PN were 65 years of age or older. PN is also more likely to occur in women and African Americans. The cause of PN is not fully understood but is believed to involve both neural and immunologic pathways that lead to the release of proinflammatory and pruritogenic cytokines. Topical agents, such as topical corticosteroids or topical calcineurin inhibitors, are considered among the first-line treatment options for PN. In September 2022, the U.S. Food and Drug Administration (FDA) approved Dupixent® (dupilumab) as the first FDA approved treatment option for PN. In August 2024, the FDA approved Nemluvio® (nemolizumab-ilto) for the treatment of adults with PN, making it only the second FDA approved treatment option for PN.

Nemluvio® (Nemolizumab-ilto) Product Summary[8]

Therapeutic Class: Interleukin-31 (IL-31) receptor antagonist

Indication(s): Treatment of adults with PN

How Supplied: Single-dose prefilled dual chamber pen containing 30mg nemolizumab-ilto lyophilized powder and diluent, water for injection

Dosing and Administration: Administered by subcutaneous (sub-Q) injection based on weight:

- <90kg: 60mg [administered as (2) 30mg injections] once followed by 30mg every 4 weeks
- ≥90kg: 60mg every 4 weeks

Efficacy: The efficacy of Nemluvio® was based primarily on 2 Phase 3, randomized, double-blind, placebo-controlled studies (OLYMPIA 1 and OLYMPIA 2).

- Key Inclusion Criteria:
  - Clinical diagnosis of PN for at least 6 months

- 18 years of age or older
- Presence of ≥20 nodular lesions
- Moderate or severe disease based on an Investigator Global Assessment (IGA) score ≥3 on a scale from 0 to 4
- Severe pruritus based on a Peak Pruritus Numeric Rating Scale (PP-NRS) score ≥7 on a scale from 0 to 10

- Efficacy Endpoint(s) Assessed by the FDA at Week 16:
  - Proportion of patients achieving both an improvement (reduction) of ≥4 in PP-NRS and IGA of 0 ("clear skin") or 1 ("almost clear skin")
  - Proportion of patients achieving IGA of 0 or 1
  - Proportion of patients achieving improvement (reduction) of ≥4 in PP-NRS
  - Proportion of patients achieving PP-NRS <2
- Results:
  - IGA of 0 or 1 and ≥4-point improvement in PP-NRS:
    - OLYMPIA 1: Achieved by 22% of patients who received nemolizumab vs. 2% of patients who received placebo [treatment difference: 15%; 95% confidence interval (CI): 8%, 21%)
    - OLYMPIA 2: Achieved by 25% of patients who received nemolizumab vs. 4% of patients who received placebo (treatment difference: 22%; 95% CI: 14%, 30%)
  - IGA of 0 or 1:
    - OLYMPIA 1: Achieved by 26% of patients who received nemolizumab vs. 7% of patients who received placebo (treatment difference: 15%; 95% CI: 7%, 23%)
    - OLYMPIA 2: Achieved by 38% of patients who received nemolizumab vs. 11% of patients who received placebo (treatment difference: 29%; 95% CI: 19%, 38%)
  - ≥4-point improvement in PP-NRS:
    - OLYMPIA 1: Achieved by 56% of patients who received nemolizumab vs. 16% of patients who received placebo (treatment difference: 38%; 95% CI: 27%, 48%)
    - OLYMPIA 2: Achieved by 49% of patients who received nemolizumab vs. 16% of patients who received placebo (treatment difference: 34%; 95% CI: 23%, 45%)
  - PP-NRS <2:
    - OLYMPIA 1: Achieved by 32% of patients who received nemolizumab vs. 4% of patients who received placebo (treatment difference: 28%; 95% CI: 20%, 36%)
    - OLYMPIA 2: Achieved by 31% of patients who received nemolizumab vs. 7% of patients who received placebo (treatment difference: 26%; 95% CI: 18%, 34%)

Cost Comparison:

Product	Cost Per Pen	Cost Per 28 Days	Cost Per Year
Nemluvio® (nemolizumab-ilto) 30mg pen	**$4,240.00**	**$8,480.00***	**$110,240.00***
Dupixent® (dupilumab) 300mg/2mL pen	$1,832.64	$3,665.28⁺	$47,648.64⁺

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost is based on the FDA approved maximum dose of 60mg every 4 weeks.
⁺Cost is based on the FDA approved maintenance dose of 300mg every 2 weeks.

Recommendations

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.

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Appendix K

Fiscal Year 2024 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Ohtuvayre™ (Ensifentrine)

Oklahoma Health Care Authority
November 2024

Current Prior Authorization Criteria

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

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.
ᵝDoes not include Breyna®; authorization of Breyna® requires a reason why the member cannot use the brand formulation (Symbicort®).
ᵅDoes 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.
ᵟIncludes all strengths other than Dulera® 50mcg/5mcg.

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.

AirDuo RespiClick® (Fluticasone Propionate/Salmeterol) Approval Criteria:
1. An FDA approved diagnosis of asthma; and
2. Member must be at or above the minimum age indicated; and
3. Failure of Advair®, Dulera®, and Symbicort® or a reason why Advair®, Dulera®, and Symbicort® are not appropriate for the member must be provided; and
4. Member must have used an inhaled corticosteroid for at least 1 month immediately prior; and
5. 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
6. A clinical situation warranting initiation with combination therapy due to severity of asthma.

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.

Breo® Ellipta® (Fluticasone Furoate/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) or chronic bronchitis and/or emphysema associated with COPD; and
    a. For a diagnosis of COPD or chronic bronchitis and/or emphysema associated with COPD, trials of Advair® and Symbicort®, consisting of at least 30 days each within the last 90 days that did not adequately control COPD symptoms; or
2. An FDA approved diagnosis of asthma in members 5 years of age and older; and
    a. For a diagnosis of asthma, trials of Advair®, Dulera®, and Symbicort® consisting of at least 30 days each within the last 120 days that did not adequately control asthma symptoms; and
3. Requests for generic fluticasone furoate/vilanterol will require a patient-specific, clinically significant reason why brand name Breo® Ellipta® cannot be used.

Breyna® (Budesonide/Formoterol Fumarate) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the brand name Symbicort® must be provided (brand formulation is preferred and does not require prior authorization).

Dulera® (Mometasone Furoate/Formoterol) 50mcg/5mcg Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be between 5 and 11 years of age; and
3. Failure of Advair® and Symbicort® or a reason why Advair® and Symbicort® are not appropriate for the member must be provided; and

4. Member must have used an inhaled corticosteroid (ICS) for at least 1 month immediately prior; and
5. 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
6. A clinical situation warranting initiation with combination therapy due to severity of asthma.

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 or a patient-specific, clinically significant reason why they are not appropriate for the member must be provided.

Symbicort Aerosphere® (Budesonide/Formoterol Fumarate) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. A patient-specific, clinically significant reason why the member cannot use brand name Symbicort® and Advair® 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®)
	formoterol nebulizer solution (Perforomist®)
	olodaterol inhalation spray (Striverdi® Respimat®)
Long-Acting Muscarinic Antagonists (LAMA)	
aclidinium inhalation powder (Tudorza® PressAir®)	revefenacin inhalation solution (Yupelri®)

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
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).

Long-Acting Beta$_2$ Agonist (LABA) and Long-Acting Muscarinic Antagonist (LAMA) Tier-2 Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD), chronic bronchitis, or emphysema; and
2. Member must be 18 years of age or older; and
3. A 4-week trial of at least 1 LABA and a 4-week trial of 1 LAMA within the past 90 days; or
4. A documented adverse effect, drug interaction, or contraindication to all available Tier-1 products; or
5. A clinical exception may apply for members who are unable to effectively use hand-actuated devices, such as Spiriva® HandiHaler®, or who are stable on nebulized therapy.

Anoro® Ellipta® (Umeclidinium/Vilanterol), Bevespi Aerosphere® (Glycopyrrolate/Formoterol Fumarate), Duaklir® Pressair® (Aclidinium Bromide/Formoterol Fumarate), and Stiolto® Respimat® (Tiotropium/ Olodaterol) 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. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting beta$_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components must be provided.

Breztri Aerosphere® (Budesonide/Glycopyrrolate/Formoterol) and Trelegy Ellipta® (Fluticasone Furoate/Umeclidinium/Vilanterol) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. A 4-week trial of at least 1 long-acting beta$_2$ agonist (LABA) and a 4-week trial of 1 long-acting muscarinic antagonist (LAMA) within the

past 90 days used concomitantly with an inhaled corticosteroid (ICS); and
4. A patient-specific, clinically significant reason why the member requires the triple combination therapy in place of the individual components or use of a LABA/ICS combination with a LAMA must be provided.

Daliresp® (Roflumilast) Approval Criteria:

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) with history of chronic bronchitis; and
2. Forced expiratory volume (FEV) ≤50% of predicted; and
3. Member is inadequately controlled on long-acting bronchodilator therapy (must have 3 or more claims for long-acting bronchodilators in the previous 6 months).

Current Prior Authorization Criteria: Asthma-Indicated Monoclonal Antibodies

Cinqair® (Reslizumab) Approval Criteria:

1. An FDA approved indication of add-on maintenance treatment of members with severe asthma with an eosinophilic phenotype; and
2. Member must be 18 years of age or older; and
3. Member must have a blood eosinophil count ≥400cells/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. Cinqair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
8. Cinqair® 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
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and

10. Member's weight should be provided on prior authorization requests. Weights should have been taken within the last 4 weeks to provide accurate weight-based dosing.

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. 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
5. 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
6. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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 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) Approval Criteria [Eosinophilic Esophagitis (EoE) Diagnosis]:

1. An FDA approved diagnosis of EoE; and
2. Member must be 12 years of age or older and weigh ≥40kg; 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 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. 1 high-dose proton pump inhibitor; and
    b. 1 swallowed inhaled 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 (Dupixent® has not been studied in combination with other biologic therapies); 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 Injection) Approval Criteria [Eosinophilic Phenotype 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 have a blood eosinophil count of ≥150cells/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. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and
8. 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
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) 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 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.

Fasenra® (Benralizumab Injection) Approval Criteria:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 12 years of age or older; and
3. Member must have a blood eosinophil count of ≥150cells/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® 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, 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. 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 prefilled syringe or prefilled autoinjector pen per 56 days will apply.

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 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, 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 Granulomatosis with Polyangiitis (EGPA) Diagnosis]:

1. An FDA approved diagnosis of EGPA; and
2. 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
3. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
4. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥7.5mg/day) for a minimum of 4 weeks duration; and
5. 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 within the last 12 months (or an advanced care practitioner with a

supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
6. For authorization of Nucala vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
7. For authorization of Nucala prefilled autoinjector or prefilled syringe, 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
8. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
9. 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 [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 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, 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 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, 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.

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® vial or pre-filled syringe, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; and
7. For authorization of Tezspire® pre-filled pen, 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.

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 for at least the past 12 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, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
9. For authorization of Xolair® prefilled autoinjector or prefilled syringe, 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, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and

7. For authorization of Xolair® prefilled autoinjector or prefilled syringe, 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, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and

11. For authorization of Xolair® prefilled autoinjector or prefilled syringe, 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.

Utilization of Asthma and COPD Maintenance Medications: Fiscal Year 2024

Comparison of Fiscal Years: Asthma and COPD Maintenance Medications Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	43,400	142,579	$46,543,911.07	$326.44	$9.25	4,014,397	5,031,673
2023 Total	**43,400**	**142,579**	**$46,543,911.07**	**$326.44**	**$9.25**	**4,014,39**	**5,031,673**
Fiscal Year 2024							
FFS	38,939	116,657	$35,314,079.43	$302.72	$8.62	3,210,555	4,097,113
Aetna	3,602	5,673	$1,497,338.77	$263.94	$7.79	149,463	192,170
Humana	4,388	7,566	$2,136,473.95	$282.38	$8.25	210,142	259,048
OCH	4,170	6,655	$1,756,679.98	$263.96	$7.81	176,219	225,042
2024 Total	**42,343**	**136,551**	**$40,704,572.13**	**$298.09**	**$8.53**	**3,746,380**	**4,773,373**
% Change	**-2.40%**	**-4.20%**	**-12.50%**	**-8.70%**	**-7.80%**	**-6.70%**	**-5.10%**
Change	**-1,057**	**-6,028**	**-$5,839,338.94**	**-$28.35**	**-$0.72**	**-268,017**	**-258,300**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
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 2023 for the asthma and COPD maintenance medications totaled $40,982,651.68[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.

Comparison of Fiscal Years: Asthma-Indicated Monoclonal Antibodies Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	931	5,734	$19,439,653.73	$3,390.24	$110.45	19,748	176,008
2023 Total	**931**	**5,734**	**$19,439,653.73**	**$3,390.24**	**$110.45**	**19,748**	**176,008**
Fiscal Year 2024							
FFS	1,244	6,291	$22,936,685.68	$3,645.95	$114.00	22,066	201,205
Aetna	225	450	$1,717,597.82	$3,816.88	$129.01	1,530	13,314
Humana	262	533	$2,027,440.81	$3,803.83	$128.84	1,796	15,736
OCH	249	466	$1,782,793.54	$3,825.74	$113.21	1,648	15,747
2024 Total	**1,441**	**7,740**	**$28,464,517.85**	**$3,677.59**	**$115.71**	**27,040**	**246,002**
% Change	**54.8%**	**35.0%**	**46.4%**	**8.5%**	**4.8%**	**36.9%**	**39.8%**
Change	**510**	**2,006**	**$9,024,864.12**	**$287.35**	**$5.26**	**7,292**	**69,994**

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

- Aggregate drug rebates collected during fiscal year 2023 for the asthma-indicated monoclonal antibodies totaled $ 6,372,140.76[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

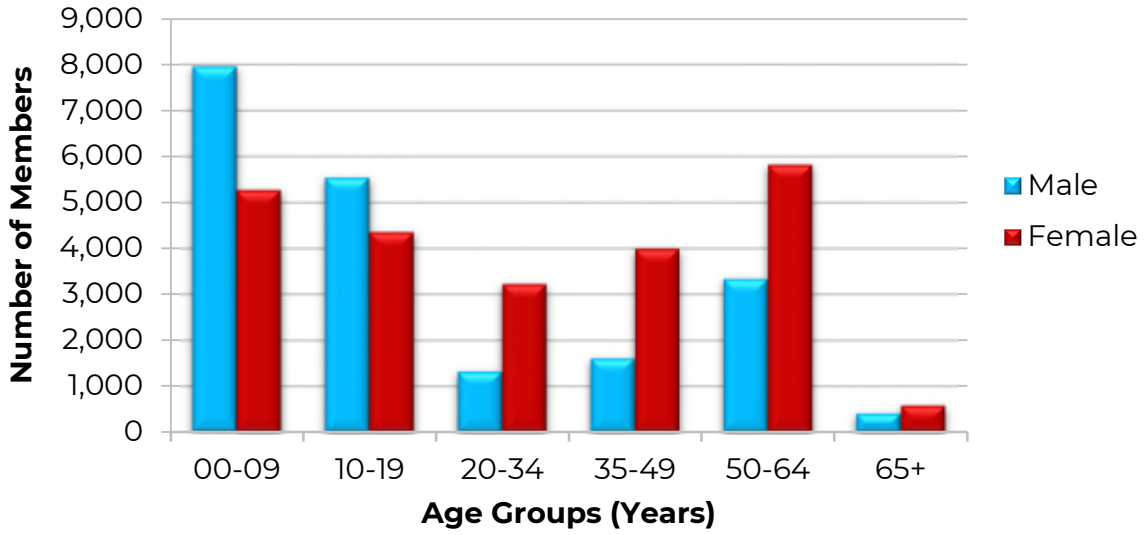
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Comparison of Fiscal Years: Asthma-Indicated Monoclonal Antibodies Medical Claims (All Plans)

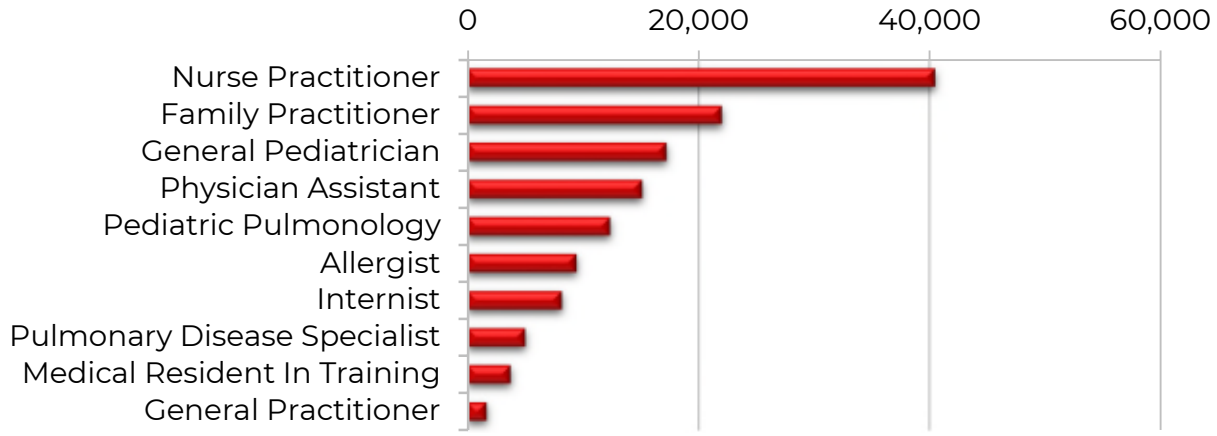
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2023					
FFS	57	473	$1,079,441.05	$2,282.12	8.3
2023 Total	**57**	**473**	**$1,079,441.05**	**$2,282.12**	**8.3**
Fiscal Year 2024					
FFS	80	557	$1,311,128.15	$2,353.91	6.96
Aetna	8	14	$19,877.40	$1,419.81	1.75
Humana	1	2	$1.20	$0.60	2
OCH	5	10	$14,909.25	$1,490.93	2
2024 Total	**85**	**583**	**$1,345,916.00**	**$2,308.60**	**6.86**
% Change	**49.12%**	**23.26%**	**24.69%**	**1.16%**	**-17.36%**
Change	**28**	**110**	**$266,474.95**	**$26.48**	**-1.44**

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



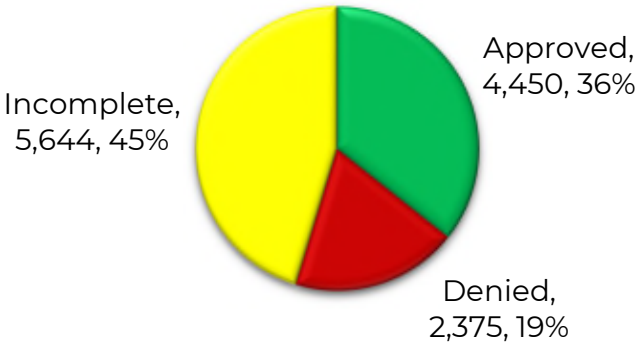
Top Prescriber Specialties of Asthma and COPD Maintenance Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Asthma and COPD Maintenance Medications

There were 12,469 prior authorization requests submitted for asthma and COPD maintenance medications during fiscal year 2024. Of those prior authorization requests, 3,845 were submitted for asthma-indicated monoclonal antibody medications. 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	3,926	35%	5,534	49%	1,838	16%	**11,298**
Aetna	180	33%	107	20%	261	48%	**548**
Humana	142	48%	3	1%	152	51%	**297**
OCH	202	62%	0	0%	124	38%	**326**
Total	**4,450**	**36%**	**5,644**	**45%**	**2,375**	**19%**	**12,469**

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[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17]

Anticipated Patent Expiration(s):

- Tudorza® Pressair® (aclidinium inhalation powder): March 2029
- Duaklir® Pressair® (aclidinium/formoterol inhalation powder): March 2029
- Symbicort® (budesonide/formoterol inhalation aerosol): October 2029
- Symbicort Aerosphere® (budesonide/formoterol inhalation aerosol): May 2030
- Spiriva® HandiHaler® (tiotropium inhalation powder): April 2030
- Striverdi® Respimat® (olodaterol inhalation spray): October 2030
- Stiolto® Respimat® (tiotropium/olodaterol inhalation spray): October 2030
- Incruse® Ellipta® (umeclidinium inhalation powder): October 2030
- Bevespi Aerosphere® (glycopyrrolate/formoterol inhalation aerosol): March 2031
- Anoro® Ellipta® (umeclidinium/vilanterol inhalation powder): April 2031
- Arnuity® Ellipta® (fluticasone furoate inhalation powder): April 2031
- Breo® Ellipta® (fluticasone furoate/vilanterol inhalation powder): April 2031
- Breztri Aerosphere® (budesonide/glycopyrrolate/formoterol aerosol): March 2031
- Spiriva® Respimat® (tiotropium soft mist inhaler): April 2031
- Trelegy® Ellipta® (fluticasone furoate/umeclidinium/vilanterol inhalation powder): April 2031
- Ohtuvayre™ (ensifentrine inhalation suspension): September 2035
- ArmonAir® Digihaler® (fluticasone propionate inhalation powder): August 2041
- QVAR® RediHaler® (beclomethasone inhalation aerosol): August 2041
- AirDuo RespiClick® (fluticasone propionate/salmeterol inhalation powder): February 2040
- AirDuo® Digihaler® (fluticasone propionate/salmeterol inhalation powder): August 2041

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

- **January 2024:** Dupixent® (dupilumab) was approved for an age expansion for patients 1 to 11 years of age who weigh at least 15kg with a diagnosis of eosinophilic esophagitis (EoE). Dupixent® was originally approved for EoE in patients 12 years of age and older in May 2022.
- **February 2024:** The FDA approved Xolair® (omalizumab) for the treatment of immunoglobulin E (IgE)-mediated food allergy for the reduction of allergic reactions in patients 1 year of age or older. Xolair® was studied in a Phase 3 trial that included 168 patients who were allergic to peanuts and at least 2 additional foods. Patients were

randomized to Xolair® or placebo for 16-20 weeks and the primary endpoint was the percentage of patients who were able to eat ≥600mg of peanut protein without moderate to severe allergic symptoms. The Xolair® group had 68% of patients meet the primary endpoint versus 6% in the placebo patients [difference: 63%; 95% confidence interval (CI): 50%, 73%].

- **April 2024:** Fasenra® (benralizumab) received an age expansion to include patients 6 years of age or older with severe eosinophilic asthma. Additionally, a new 10mg dose will be available for patients weighing <35kg. Fasenra® was originally approved for patients 12 years of age or older with severe eosinophilic asthma in November 2017.
- **June 2024:** The FDA approved Ohtuvayre™ (ensifentrine) for the maintenance treatment of COPD in adults.
- **September 2024:** Dupixent® (dupilumab) was approved for an age expansion as add-on maintenance for chronic rhinosinusitis with nasal polyps (CRSwNP) in patients who are 12 years of age or older. Dupixent® was previously approved for adults with CRSwNP in June 2019.
- **September 2024:** An Abbreviated New Drug Application (ANDA) was approved for formoterol fumarate inhalation solution that includes a LC PLUS nebulizer co-packaged in a kit.
- **September 2024:** Fasenra® (benralizumab) received a new indication for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in patients 18 years of age or older. The safety and efficacy of Fasenra® for EGPA were studied in the MANDARA Phase 3 non-inferiority trial where patients were randomized to Fasenra® 30mg or mepolizumab 100mg. Fasenra® was found to be non-inferior to mepolizumab, and 41% of patients in the Fasenra® arm were tapered off oral corticosteroids versus 26% in the mepolizumab arm (difference: 16%; 95% CI: 1%, 31%).
- **September 2024:** Dupixent® (dupilumab) was approved for a new indication as add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. The safety and efficacy of Dupixent® were studied in 2 Phase 3 trials, BOREAS and NOTUS, in patients currently on maximal standard of care inhaled therapy [long-acting $beta_2$ agonist/long-acting muscarinic agonist/inhaled corticosteroid (LABA/LAMA/ICS)] and blood eosinophil count ≥300 cells/mcL. The primary endpoint for both trials was the annualized rate of acute moderate or severe COPD exacerbations. Dupixent® showed a 30% reduction in the BOREAS trial and a 34% reduction in the NOTUS trial when compared to placebo. Additionally, improvements in post-bronchodilator forced expiratory volume in 1 second (FEV_1) were assessed, and Dupixent® showed significant improvements in each trial, 74mL in BOREAS and 68mL in NOTUS.

News:

- **April 2024:** In April 2024, it was announced that Teva will be discontinuing the Digihaler® products, including AirDuo® Digihaler®, ArmonAir® Digihaler®, and Proair® Digihaler®, on June 1, 2024. Currently these 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.

Guideline Update(s):

- **Global Initiative for Asthma (GINA) Guideline Update:** The GINA guidelines have been updated for 2024. Some notable updates include:
  - The diagnostic flowchart for clinical practice has been revised to allow for selection of different initial lung function tests, depending on local resources.
  - There is clarification that assessment of symptom control should not be limited to the most recent 4 weeks. The assessment of symptom control should include patients' risk for exacerbation, accelerated decline in lung function, and medication side effects.
  - Track 1 has been updated with considerations for which patients should be started at Step 3 and use ICS-formoterol as maintenance-and-reliever therapy (MART) rather than as-needed-only. Although there is no specific evidence to guide a provider's choice, some examples when it is recommended are patients with daily symptoms, current smokers, low lung function, or recent severe or history of life-threatening exacerbations.
  - The 2024 treatment figure for adults and adolescents has been updated to include asthma medications including ICS as a reminder that all patients with asthma should be receiving ICS-containing therapy.

Pipeline:

- **CT-P39:** CT-P39 is an investigational product seeking an interchangeable biosimilar designation to the current FDA approved medication Xolair® (omalizumab). A Biologics License Application (BLA) has been submitted to the FDA with Phase 3 data demonstrating comparable efficacy and safety to Xolair®. The BLA submission includes all indications for which Xolair® is currently approved, including asthma, CRSwNP, IgE-mediated food allergy, and chronic spontaneous urticaria (CSU).
- **Depemokimab:** Depemokimab is an investigational interleukin-5 (IL-5) antibody, given once every 6 months, that is being studied for severe

asthma with type 2 inflammation characterized by a blood eosinophil count. Two Phase 3 trials, SWIFT-1 and SWIFT-2, have met the primary endpoint of a reduction in the annualized rate of clinically significant exacerbations over 52 weeks versus placebo. Further analysis of the data is ongoing and depemokimab is also being studied in Phase 3 trials for EGPA, CRSwNP, and hypereosinophilic syndrome (HES).

- **Dupixent® (Dupilumab):** Dupixent® is currently in Phase 3 trials to reduce itching and urticaria in patients with CSU whose symptoms are not controlled with H1-antihistamine therapy. The Phase 3 LIBERTY-CUPID study C showed that patients treated with Dupixent® experienced an 8.64-point reduction in itch severity versus a 6.10-point reduction for those on placebo. Study C is a replicated study to LIBERTY-CUPID study A that was conducted after a Complete Response Letter (CRL) was received from the FDA requesting additional efficacy data. Study C is intended to support regulatory submission in the United States in response to the CRL.
- **Nucala (Mepolizumab):** Nucala is currently being studied in a Phase 3 trial in adults with COPD, and results showed a statistically significant and clinically meaningful reduction in the annualized rate of moderate/severe exacerbations versus placebo. Further analysis of the data is ongoing and a submission to the FDA has not yet been completed.
- **Tezspire® (Tezepelumab):** A Phase 2a trial has shown that Tezspire® may have potential as an add-on treatment for patients with COPD, although it did not meet the primary endpoint in a mid-stage trial. Secondary endpoints of the trial did show improvements in FEV_1 and symptom burden and appeared to show higher results in patients with blood eosinophil counts of at least 150 cells/mcL. A Phase 3 program is currently being planned.

Ohtuvayre™ (Ensifentrine) Product Summary[18]

Therapeutic Class: Phosphodiesterase (PDE) 3 and PDE4 inhibitor

Indication(s): Maintenance treatment of COPD in adults

How Supplied: 3mg/2.5mL inhalation suspension in unit-dose ampules

Dosing and Administration:

- 3mg (1 ampule) twice daily via oral inhalation with a standard jet nebulizer with a mouthpiece
- Ohtuvayre™ should not be physically mixed with other drugs or added to solutions containing other drugs

Efficacy: The efficacy of Ohtuvayre™ was studied in 2 randomized, double-blind, Phase 3 trials, ENHANCE-1 and ENHANCE-2. The 2 trials enrolled a total of 1,553 patients with moderate to severe COPD.

- Key Inclusion Criteria:
  - Clinical diagnosis of COPD
  - Pre- and post-albuterol FEV_1/forced vital capacity (FVC) ratio <0.70
  - Post-albuterol FEV_1 ≥30% and ≤70% of predicted normal (GOLD 2 and GOLD 3 ranges)
  - Grade ≥2 on the Modified Medical Research Council (mMRC) dyspnea scale
  - No maintenance therapy or stable maintenance therapy with either a LABA or LAMA +/- ICS
- Key Exclusion Criteria:
  - Asthma diagnosis
  - LAMA/LABA dual therapy regimen
  - LAMA/LABA/ICS triple therapy
- Intervention(s):
  - Randomized 5:3 to Ohtuvayre™ 3mg twice daily or placebo
- Primary Endpoint(s):
  - Change from baseline in FEV_1 area under the curve (AUC_{0-12H}) post dose at week 12
- Results:
  - ENHANCE-1: 87mL increase in FEV_1 AUC_{0-12h} compared to placebo (95% CI: 55, 118)
  - ENHANCE-2: 94mL increase in FEV_1 AUC_{0-12h} compared to placebo (95% CI: 65, 124)

Cost: The Wholesale Acquisition Cost (WAC) of Ohtuvayre™ is $19.67 per mL or $49.18 per 2.5mL ampule. This results in an estimated cost of $2,950.50 per 30 days and $35,406.00 per year based on recommended dosing.

Recommendations

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; 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 [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.

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 recommends the following changes to the approval criteria for Nucala (mepolizumab) based on net costs (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 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
3. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
4. 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
5. 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 within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and

6. For authorization of Fasenra® 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
7. For authorization of Fasenra® prefilled autoinjector pen, 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
8. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 28 days will apply.
9. 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® 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, 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 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
3. Diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) will not be approved; and
4. Failure to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥7.5mg/day) for a minimum of 4 weeks duration; and
5. 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 within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, pulmonary specialist, or rheumatologist); and
6. For authorization of Nucala vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
7. For authorization of Nucala prefilled autoinjector or prefilled syringe, 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

8. A patient-specific, clinically significant reason why the member cannot use Fasenra® (benralizumab injection) must be provided; and
9. A quantity limit of 3 vials, prefilled autoinjectors, or prefilled syringes per 28 days will apply; and
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 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.

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 (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.

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. Approval of Tier-1 products may be considered 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).

Utilization Details of Asthma and COPD Maintenance Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ICS/LABA COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
SYMBICORT AER 160/4.5MCG	14,755	5,144	$5,354,012.57	$362.86	2.87	15.16%
FLUTIC/SALME AER 250/50MCG	7,287	3,183	$872,095.76	$119.68	2.29	2.47%
SYMBICORT AER 80/4.5MCG	5,533	2,493	$1,655,822.44	$299.26	2.22	4.69%
ADVAIR HFA AER 115/21MCG	4,602	1,814	$1,656,187.31	$359.88	2.54	4.69%
FLUTIC/SALME AER 115/21MCG	3,648	1,667	$996,879.35	$273.27	2.19	2.82%
ADVAIR DISKUS AER 250/50MCG	3,183	1,529	$1,152,565.31	$362.10	2.08	3.26%
DULERA AER 200/5MCG	3,129	990	$1,095,939.09	$350.25	3.16	3.10%
FLUTIC/SALME AER 100/50MCG	2,190	1,065	$215,263.59	$98.29	2.06	0.61%
FLUTIC/SALME AER 500/50MCG	2,147	795	$433,223.85	$201.78	2.7	1.23%
DULERA AER 100/5MCG	1,832	706	$631,423.52	$344.66	2.59	1.79%
ADVAIR DISKUS AER 500/50MCG	1,348	563	$687,361.19	$509.91	2.39	1.95%
ADVAIR HFA AER 45/21MCG	1,157	510	$320,069.95	$276.64	2.27	0.91%
FLUTIC/SALME AER 45/21MCG	1,151	554	$248,406.02	$215.82	2.08	0.70%
FLUTIC/SALME AER 230/21MCG	1,142	490	$414,567.54	$363.02	2.33	1.17%
ADVAIR HFA AER 230/21MCG	1,103	467	$554,868.35	$503.05	2.36	1.57%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ADVAIR DISKUS AER 100/50MCG	1,039	517	$274,206.22	$263.91	2.01	0.78%
BUDES/FORMOT AER 80/4.5MCG	311	149	$62,299.63	$200.32	2.09	0.18%
BREYNA AER 80/4.5MCG	94	52	$20,188.42	$214.77	1.81	0.06%
WIXELA INHUB AER 100/50MCG	28	16	$2,340.75	$83.60	1.75	0.01%
WIXELA INHUB AER 250/50MCG	22	10	$3,115.70	$141.62	2.2	0.01%
WIXELA INHUB AER 500/50MCG	6	4	$983.30	$163.88	1.5	0.00%
BUDES/FORMOT AER 160/4.5MCG	3	2	$1,017.75	$339.25	1.5	0.00%
FLUTIC/SALME INH 232/14MCG	1	1	$101.27	$101.27	1	0.00%
FLUTIC/SALME INH 113/14MCG+	1	1	$0.00	$0.00	1	0.00%
SUBTOTAL	**55,712**	**22,722**	**$16,652,938.88**	**$298.91**	**2.45**	**47.16%**
TIER-2 UTILIZATION						
BREO ELLIPTA INH 200/25MCG	139	33	$51,148.02	$367.97	4.21	0.14%
BREO ELLIPTA INH 100/25MCG	130	31	$45,152.59	$347.33	4.19	0.13%
FLUTIC/VILAN INH 200/25MCG	43	15	$9,560.43	$222.34	2.87	0.03%
FLUTIC/VILAN INH 100/25MCG	28	8	$6,293.66	$224.77	3.5	0.02%
DULERA AER 50/5MCG	15	10	$4,877.89	$325.19	1.5	0.01%
SUBTOTAL	**355**	**97**	**$117,032.59**	**$329.67**	**3.66**	**0.33%**
ICS/LABA TOTAL	**56,067**	**22,819**	**$16,769,971.47**	**$299.11**	**2.46**	**47.49%**
INDIVIDUAL COMPONENT ICS PRODUCTS						
TIER-1 UTILIZATION						
FLUTICASONE HFA AER 110MCG	11,879	6,229	$2,297,090.74	193.37	1.91	6.50%
FLUTICASONE HFA AER 44MCG	11,398	6,025	$1,570,665.30	$137.80	1.89	4.45%
FLOVENT HFA AER 110MCG	3,174	1,979	$863,275.77	$271.98	1.6	2.44%
FLOVENT HFA AER 44MCG	3,094	1,976	$632,091.16	$204.30	1.57	1.79%
BUDESONIDE SUS 0.5MG/2ML	3,051	1,624	$167,135.16	$54.78	1.88	0.47%
BUDESONIDE SUS 0.25MG/2ML	1,739	1,170	$133,849.05	$76.97	1.49	0.38%
FLUTICASONE HFA AER 220MCG	1,155	634	$329,137.81	$284.97	1.82	0.93%
PULMICORT INH 90MCG	632	370	$137,303.63	$217.25	1.71	0.39%
ASMANEX HFA AER 100MCG	577	326	$94,270.18	$163.38	1.77	0.27%
PULMICORT INH 180MCG	540	303	$150,123.82	$278.01	1.78	0.43%
FLOVENT HFA AER 220MCG	447	290	$186,793.78	$417.88	1.54	0.53%
BUDESONIDE SUS 1MG/2ML	379	158	$125,434.01	$330.96	2.4	0.36%
FLOVENT DISKUS AER 100MCG	206	126	$50,445.93	$244.88	1.63	0.14%
ALVESCO AER 80MCG	187	102	$51,264.23	$274.14	1.83	0.15%
FLOVENT DISKUS AER 50MCG	170	101	$36,956.35	$217.39	1.68	0.10%
ASMANEX HFA AER 200 MCG	157	79	$29,559.52	$188.28	1.99	0.08%
FLUTICASONE AER 100MCG	127	72	$21,609.47	$170.15	1.76	0.06%
ASMANEX 60 AER 220MCG	107	41	$22,113.41	$206.67	2.61	0.06%
FLOVENT DISKUS AER 250MCG	103	51	$33,563.18	$325.86	2.02	0.10%
ARNUITY ELLIPTA INH 100MCG	98	52	$16,384.62	$167.19	1.88	0.05%
FLUTICASONE AER 50MCG	74	51	$12,240.85	$165.42	1.45	0.03%
ALVESCO AER 160MCG	67	23	$18,318.04	$273.40	2.91	0.05%
FLUTICASONE AER 250MCG	59	33	$13,034.90	$220.93	1.79	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ASMANEX 30 AER 220MCG	56	24	$11,906.09	$212.61	2.33	0.03%
ASMANEX 120 AER 220MCG	48	25	$15,580.87	$324.60	1.92	0.04%
ASMANEX 30 AER 110MCG	40	17	$6,184.24	$154.61	2.35	0.02%
ARNUITY ELLIPTA INH 200MCG	32	16	$7,842.83	$245.09	2	0.02%
ASMANEX HFA AER 50MCG	31	24	$3,372.46	$108.79	1.29	0.01%
ARNUITY ELLIPTA INH 50MCG	7	6	$1,331.85	$190.26	1.17	0.00%
ASMANEX 14 AER 220MCG	2	1	$100.42	$50.21	2	0.00%
PULMICORT SUS 0.25MG/2ML	2	2	$545.74	$272.87	1	0.00%
SUBTOTAL	**39,638**	**21,930**	**$7,039,525.41**	**$177.60**	**1.81**	**19.93%**
TIER-2 UTILIZATION						
QVAR REDIHALER AER 80MCG	45	10	$11,598.31	$257.74	4.5	0.03%
QVAR REDIHALER AER 40MCG	6	4	$814.80	$135.80	1.5	0.00%
SUBTOTAL	**51**	**14**	**$12,413.11**	**$243.39**	**3.64**	**0.04%**
ICS TOTAL	**39,689**	**21,944**	**$7,051,938.52**	**$177.68**	**1.81**	**19.97%**
INDIVIDUAL COMPONENT LAMA PRODUCTS						
TIER-1 UTILIZATION						
SPIRIVA SPR 2.5MCG	7,489	2,199	$3,702,541.12	$494.40	3.41	10.48%
SPIRIVA CAP HANDIHALER 18MCG	3,828	1,489	$2,724,067.39	$711.62	2.57	7.71%
SPIRIVA AER 1.25MCG	3,594	1,103	$1,699,669.33	$472.92	3.26	4.81%
TIOTROPIUM BROM CAP 18MCG	956	608	$646,058.42	$675.79	1.57	1.83%
INCRUSE ELLIPTA INH 62.5MCG	239	108	$81,429.61	$340.71	2.21	0.23%
TUDORZA PRES AER 400MCG/ACT	36	10	$18,753.41	$520.93	3.6	0.05%
SUBTOTAL	**16,142**	**5,517**	**$8,872,519.28**	**$549.65**	**2.93**	**25.12%**
TIER-2 UTILIZATION						
YUPELRI SOL 175MCG/3ML	82	28	$96,143.36	$1,172.48	2.93	0.27%
SUBTOTAL	**82**	**28**	**$96,143.36**	**$1,172.48**	**2.93**	**0.27%**
LAMA TOTAL	**16,224**	**5,545**	**$8,968,662.64**	**$552.80**	**2.93**	**25.40%**
LABA/LAMA/ICS COMBINATION PRODUCTS						
TRELEGY AER 100/62.5/25MCG	1,350	286	$832,660.52	$616.79	4.72	2.36%
TRELEGY AER 200/62.5/25MCG	1,094	223	$669,896.40	$612.34	4.91	1.90%
BREZTRI AEROSPHERE 160/9/4.8MCG	572	149	$388,667.91	$679.49	3.84	1.10%
LABA/LAMA/ICS TOTAL	**3,016**	**658**	**$1,891,224.83**	**$627.06**	**4.58**	**5.36%**
INDIVIDUAL COMPONENT LABA PRODUCTS						
TIER-1 UTILIZATION						
SEREVENT DISKUS AER 50MCG	743	303	$355,587.57	$478.58	2.45	1.01%
SUBTOTAL	**743**	**303**	**$355,587.57**	**$478.58**	**2.45**	**1.01%**
TIER-2 UTILIZATION						
ARFORMOTEROL NEB 15MCG/2ML	82	24	$12,973.24	$158.21	3.42	0.04%
FORMOTEROL NEB 20MCG/2ML	51	12	$20,974.68	$411.27	4.25	0.06%
BROVANA NEB 15MCG	1	1	$1,189.29	$1,189.29	1	0.00%
PERFOROMIST NEB 20MCG	1	1	$1,086.71	$1,086.71	1	0.00%
SUBTOTAL	**135**	**38**	**$36,223.92**	**$268.33**	**3.55**	**0.10%**
LABA TOTAL	**878**	**341**	**$391,811.49**	**$446.25**	**2.57**	**1.11%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LABA/LAMA COMBINATION PRODUCTS						
ANORO ELLIPTA AER 62.5/25MCG	346	64	$151,264.09	$437.18	5.41	0.43%
STIOLTO AER 2.5/2.5MCG	129	35	$58,872.67	$456.38	3.69	0.17%
BEVESPI AER 9/4.8MCG	25	7	$10,374.18	$414.97	3.57	0.03%
LABA/LAMA TOTAL	**500**	**106**	**$220,510.94**	**$441.02**	**4.72**	**0.62%**
PDE4 ENZYME INHIBITOR PRODUCTS						
ROFLUMILAST TAB 500MCG	207	38	$4,511.52	$21.79	5.45	0.01%
ROFLUMILAST TAB 250MCG	45	13	$5,292.27	$117.61	3.46	0.01%
DALIRESP TAB 250MCG	21	2	$5,936.81	$282.71	10.5	0.02%
DALIRESP TAB 500MCG	10	4	$4,218.94	$421.89	2.5	0.01%
PDE4 ENZYME INHIBITOR TOTAL	**283**	**57**	**$19,959.54**	**$70.53**	**4.96**	**0.06%**
TOTAL	**116,657**	**38,939***	**$35,314,079.43**	**$302.72**	**3**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; AER = aerosol; BROM = bromide; BUDES = budesonide; CAP = capsule; FLUTIC = fluticasone; FORMOT = formoterol; HFA = hydrofluoroalkane; ICS = inhaled corticosteroid; INH = inhaler; LABA = long-acting beta$_2$ agonist; LAMA = long-acting muscarinic antagonist; NEB = nebulizer; PDE4 = phosphodiesterase-4; PRES = Pressair; SALME = salmeterol; SOL = solution; SPR = spray; TAB = tablet; VILAN = vilanterol
⁺The claim for fluticasone/salmeterol 113/14MCG in FY24 was for 1 member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ICS/LABA COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
SYMBICORT AER 160/4.5MCG	656	442	$174,711.48	$266.33	1.48	11.67%
FLUTIC/SALME AER 250/50MCG	420	302	$40,537.57	$96.52	1.39	2.71%
SYMBICORT AER 80/4.5MCG	361	278	$83,008.71	$229.94	1.3	5.54%
FLUTIC/SALME AER 115/21MCG	236	172	$58,999.30	$250.00	1.37	3.94%
DULERA AER 200/5MCG	192	112	$66,873.61	$348.30	1.71	4.47%
FLUTIC/SALME AER 100/50MCG	160	122	$11,184.70	$69.90	1.31	0.75%
ADVAIR HFA AER 115/21MCG	157	118	$51,759.83	$329.68	1.33	3.46%
DULERA AER 100/5MCG	129	87	$45,497.20	$352.69	1.48	3.04%
FLUTIC/SALME AER 500/50MCG	124	80	$15,229.72	$122.82	1.55	1.02%
FLUTIC/SALME AER 45/21MCG	115	82	$24,435.36	$212.48	1.4	1.63%
ADVAIR DISKUS AER 250/50MCG	67	59	$17,297.58	$258.17	1.14	1.16%
FLUTIC/SALME AER 230/21MCG	63	53	$21,323.90	$338.47	1.19	1.42%
ADVAIR HFA AER 45/21MCG	39	29	$10,300.20	$264.11	1.34	0.69%
ADVAIR HFA AER 230/21MCG	33	24	$15,820.98	$479.42	1.38	1.06%
ADVAIR DISKUS AER 100/50MCG	29	23	$5,268.99	$181.69	1.26	0.35%
ADVAIR DISKUS AER 500/50MCG	27	22	$8,701.98	$322.30	1.23	0.58%
BUDES/FORMOT AER 80/4.5MCG	15	9	$2,743.83	$182.92	1.67	0.18%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BUDES/FORMOT AER 160/4.5MCG	12	9	$2,580.74	$215.06	1.33	0.17%
BREYNA AER 80/4.5MCG	6	3	$1,380.68	$230.11	2	0.09%
WIXELA INHUB AER 250/50MCG	6	6	$499.36	$83.23	1	0.03%
BREYNA AER 160/4.5MCG	4	2	$764.74	$191.19	2	0.05%
WIXELA INHUB AER 500/50MCG	2	2	$276.46	$138.23	1	0.02%
FLUTIC/SALME INH 55/14MCG	2	2	$215.00	$107.50	1	0.01%
WIXELA INHUB AER 100/50MCG	2	2	$147.74	$73.87	1	0.01%
FLUTIC/SALME INH 113/14MCG	1	1	$104.73	$104.73	1	0.01%
SUBTOTAL	**2,858**	**2,041**	**$659,664.39**	**$230.81**	**1.4**	**44.06%**
TIER-2 UTILIZATION						
BREO ELLIPTA INH 100/25MCG	27	17	$10,851.06	$401.89	1.59	0.72%
BREO ELLIPTA INH 200/25MCG	13	9	$5,223.49	$401.81	1.44	0.35%
DULERA AER 50/5MCG	2	2	$678.19	$339.10	1	0.05%
SUBTOTAL	**42**	**28**	**$16,752.74**	**$398.87**	**1.5**	**1.12%**
ICS/LABA TOTAL	**2,900**	**2,069**	**$676,417.13**	**$233.25**	**1.4**	**45.17%**
INDIVIDUAL COMPONENT ICS PRODUCTS						
TIER-1 UTILIZATION						
FLUTICASONE HFA AER 44MCG	687	525	$92,644.77	$134.85	1.31	6.19%
FLUTICASONE HFA AER 110MCG	672	518	$120,629.97	$179.51	1.3	8.06%
BUDESONIDE SUS 0.5MG/2ML	127	91	$7,303.92	$57.51	1.4	0.49%
BUDESONIDE SUS 0.25MG/2ML	93	75	$7,179.35	$77.20	1.24	0.48%
FLUTICASONE HFA AER 220MCG	56	42	$15,140.60	$270.37	1.33	1.01%
PULMICORT INH 90MCG	34	24	$7,780.62	$228.84	1.42	0.52%
ASMANEX HFA AER 100MCG	26	21	$2,802.56	$107.79	1.24	0.19%
FLOVENT HFA AER 44MCG	16	13	$3,319.06	$207.44	1.23	0.22%
BUDESONIDE SUS 1MG/2ML	15	13	$3,279.40	$218.63	1.15	0.22%
FLUTICASONE AER 100MCG	14	9	$2,407.38	$171.96	1.56	0.16%
PULMICORT INH 180MCG	14	11	$3,713.47	$265.25	1.27	0.25%
FLUTICASONE AER 50MCG	12	10	$2,002.50	$166.88	1.2	0.13%
FLOVENT HFA AER 110MCG	10	9	$2,738.78	$273.88	1.11	0.18%
ARNUITY ELLIPTA INH 50MCG	7	6	$1,482.04	$211.72	1.17	0.10%
FLUTICASONE AER 250MCG	6	6	$1,377.20	$229.53	1	0.09%
ALVESCO AER 80MCG	6	6	$1,646.04	$274.34	1	0.11%
ASMANEX HFA AER 200MCG	5	5	$622.92	$124.58	1	0.04%
ASMANEX 120 AER 220MCG	4	3	$694.82	$173.71	1.33	0.05%
ARNUITY ELLIPTA INH 200MCG	3	1	$837.38	$279.13	3	0.06%
ASMANEX HFA AER 50MCG	3	3	$302.01	$100.67	1	0.02%
ARNUITY ELLIPTA INH 100MCG	2	2	$422.76	$211.38	1	0.03%
ALVESCO AER 160MCG	2	2	$549.46	$274.73	1	0.04%
ASMANEX 60 AER 220MCG	2	1	$248.68	$124.34	2	0.02%
ASMANEX 30 AER 110MCG	2	2	$201.42	$100.71	1	0.01%
FLOVENT HFA AER 220MCG	1	1	$419.01	$419.01	1	0.03%
SUBTOTAL	**1,819**	**1,399**	**$279,746.12**	**$153.79**	**1.3**	**18.68%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-2 UTILIZATION						
QVAR REDIHALER AER 80MCG	21	17	$6,014.70	$286.41	1.24	0.40%
QVAR REDIHALER AER 40MCG	9	9	$1,951.26	$216.81	1	0.13%
SUBTOTAL	**30**	**26**	**$7,965.96**	**$265.53**	**1.15**	**0.53%**
ICS TOTAL	**1,849**	**1,425**	**$287,712.08**	**$155.60**	**1.3**	**19.21%**
INDIVIDUAL COMPONENT LAMA PRODUCTS						
TIER-1 UTILIZATION						
SPIRIVA SPR 2.5MCG	267	161	$137,294.85	$514.21	1.66	9.17%
SPIRIVA AER 1.25MCG	191	110	$98,583.68	$516.14	1.74	6.58%
SPIRIVA CAP HANDIHALER 18MCG	141	98	$110,980.30	$787.09	1.44	7.41%
INCRUSE ELLIPTA INH 62.5MCG	22	14	$7,723.58	$351.07	1.57	0.52%
TIOTROPIUM BROM CAP 18MCG	2	2	$1,510.82	$755.41	1	0.10%
LAMA TOTAL	**623**	**385**	**$356,093.23**	**$571.58**	**1.62**	**23.78%**
LABA/LAMA/ICS COMBINATION PRODUCTS						
TRELEGY AER 100/62.5/25MCG	100	70	$64,326.86	$643.27	1.43	4.30%
TRELEGY AER 200/62.5/25MCG	89	57	$57,260.70	$643.38	1.56	3.82%
BREZTRI AEROSPHERE 160/9/4.8MCG	49	31	$30,882.10	$630.25	1.58	2.06%
LABA/LAMA/ICS TOTAL	**238**	**158**	**$152,469.66**	**$640.63**	**1.51**	**10.18%**
INDIVIDUAL COMPONENT LABA PRODUCTS						
TIER-1 UTILIZATION						
SEREVENT DISKUS AER 50MCG	27	17	$12,067.05	$446.93	1.59	0.81%
SUBTOTAL	**27**	**17**	**$12,067.05**	**$446.93**	**1.59**	**0.81%**
TIER-2 UTILIZATION						
ARFORMOTEROL NEB 15MCG/2ML	2	2	$245.96	$122.98	1	0.02%
FORMOTEROL NEB 20MCG/2ML	1	1	$288.56	$288.56	1	0.02%
SUBTOTAL	**3**	**3**	**$534.52**	**$178.17**	**1**	**0.04%**
LABA TOTAL	**30**	**20**	**$12,601.57**	**$420.05**	**1.5**	**0.84%**
LABA/LAMA COMBINATION PRODUCTS						
STIOLTO AER 2.5/2.5MCG	14	11	$6,649.45	$474.96	1.27	0.44%
ANORO ELLIPTA AER 62.5/25MCG	10	10	$4,665.90	$466.59	1	0.31%
BEVESPI AER 9/4.8MCG	1	1	$425.83	$425.83	1	0.03%
LABA/LAMA TOTAL	**25**	**22**	**$11,741.18**	**$469.65**	**1.14**	**0.78%**
PDE4 ENZYME INHIBITOR PRODUCTS						
ROFLUMILAST TAB 500MCG	6	4	$123.23	$20.54	1.5	0.01%
ROFLUMILAST TAB 250MCG	2	2	$180.69	$90.35	1	0.01%
PDE4 ENZYME INHIBITOR TOTAL	**8**	**6**	**$303.92**	**$37.99**	**1.33**	**0.02%**
TOTAL	**5,673**	**3,602***	**$1,497,338.77**	**$263.94**	**1.57**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; AER = aerosol; BROM = bromide; BUDES = budesonide; CAP = capsule; FLUTIC = fluticasone; FORMOT = formoterol; HFA = hydrofluoroalkane; ICS = inhaled corticosteroid; INH = inhaler; LABA = long-acting beta$_2$ agonist; LAMA = long-acting muscarinic antagonist; NEB = nebulizer; PDE4 = phosphodiesterase-4; PRES = Pressair; SALME = salmeterol; SOL = solution; SPR = spray; TAB = tablet; VILAN = vilanterol
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.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ICS/LABA COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
SYMBICORT AER 160/4.5MCG	883	553	$238,925.31	$270.58	1.6	11.18%
FLUTIC/SALME AER 250/50MCG	437	300	$46,114.42	$105.52	1.46	2.16%
SYMBICORT AER 80/4.5MCG	435	299	$97,821.82	$224.88	1.45	4.58%
FLUTIC/SALME AER 115/21MCG	318	219	$83,067.83	$261.22	1.45	3.89%
DULERA AER 200/5MCG	186	109	$67,027.87	$360.36	1.71	3.14%
FLUTIC/SALME AER 100/50MCG	152	120	$12,064.10	$79.37	1.27	0.56%
ADVAIR HFA AER 115/21MCG	149	107	$48,466.19	$325.28	1.39	2.27%
WIXELA INHUB AER 250/50MCG	141	105	$14,347.07	$101.75	1.34	0.67%
FLUTIC/SALME AER 500/50MCG	123	79	$17,621.99	$143.27	1.56	0.82%
ADVAIR DISKUS AER 250/50MCG	119	79	$27,267.38	$229.14	1.51	1.28%
FLUTIC/SALME AER 230/21MCG	119	81	$41,459.77	$348.40	1.47	1.94%
FLUTIC/SALME AER 45/21MCG	110	74	$22,289.17	$202.63	1.49	1.04%
DULERA AER 100/5MCG	102	69	$35,344.61	$346.52	1.48	1.65%
WIXELA INHUB AER 100/50MCG	53	46	$4,118.02	$77.70	1.15	0.19%
ADVAIR DISKUS AER 500/50MCG	48	33	$16,568.94	$345.19	1.45	0.78%
WIXELA INHUB AER 500/50MCG	37	29	$5,406.18	$146.11	1.28	0.25%
ADVAIR HFA AER 45/21MCG	35	25	$8,812.51	$251.79	1.4	0.41%
ADVAIR HFA AER 230/21MCG	32	26	$15,390.07	$480.94	1.23	0.72%
ADVAIR DISKUS AER 100/50MCG	29	22	$5,266.65	$181.61	1.32	0.25%
FLUTIC/SALME INH 113/14MCG	6	3	$641.34	$106.89	2	0.03%
FLUTIC/SALME INH 232/14MCG	2	1	$219.24	$109.62	2	0.01%
FLUTIC/SALME INH 55/14MCG	2	1	$218.29	$109.15	2	0.01%
SUBTOTAL	**3,518**	**2,380**	**$808,458.77**	**$229.81**	**1.48**	**37.84%**
TIER-2 UTILIZATION						
BREO ELLIPTA INH 100/25MCG	51	32	$19,839.28	$389.01	1.59	0.93%
BREO ELLIPTA INH 200/25MCG	49	27	$19,692.73	$401.89	1.81	0.92%
DULERA AER 50/5MCG	4	3	$1,356.18	$339.05	1.33	0.06%
BREO ELLIPTA INH 50/25MCG	3	3	$1,255.89	$418.63	1	0.06%
SUBTOTAL	**107**	**65**	**$42,144.08**	**$393.87**	**1.65**	**1.97%**
ICS/LABA TOTAL	**3,625**	**2,445**	**$850,602.85**	**$234.65**	**1.48**	**39.81%**
INDIVIDUAL COMPONENT ICS PRODUCTS						
TIER-1 UTILIZATION						
FLUTICASONE HFA AER 110MCG	853	627	$155,462.12	$182.25	1.36	7.28%
FLUTICASONE HFA AER 44MCG	851	622	$115,701.52	$135.96	1.37	5.42%
BUDESONIDE SUS 0.5MG/2ML	146	106	$8,239.98	$56.44	1.38	0.39%
BUDESONIDE SUS 0.25MG/2ML	102	85	$7,664.32	$75.14	1.2	0.36%
FLUTICASONE HFA AER 220MCG	97	77	$27,107.08	$279.45	1.26	1.27%
PULMICORT INH 90MCG	48	39	$11,162.44	$232.55	1.23	0.52%
PULMICORT INH 180MCG	37	33	$11,337.50	$306.42	1.12	0.53%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ARNUITY ELLIPTA INH 100MCG	23	11	$4,862.08	$211.39	2.09	0.23%
ASMANEX HFA AER 100 MCG	23	16	$2,479.27	$107.79	1.44	0.12%
FLUTICASONE AER 100MCG	13	8	$1,818.64	$139.90	1.63	0.09%
ASMANEX HFA AER 200MCG	12	10	$1,495.02	$124.59	1.2	0.07%
BUDESONIDE SUS 1MG/2ML	10	7	$2,880.25	$288.03	1.43	0.13%
ALVESCO AER 160MCG	9	4	$2,472.73	$274.75	2.25	0.12%
FLUTICASONE AER 50MCG	8	6	$1,290.82	$161.35	1.33	0.06%
ARNUITY ELLIPTA INH 200MCG	7	4	$1,954.02	$279.15	1.75	0.09%
ASMANEX 60 AER 220MCG	6	6	$971.42	$161.90	1	0.05%
ALVESCO AER 80MCG	6	3	$1,647.20	$274.53	2	0.08%
FLOVENT HFA AER 110MCG	5	5	$1,369.32	$273.86	1	0.06%
FLOVENT HFA AER 44MCG	5	5	$856.51	$171.30	1	0.04%
ASMANEX HFA AER 50MCG	4	3	$403.62	$100.91	1.33	0.02%
FLUTICASONE AER 250MCG	4	4	$1,281.42	$320.36	1	0.06%
ASMANEX 30 AER 110MCG	3	3	$302.18	$100.73	1	0.01%
ASMANEX 120 AER 220MCG	1	1	$173.74	$173.74	1	0.01%
PULMICORT SUS 0.25MG/2ML	1	1	$262.03	$262.03	1	0.01%
FLOVENT HFA AER 220MCG	1	1	$418.46	$418.46	1	0.02%
SUBTOTAL	**2,275**	**1,687**	**$363,613.69**	**$159.83**	**1.35**	**17.02%**
TIER-2 UTILIZATION						
QVAR REDIHALER AER 40MCG	22	20	$4,771.03	$216.87	1.1	0.22%
QVAR REDIHALER AER 80MCG	21	16	$6,015.04	$286.43	1.31	0.28%
SUBTOTAL	**43**	**36**	**$10,786.07**	**$250.84**	**1.19**	**0.50%**
ICS TOTAL	**2,318**	**1,723**	**$374,399.76**	**$161.52**	**1.35**	**17.52%**
INDIVIDUAL COMPONENT LAMA PRODUCTS						
TIER-1 UTILIZATION						
SPIRIVA SPR 2.5MCG	498	267	$256,414.64	$514.89	1.87	12.00%
SPIRIVA CAP HANDIHALER 18MCG	219	139	$147,264.21	$672.44	1.58	6.89%
SPIRIVA AER 1.25MCG	217	129	$112,006.89	$516.16	1.68	5.24%
INCRUSE ELLIPTA INH 62.5MCG	21	11	$7,372.99	$351.09	1.91	0.35%
TUDORZA PRES AER 400MCG/ACT	4	2	$1,845.64	$461.41	2	0.09%
SUBTOTAL	**959**	**548**	**$524,904.37**	**$547.35**	**1.75**	**24.57%**
TIER-2 UTILIZATION						
YUPELRI SOL 175MCG/3ML	6	4	$7,884.42	$1,314.07	1.5	0.37%
SUBTOTAL	**6**	**4**	**$7,884.42**	**$1,314.07**	**1.5**	**0.37%**
LAMA TOTAL	**965**	**552**	**$532,788.79**	**$552.11**	**1.75**	**24.94%**
LABA/LAMA/ICS COMBINATION PRODUCTS						
TRELEGY AER 100/62.5/25MCG	193	113	$122,772.30	$636.13	1.71	5.75%
TRELEGY AER 200/62.5/25MCG	184	99	$118,998.53	$646.73	1.86	5.57%
BREZTRI AEROSPHERE 160/9/4.8MCG	116	80	$73,127.76	$630.41	1.45	3.42%
LABA/LAMA/ICS TOTAL	**493**	**292**	**$314,898.59**	**$638.74**	**1.69**	**14.74%**
LABA/LAMA COMBINATION PRODUCTS						
ANORO ELLIPTA AER 62.5/25MCG	50	31	$23,346.53	$466.93	1.61	1.09%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
STIOLTO AER 2.5/2.5MCG	40	25	$19,010.18	$475.25	1.6	0.89%
BEVESPI AER 9/4.8MCG	1	1	$425.83	$425.83	1	0.02%
LABA/LAMA TOTAL	**91**	**57**	**$42,782.54**	**$470.14**	**1.6**	**2.00%**
INDIVIDUAL COMPONENT LABA PRODUCTS						
TIER-1 UTILIZATION						
SEREVENT DISKUS AER 50MCG	44	23	$18,343.82	$416.91	1.91	0.86%
SUBTOTAL	**44**	**23**	**$18,343.82**	**$416.91**	**1.91**	**0.86%**
TIER-2 UTILIZATION						
ARFORMOTEROL NEB 15MCG/2ML	4	3	$567.65	$141.91	1.33	0.03%
BROVANA NEB 15MCG	1	1	$1,193.29	$1,193.29	1	0.06%
SUBTOTAL	**5**	**4**	**$1,760.94**	**$352.19**	**1.25**	**0.08%**
LABA TOTAL	**49**	**27**	**$20,104.76**	**$410.30**	**1.81**	**0.94%**
PDE4 ENZYME INHIBITOR PRODUCTS						
ROFLUMILAST TAB 500MCG	18	11	$373.62	$20.76	1.64	0.02%
ROFLUMILAST TAB 250MCG	7	3	$523.04	$74.72	2.33	0.02%
PDE4 ENZYME INHIBITOR TOTAL	**25**	**14**	**$896.66**	**$35.87**	**1.79**	**0.04%**
TOTAL	**7,566**	**4,388***	**$2,136,473.95**	**$282.38**	**1.72**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; AER = aerosol; BUDES = budesonide; CAP = capsule; FLUTIC = fluticasone; FORMOT = formoterol; HFA = hydrofluoroalkane; ICS = inhaled corticosteroid; INH = inhaler; LABA = long-acting beta$_2$ agonist; LAMA = long-acting muscarinic antagonist; NEB = nebulizer; PDE4 = phosphodiesterase-4; PRES = Pressair; SALME = salmeterol; SOL = solution; SPR = spray; TAB = tablet; VILAN = vilanterol
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.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ICS/LABA COMBINATION PRODUCTS						
TIER-1 UTILIZATION						
SYMBICORT AER 160/4.5MCG	378	264	$105,646.23	$279.49	1.43	6.01%
FLUTIC/SALME AER 250/50MCG	325	240	$31,325.91	$96.39	1.35	1.78%
FLUTIC/SALME AER 115/21MCG	282	196	$81,812.14	$290.11	1.44	4.66%
SYMBICORT AER 80/4.5MCG	256	180	$57,393.83	$224.19	1.42	3.27%
ADVAIR HFA AER 115/21MCG	240	163	$79,147.95	$329.78	1.47	4.51%
DULERA AER 200/5MCG	180	118	$63,072.85	$350.40	1.53	3.59%
FLUTIC/SALME AER 100/50MCG	149	106	$11,076.67	$74.34	1.41	0.63%
BUDES/FORMOT AER 160/4.5MCG	143	120	$35,251.01	$246.51	1.19	2.01%
FLUTIC/SALME AER 500/50MCG	114	74	$15,425.59	$135.31	1.54	0.88%
BUDES/FORMOT AER 80/4.5MCG	112	90	$21,497.10	$191.94	1.24	1.22%
WIXELA INHUB AER 250/50MCG	112	83	$10,971.60	$97.96	1.35	0.62%
FLUTIC/SALME AER 45/21MCG	112	76	$25,475.56	$227.46	1.47	1.45%
BREYNA AER 80/4.5MCG	106	78	$19,438.51	$183.38	1.36	1.11%
DULERA AER 100/5MCG	103	74	$35,673.94	$346.35	1.39	2.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BREYNA AER 160/4.5MCG	102	74	$21,656.91	$212.32	1.38	1.23%
ADVAIR HFA AER 45/21MCG	81	59	$21,356.10	$263.66	1.37	1.22%
FLUTIC/SALME AER 230/21MCG	66	44	$24,340.22	$368.79	1.50	1.39%
FLUTICASONE HFA AER 220MCG	63	53	$18,965.19	$301.03	1.19	1.08%
ADVAIR DISKUS AER 250/50MCG	57	43	$11,728.18	$205.76	1.33	0.67%
ADVAIR HFA AER 230/21MCG	40	31	$18,177.36	$454.43	1.29	1.03%
WIXELA INHUB AER 100/50MCG	39	29	$3,161.72	$81.07	1.34	0.18%
WIXELA INHUB AER 500/50MCG	35	25	$5,287.93	$151.08	1.4	0.30%
ADVAIR DISKUS AER 500/50MCG	34	22	$9,540.93	$280.62	1.55	0.54%
ADVAIR DISKUS AER 100/50MCG	23	16	$4,299.88	$186.95	1.44	0.24%
FLUTIC/SALME INH 113/14MCG	5	3	$551.62	$110.32	1.67	0.03%
FLUTIC/SALME INH 232/14MCG	1	1	$119.99	$119.99	1	0.01%
SUBTOTAL	**3,158**	**2,262**	**$732,394.92**	**$231.92**	**1.4**	**41.69%**
TIER-2 UTILIZATION						
BREO ELLIPTA INH 100/25MCG	15	11	$6,030.77	$402.05	1.36	0.34%
FLUTIC/VILAN INH 100/25MCG	14	11	$3,652.74	$260.91	1.27	0.21%
BREO ELLIPTA INH 200/25MCG	10	6	$4,018.61	$401.86	1.67	0.23%
FLUTIC/VILAN INH 200/25MCG	6	6	$1,565.46	$260.91	1	0.09%
BREO ELLIPTA INH 50/25MCG	2	1	$821.03	$410.52	2	0.05%
DULERA AER 50/5MCG	1	1	$339.45	$339.45	1	0.02%
SUBTOTAL	**48**	**36**	**$16,428.06**	**$342.25**	**1.33**	**0.94%**
ICS/LABA TOTAL	**3,206**	**2,298**	**$748,822.98**	**$233.57**	**1.4**	**42.63%**
INDIVIDUAL COMPONENT ICS PRODUCTS						
TIER-1 UTILIZATION						
FLUTICASONE HFA AER 44MCG	925	687	$138,718.05	$149.97	1.35	7.90%
FLUTICASONE HFA AER 110MCG	884	652	$183,626.69	$207.72	1.36	10.45%
BUDESONIDE SUS 0.25MG/2ML	148	118	$11,903.25	$80.43	1.25	0.68%
BUDESONIDE SUS 0.5MG/2ML	135	101	$7,787.41	$57.68	1.34	0.44%
PULMICORT INH 90MCG	39	33	$8,975.90	$230.15	1.18	0.51%
PULMICORT INH 180MCG	36	31	$10,818.63	$300.52	1.16	0.62%
ASMANEX HFA AER 100MCG	26	20	$2,802.66	$107.79	1.3	0.16%
BUDESONIDE SUS 1MG/2ML	24	12	$6,655.82	$277.33	2	0.38%
FLUTICASONE AER 50MCG	20	14	$2,947.41	$147.37	1.43	0.17%
FLOVENT HFA AER 110MCG	17	12	$4,655.66	$273.86	1.42	0.27%
FLOVENT HFA AER 44MCG	13	12	$2,696.98	$207.46	1.08	0.15%
ARNUITY ELLIPTA INH 100MCG	12	8	$2,536.72	$211.39	1.5	0.14%
FLUTICASONE AER 250MCG	11	7	$2,596.63	$236.06	1.57	0.15%
FLUTICASONE AER 100MCG	9	8	$1,831.04	$203.45	1.13	0.10%
ARNUITY ELLIPTA INH 200MCG	8	5	$2,232.92	$279.12	1.6	0.13%
ALVESCO AER 80MCG	7	5	$1,921.97	$274.57	1.4	0.11%
ASMANEX HFA AER 200MCG	7	5	$872.10	$124.59	1.4	0.05%
FLOVENT HFA AER 220MCG	4	4	$1,675.49	$418.87	1	0.10%
ASMANEX 120 AER 220MCG	3	2	$521.18	$173.73	1.5	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ARNUITY ELLIPTA INH 50MCG	3	2	$634.78	$211.59	1.5	0.04%
FLOVENT DISKUS AER 50MCG	2	2	$394.38	$197.19	1	0.02%
ASMANEX HFA AER 50MCG	2	2	$202.28	$101.14	1	0.01%
ASMANEX 60 AER 220MCG	1	1	$124.26	$124.26	1	0.01%
ASMANEX 30 AER 220MCG	1	1	$107.84	$107.84	1	0.01%
ASMANEX 30 AER 110MCG	1	1	$100.69	$100.69	1	0.01%
FLOVENT DISKUS AER 100MCG	1	1	$207.41	$207.41	1	0.01%
SUBTOTAL	**2,339**	**1,746**	**$397,548.15**	**$169.97**	**1.34**	**22.63%**
TIER-2 UTILIZATION						
QVAR REDIHALER AER 40MCG	28	22	$6,277.57	$224.20	1.27	0.36%
QVAR REDIHALER AER 80MCG	27	22	$7,733.72	$286.43	1.23	0.44%
SUBTOTAL	**55**	**44**	**$14,011.29**	**$254.75**	**1.25**	**0.80%**
ICS TOTAL	**2,394**	**1,790**	**$411,559.44**	**$171.91**	**1.34**	**23.43%**
INDIVIDUAL COMPONENT LAMA PRODUCTS						
TIER-1 UTILIZATION						
SPIRIVA SPR 2.5MCG	261	164	$134,679.78	$516.01	1.59	7.67%
SPIRIVA AER 1.25MCG	199	121	$102,552.78	$515.34	1.64	5.84%
SPIRIVA CAP HANDIHALER 18MCG	88	59	$57,939.35	$658.40	1.49	3.30%
TIOTROPIUM BROM CAP 18MCG	43	36	$27,417.94	$637.63	1.19	1.56%
INCRUSE ELLIPTA INH 62.5MCG	18	12	$6,319.62	$351.09	1.5	0.36%
SUBTOTAL	**609**	**392**	**$328,909.47**	**$540.08**	**1.55**	**18.72%**
TIER-2 UTILIZATION						
YUPELRI SOL 175MCG/3ML	5	3	$6,570.06	$1,314.01	1.67	0.37%
SUBTOTAL	**5**	**3**	**$6,570.06**	**$1,314.01**	**1.67**	**0.37%**
LAMA TOTAL	**614**	**395**	**$335,479.53**	**$546.38**	**1.55**	**19.10%**
LABA/LAMA/ICS COMBINATION PRODUCTS						
TRELEGY AER 100/62.5/25MCG	164	94	$106,333.81	$648.38	1.74	6.05%
TRELEGY AER 200/62.5/25MCG	85	52	$55,322.08	$650.85	1.63	3.15%
BREZTRI AEROSPHERE 160/9/4.8MCG	83	59	$52,321.55	$630.38	1.41	2.98%
LABA/LAMA/ICS TOTAL	**332**	**205**	**$213,977.44**	**$644.51**	**1.62**	**12.18%**
LABA/LAMA COMBINATION PRODUCTS						
ANORO ELLIPTA AER 62.5/25MCG	33	18	$15,403.41	$466.77	1.83	0.88%
STIOLTO AER 2.5/2.5MCG	26	17	$12,820.96	$493.11	1.53	0.73%
BEVESPI AER 9/4.8MCG	2	1	$851.85	$425.93	2	0.05%
LABA/LAMA TOTAL	**61**	**36**	**$29,076.22**	**$476.66**	**1.69**	**1.66%**
INDIVIDUAL COMPONENT LABA PRODUCTS						
TIER-1 UTILIZATION						
SEREVENT DISKUS AER 50MCG	30	18	$13,317.36	$443.91	1.67	0.76%
SUBTOTAL	**30**	**18**	**$13,317.36**	**$443.91**	**1.67**	**0.76%**
TIER-2 UTILIZATION						
ARFORMOTEROL NEB 15MCG/2ML	5	4	$789.19	$157.84	1.25	0.04%
FORMOTEROL NEB 20MCG/2ML	3	2	$1,152.15	$384.05	1.5	0.07%
BROVANA NEB 15MCG	2	1	$2,290.54	$1,145.27	2	0.13%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**10**	**7**	**$4,231.88**	**$423.19**	**1.43**	**0.24%**
LABA TOTAL	**40**	**25**	**$17,549.24**	**$438.73**	**1.6**	**1.00%**
PDE4 ENZYME INHIBITOR PRODUCTS						
ROFLUMILAST TAB 500MCG	7	5	$147.82	$21.12	1.4	0.01%
ROFLUMILAST TAB 250MCG	1	1	$67.31	$67.31	1	0.00%
PDE4 ENZYME INHIBITOR TOTAL	**8**	**6**	**$215.13**	**$26.89**	**1.33**	**0.01%**
TOTAL	**6,655**	**4,170***	**$1,756,679.98**	**$263.96**	**1.6**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; AER = aerosol; BROM = bromide; BUDES = budesonide; CAP = capsule; FLUTIC = fluticasone; FORMOT = formoterol; HFA = hydrofluoroalkane; ICS = inhaled corticosteroid; INH = inhaler; LABA = long-acting beta$_2$ agonist; LAMA = long-acting muscarinic antagonist; NEB = nebulizer; PDE4 = phosphodiesterase-4; PRES = Pressair; SALME = salmeterol; SOL = solution; SPR = spray; TAB = tablet; VILAN = vilanterol
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.

Utilization Details of Asthma-Indicated Monoclonal Antibodies: Fiscal Year 2023

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DUPILUMAB PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	2,933	602	$11,044,058.03	$3,765.45	4.87	48.15%
DUPIXENT INJ 300MG/2ML SYR	1,214	271	$4,325,967.35	$3,563.40	4.48	18.86%
DUPIXENT INJ 200MG/1.14ML SYR	903	183	$3,175,746.08	$3,516.88	4.93	13.85%
DUPIXENT INJ 200MG/1.4ML PEN	524	122	$1,921,948.97	$3,667.84	4.3	8.38%
SUBTOTAL	**5,574**	**1,178**	**$20,467,720.43**	**$3,672.00**	**4.73**	**89.24%**
OMALIZUMAB PRODUCTS						
XOLAIR INJ 150MG/ML SYR	272	47	$840,696.71	$3,090.80	5.79	3.67%
XOLAIR INJ 75MG/0.5ML SYR	79	13	$85,006.78	$1,076.04	6.08	0.37%
XOLAIR SOL 150MG	16	3	$39,836.03	$2,489.75	5.33	0.17%
SUBTOTAL	**367**	**63**	**$965,539.52**	**$2,630.90**	**5.83**	**4.21%**
BENRALIZUMAB PRODUCTS						
FASENRA INJ 30MG/ML PEN	138	43	$713,323.27	$5,169.01	3.21	3.11%
FASENRA INJ 30MG/ML SYR	37	12	$201,333.94	$5,441.46	3.08	0.88%
SUBTOTAL	**175**	**55**	**$914,657.21**	**$5,226.61**	**3.18**	**3.99%**
MEPOLIZUMAB PRODUCTS						
NUCALA INJ 100MG/ML AUTO	73	15	$273,362.10	$3,744.69	4.87	1.19%
NUCALA INJ 100MG	23	4	$78,076.99	$3,394.65	5.75	0.34%
NUCALA INJ 40MG/0.4ML SYR	23	2	$33,555.15	$1,458.92	11.5	0.15%
SUBTOTAL	**119**	**21**	**$384,994.24**	**$3,235.25**	**5.67**	**1.68%**
TEZEPELUMAB-EKKO PRODUCTS						
TEZSPIRE SOL 210MG SYR	45	8	$161,271.08	$3,583.80	5.63	0.70%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TEZSPIRE INJ 210MG AUTO	11	6	$42,503.20	$3,863.93	1.83	0.19%
SUBTOTAL	**56**	**14**	**$203,774.28**	**$3,638.83**	**4**	**0.89%**
TOTAL	**6,291**	**1,244***	**$22,936,685.68**	**$3,645.95**	**5.06**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; INJ = injection; SOL = solution; SYR = syringe
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: The above utilization data includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DUPILUMAB PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	188	98	$733,440.36	$3,901.28	1.92	42.70%
DUPIXENT INJ 300MG/2ML SYR	92	52	$353,433.85	$3,841.67	1.77	20.58%
DUPIXENT INJ 200MG/1.14ML PEN	57	28	$213,356.04	$3,743.09	2.04	12.42%
DUPIXENT INJ 200MG/1.14 SYR	55	26	$203,540.35	$3,700.73	2.12	11.85%
SUBTOTAL	**392**	**204**	**$1,503,770.60**	**$3,836.15**	**1.92**	**87.55%**
OMALIZUMAB PRODUCTS						
XOLAIR INJ 150MG/ML SYR	15	6	$42,448.35	$2,829.89	2.5	2.47%
XOLAIR SOL 150MG	4	2	$11,087.44	$2,771.86	2	0.65%
XOLAIR INJ 75MG/0.5ML SYR	4	1	$4,541.95	$1,135.49	4	0.26%
SUBTOTAL	**23**	**9**	**$58,077.74**	**$2,525.12**	**2.56**	**3.38%**
BENRALIZUMAB PRODUCTS						
FASENRA INJ 30MG/ML PEN	14	9	$79,634.24	$5,688.16	1.56	4.64%
FASENRA INJ 30MG/ML SYR	1	1	$5,688.16	$5,688.16	1	0.33%
SUBTOTAL	**15**	**10**	**$85,322.40**	**$5,688.16**	**1.5**	**4.97%**
MEPOLIZUMAB PRODUCTS						
NUCALA INJ 100MG/ML AUTO	5	2	$18,501.20	$3,700.24	2.5	1.08%
NUCALA INJ 40MG/0.4ML SYR	4	1	$5,947.80	$1,486.95	4	0.35%
SUBTOTAL	**9**	**3**	**$24,449.00**	**$2,716.56**	**3**	**1.42%**
TEZEPELUMAB-EKKO PRODUCTS						
TEZSPIRE SOL 210MG SYR	6	2	$24,306.78	$4,051.13	3	1.42%
TEZSPIRE INJ 210MG AUTO	5	4	$21,671.30	$4,334.26	1.25	1.26%
SUBTOTAL	**11**	**6**	**$45,978.08**	**$4,179.83**	**1.83**	**2.68%**
TOTAL	**450**	**225***	**$1,717,597.82**	**$3,816.88**	**2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; INJ = injection; SOL = solution; SYR = syringe
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.
Please note: The above utilization data includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DUPILUMAB PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	265	129	$1,020,882.55	$3,852.39	2.05	50.35%
DUPIXENT INJ 200MG/1.14ML SYR	70	34	$259,179.68	$3,702.57	2.06	12.78%
DUPIXENT INJ 300MG/2ML SYR	69	41	$257,735.12	$3,735.29	1.68	12.71%
DUPIXENT INJ 200MG/1.14ML PEN	61	33	$228,482.51	$3,745.61	1.85	11.27%
SUBTOTAL	**465**	**237**	**$1,766,279.86**	**$3,798.45**	**1.96**	**87.12%**
OMALIZUMAB PRODUCTS						
XOLAIR INJ 150MG/ML SYR	20	9	$61,276.46	$3,063.82	2.22	3.02%
XOLAIR INJ 75MG/0.5ML SYR	5	2	$5,105.45	$1,021.09	2.5	0.25%
XOLAIR INJ 300MG/2ML SYR	3	1	$6,659.31	$2,219.77	3	0.33%
XOLAIR SOL 150MG	2	1	$4,439.54	$2,219.77	2	0.22%
XOLAIR INJ 300MG/2ML AUTO	1	1	$2,219.77	$2,219.77	1	0.11%
SUBTOTAL	**31**	**14**	**$79,700.53**	**$2,570.98**	**2.21**	**3.93%**
BENRALIZUMAB PRODUCTS						
FASENRA INJ 30MG/ML PEN	18	10	$102,386.88	$5,688.16	1.8	5.05%
FASENRA INJ 30MG/ML SYR	6	4	$34,128.96	$5,688.16	1.5	1.68%
SUBTOTAL	**24**	**14**	**$136,515.84**	**$5,688.16**	**1.71**	**6.73%**
MEPOLIZUMAB PRODUCTS						
NUCALA INJ 100MG/ML AUTO	9	4	$33,302.16	$3,700.24	2.25	1.64%
NUCALA INJ 40MG/0.4ML SYR	2	1	$2,973.90	$1,486.95	2	0.15%
SUBTOTAL	**11**	**5**	**$36,276.06**	**$3,297.82**	**2.2**	**1.79%**
TEZEPELUMAB-EKKO PRODUCTS						
TEZSPIRE INJ 210MG AUTO	2	1	$8,668.52	$4,334.26	2	0.43%
SUBTOTAL	**2**	**1**	**$8,668.52**	**$4,334.26**	**2**	**0.43%**
TOTAL	**533**	**262***	**$2,027,440.81**	**$3,803.83**	**2.03**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; INJ = injection; SOL = solution; SYR = syringe
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.
Please note: The above utilization data includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Oklahoma Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DUPILUMAB PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	231	120	$903,258.65	$3,910.21	1.93	50.67%
DUPIXENT INJ 300MG/2ML SYR	85	48	$305,975.37	$3,599.71	1.77	17.16%
DUPIXENT INJ 200MG/1.14ML PEN	69	39	$255,428.42	$3,701.86	1.77	14.33%
DUPIXENT INJ 200MG/1.41ML SYR	49	26	$183,745.10	$3,749.90	1.88	10.31%
SUBTOTAL	**434**	**233**	**$1,648,407.54**	**$3,798.17**	**1.86**	**92.46%**
OMALIZUMAB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
XOLAIR INJ 150MG/ML SYR	8	4	$23,734.74	$2,966.84	2	1.33%
XOLAIR INJ 300MG/2ML AUTO	1	1	$2,781.33	$2,781.33	1	0.16%
XOLAIR INJ 300MG/2ML SYR	1	1	$2,781.33	$2,781.33	1	0.16%
SUBTOTAL	**10**	**6**	**$29,297.40**	**$2,929.74**	**1.67**	**1.64%**
BENRALIZUMAB PRODUCTS						
FASENRA INJ 30MG/ML PEN	8	5	$45,505.28	$5,688.16	1.6	2.55%
FASENRA INJ 30MG/MLSYR	2	2	$11,376.32	$5,688.16	1	0.64%
SUBTOTAL	**10**	**7**	**$56,881.60**	**$5,688.16**	**1.43**	**3.19%**
MEPOLIZUMAB PRODUCTS						
NUCALA INJ 100MG/ML AUTO	5	3	$18,501.20	$3,700.24	1.67	1.04%
NUCALA INJ 100MG/ML SYR	1	1	$3,700.24	$3,700.24	1	0.21%
SUBTOTAL	**6**	**4**	**$22,201.44**	**$3,700.24**	**1.5**	**1.25%**
TEZEPELUMAB-EKKO PRODUCTS						
TEZSPIRE INJ 210MG AUTO	6	3	$26,005.56	$4,334.26	2	1.46%
SUBTOTAL	**6**	**3**	**$26,005.56**	**$4,334.26**	**2**	**1.46%**
TOTAL	**466**	**249***	**$1,782,793.54**	**$3,825.74**	**1.87**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AUTO = autoinjector; INJ = injection; SOL = solution; SYR = syringe
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: Only data from 04/01/2024 to 06/30/2024 are available for the SoonerSelect plans.
Please note: The above utilization data includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Fee-For-Service Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OMALIZUMAB INJ (J2357)	458	58	$914,507.85	$1,996.74	7.9
TEZEPELUMAB-EKKO INJ (J2356)	61	11	$236,518.80	$3,877.36	5.55
BENRALIZUMAB INJ (J0517)	22	8	$112,021.50	$5,091.89	2.75
MEPOLIZUMAB INJ (J2812)	16	3	$48,080	$3,005.00	5.33
TOTAL	**557**	**80**	**$1,311,128.15**	**$2,353.91**	**6.96**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
INJ = injection
Fiscal Year 2024 = 07/01/2023 to 06/30/2024
Please note: The above medical utilization data for omalizumab (J2357) and mepolizumab (J2182) includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Aetna Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OMALIZUMAB INJ (J2357)	10	5	$19,877.40	$1,987.74	2
BENRALIZUMAB INJ (J0517)	2	2	$0.00¥	$0.00¥	1
TEZEPELUMAB-EKKO INJ (J2356)	2	1	$0.00¥	$0.00¥	2
TOTAL	**14**	**8**	**$19,877.40**	**$1,419.81**	**1.75**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
¥These claims appear to have the medication billed as a pharmacy claim but the administration at a provider's office billed as a medical claim for the medication-specific HCPCS code; thus, total cost listed is not a true reflection of medication cost.
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.
Please note: The above medical utilization data for omalizumab (J2357) and mepolizumab (J2182) includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Humana Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OMALIZUMAB INJ (J2357)	2	1	$1.20¥	$0.60¥	2
TOTAL	**2**	**1**	**$1.20**	**$0.60**	**2**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
¥These claims appear to have the medication billed as a pharmacy claim but the administration at a provider's office billed as a medical claim for the medication-specific HCPCS code; thus, total cost listed is not a true reflection of medication cost.
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.
Please note: The above medical utilization data for omalizumab (J2357) includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

Oklahoma Complete Heath Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OMALIZUMAB INJ (J2357)	8	4	$14,909.25	$1,863.66	2
BENRALIZUMAB INJ (J0517)	2	1	$0.00¥	$0.00¥	2
TOTAL	**10**	**5**	**$14,909.25**	**$1,490.93**	**2**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
¥These claims appear to have the medication billed as a pharmacy claim but the administration at a provider's office billed as a medical claim for the medication-specific HCPCS code; thus, total cost listed is not a true reflection of medication cost.
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.
Please note: The above medical utilization data for omalizumab (J2357) includes all FDA-approved diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

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Appendix L

Fiscal Year 2024 Annual Review of Atopic Dermatitis (AD) Medications and 30-Day Notice to Prior Authorize Ebglyss™ (Lebrikizumab-lbkz)

Oklahoma Health Care Authority
November 2024

Current Prior Authorization Criteria

Approval criteria for Dupixent® (dupilumab injection) for indications other than AD can be found in the Fiscal Year 2024 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications report, which is also being presented at the November 2024 Drug Utilization Review (DUR) Board meeting. Dupixent® is reviewed annually with the asthma and COPD maintenance medications. Utilization data for Rinvoq® (upadacitinib) and approval criteria for indications other than AD can be found in the October 2024 DUR Board packet. This medication and criteria are reviewed annually with the targeted immunomodulator agents.

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 18 years of age or older; 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. 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
5. 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
6. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted 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) that resulted in inadequate response (or have a contraindication or documented intolerance); and
6. 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
7. 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
8. 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
9. 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. Additionally, compliance will be evaluated for continued approval; and
10. 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. 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
5. 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
6. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Elidel® (Pimecrolimus Cream) and Protopic® (Tacrolimus Ointment) Approval Criteria:

1. The first 90 days of a 12-month period will be covered without prior authorization; and
2. After the initial period, authorization may be granted with documentation of 1 trial with a Tier-1 topical corticosteroid at least 6 weeks in duration within the past 90 days; and
3. Therapy will be approved only once each 90-day period to ensure appropriate short-term and intermittent utilization as advised by the FDA; and
4. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 100 grams for all other areas; and
5. Authorizations will be restricted to those members who are not immunocompromised; and
6. Members must meet all of the following criteria:
    a. An FDA approved indication:
        i. Elidel®: Short-term and intermittent treatment for mild-to-moderate atopic dermatitis (eczema); or
        ii. Protopic®: Short-term and intermittent treatment for moderate-to-severe atopic dermatitis (eczema); and
    b. Age restrictions:
        i. Elidel® 1% is restricted to 2 years of age and older; and

    ii. Protopic® 0.03% is restricted to 2 years of age and older; and
    iii. Protopic® 0.1% is restricted to 15 years of age and older; or
7. Clinical exceptions for the trial requirement may be considered for the following:
    a. Documented adverse effect, drug interaction, or contraindication to Tier-1 topical corticosteroids; or
    b. Atopic dermatitis of the face or groin where prescriber does not want to use topical corticosteroids; or
8. Clinical exceptions for the age restrictions (for members younger than the FDA approved age) may be considered for the following:
    a. Prescribed by a dermatologist.

Eucrisa® (Crisaborole Ointment) Approval Criteria:

1. An FDA approved indication for treatment of mild-to-moderate atopic dermatitis (eczema); and
2. Member must be at least 3 months of age or older; and
3. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with a topical corticosteroid or topical calcineurin inhibitor (or have a contraindication or documented intolerance); and
4. A quantity limit of 1 tube per 30 days will apply; and
5. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
6. Clinical exceptions for the trial requirement may be considered for the following:
    a. Documented adverse effect, drug interaction, or contraindication to topical corticosteroids; or
    b. Atopic dermatitis of the face or groin where prescriber does not want to use topical corticosteroids; or
7. Clinical exceptions for the age restriction (for members younger than the FDA approved age) may be considered for the following:
    a. Prescribed by a dermatologist.

Opzelura® (Ruxolitinib 1.5% Cream) Approval Criteria [Atopic Dermatitis Diagnosis]:

1. An FDA approved indication for short-term and non-continuous treatment of mild-to-moderate atopic dermatitis; and
2. Member must be 12 years of age or older; and
3. Member must not be immunocompromised; and
4. Member must have a body surface area (BSA) involvement ≤20%; and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):

    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (TCS); and
    b. 1 topical calcineurin inhibitor (TCI) [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
    c. Eucrisa® (crisaborole); and
6. Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and
7. Prescriber must verify female members are not breastfeeding; and
8. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the Opzelura® pregnancy registry; and
9. Approvals will be for a maximum duration of 8 weeks of treatment; and
10. Reauthorization may be considered if member has a recent TCS, TCI, or Eucrisa® trial (or a contraindication or documented intolerance); and
    a. Additionally, the prescriber must document the member had a positive response to and tolerated previous treatment with Opzelura®; and
11. Subsequent approvals will only be considered once each 90-day period to ensure appropriate short-term and non-continuous utilization.

Opzelura® (Ruxolitinib 1.5% Cream) Approval Criteria [Nonsegmental Vitiligo Diagnosis]:

1. An FDA approved indication of nonsegmental vitiligo; and
2. The member's body surface area (BSA) involvement must be provided and must be ≤10%; and
3. Member must be 12 to 20 years of age; and
4. Member must have documented trials within the last 6 months for a minimum of 12 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (used continuously or intermittently); and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
5. Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and
6. Prescriber must verify female members are not breastfeeding; and
7. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the Opzelura® pregnancy registry; and
8. Initial approvals will be for a duration of 24 weeks of treatment; and

9. Reauthorization for an additional 28 weeks of treatment (to complete 1 year of treatment) may be considered if the prescriber documents both of the following:
    a. The member had a positive response to and tolerated previous treatment with Opzelura®; and
    b. The member has been evaluated by the prescriber and continues to require treatment with Opzelura®; and
10. Further approval beyond 1 year of treatment will require patient-specific, clinically significant information to support the member's need for additional treatment.

Prudoxin® and Zonalon® (Doxepin Cream) Approval Criteria:

1. An FDA approved indication for the short-term (up to 8 days) management of moderate pruritus in members with atopic dermatitis or lichen simplex chronicus; and
2. Requests for longer use than 8 days will not generally be approved. Chronic use beyond 8 days may result in higher systemic levels and should be avoided.

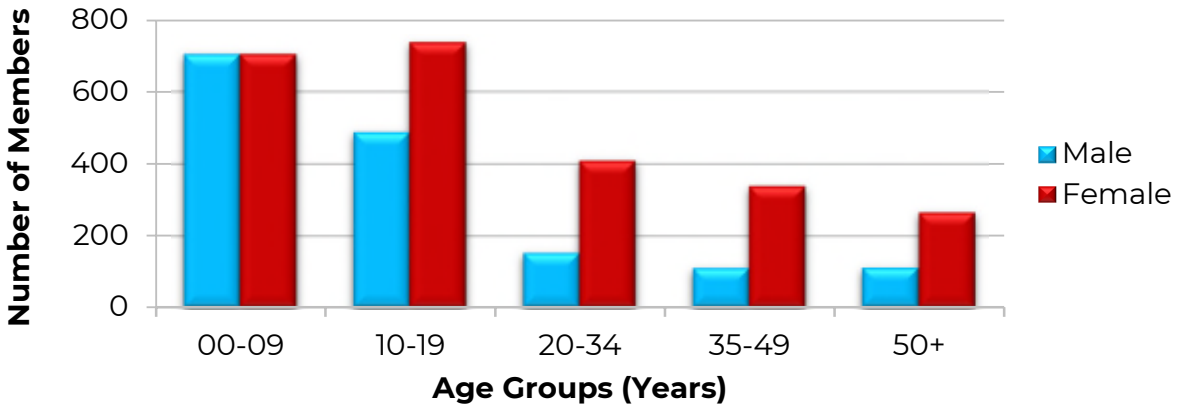
Utilization of AD Medications: Fiscal Year 2024

Comparison of Fiscal Years (All Plans)

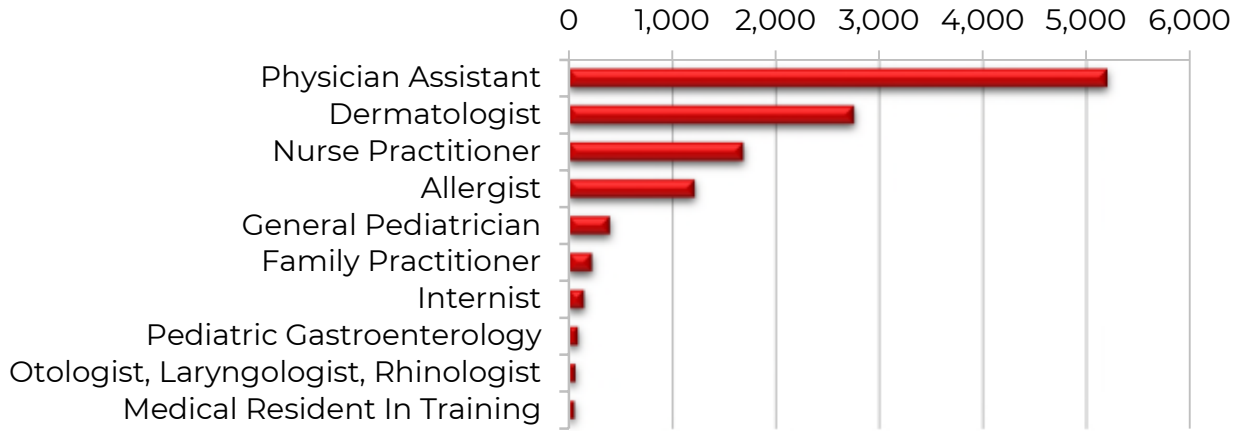
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2023							
FFS	3,345	9,909	$19,090,169.48	$1,926.55	$62.10	266,725	307,415
2023 Total	**3,345**	**9,909**	**$19,090,169.48**	**$1,926.55**	**$62.10**	**266,725**	**307,415**
Fiscal Year 2024							
FFS	3,396	9,752	$22,001,331.62	$2,256.08	$71.26	226,354	308,755
Aetna	444	733	$1,640,439.77	$2,237.98	$78.02	18,837	21,026
Humana	503	841	$1,900,025.82	$2,259.25	$80.07	22,265	23,729
OCH	474	772	$1,786,740.10	$2,314.43	$74.25	18,919	24,063
2024 Total	**4,012**	**12,104**	**$27,328,537.31**	**$2,257.81**	**$72.35**	**286,493**	**377,745**
% Change	**19.90%**	**22.20%**	**43.20%**	**17.20%**	**16.50%**	**7.40%**	**22.90%**
Change	**667**	**2,195**	**$8,238,367.83**	**$331.26**	**$10.25**	**19,768**	**70,330**

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.
Utilization data includes Dupixent® used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.

Demographics of Members Utilizing AD Medications (All Plans)



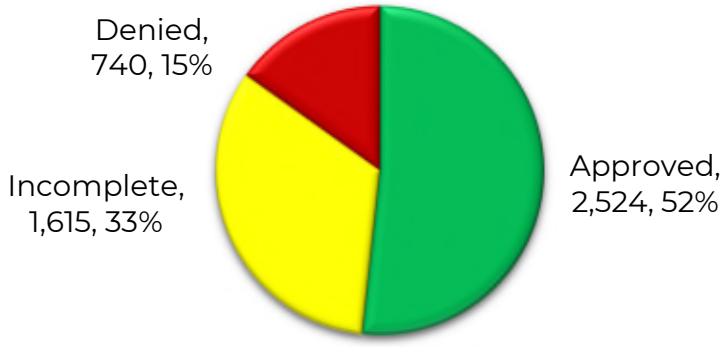
Top Prescriber Specialties of AD Medications by Number of Claims (All Plans)



Prior Authorization of AD Medications

There were 4,879 prior authorization requests submitted for AD 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	2,180	50%	1,598	37%	595	14%	**4,373**
Aetna	119	58%	15	7%	71	35%	**205**
Humana	95	78%	2	2%	25	20%	**122**
OCH	130	73%	0	0%	49	27%	**179**
Total	**2,524**	**52%**	**1,615**	**33%**	**740**	**15%**	**4,879**

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

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

Anticipated Patent Expiration(s):

- Eucrisa® (crisaborole): July 2030
- Cibinqo® (abrocitinib): February 2034
- Rinvoq® (upadacitinib): March 2038
- Opzelura® (ruxolitinib): May 2041

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

- **December 2023:** The FDA approved Adbry® (tralokinumab-ldrm) for an age expansion for the treatment of moderate-to-severe AD in patients 12 years of age or older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Previously, Adbry® was only FDA approved for the treatment of adults with this indication.
- **June 2024:** The FDA approved Adbry® for a new single-dose autoinjector for the treatment of adults with moderate-to-severe AD. The FDA approved dosing of Adbry® for adults is an initial loading dose of 600mg followed by 300mg every other week thereafter. The autoinjector is available as a 300mg/2mL solution which will require half as many injections to achieve the recommended dosing when compared to the other available formulation, the 150mg/mL single-dose syringes, which required 4 separate injections for the 600mg loading dose and 2 separate injections for each 300mg maintenance dose.
- **September 2024:** The FDA approved Ebglyss™ (lebrikizumab-lbkz) for the treatment of adult and pediatric patients 12 years of age and older who weigh at least 40kg with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Ebglyss™ can be used with or without topical corticosteroids (TCS).

Guideline Update(s):

- **American Academy of Dermatology (AAD):**
  - Updated guidelines were published for the management of AD with phototherapy and systemic therapies in adults. These guidelines update the previous 2014 AAD guidelines, but only provide recommendations for adults. For pediatric patients, the previous 2014 AAD guidelines should continue to be referenced, but the AAD is planning to provide updated pediatric recommendations in a future guideline. Key recommendations made for systemic therapies in adult patients with AD include:
    - Strong recommendations (based on moderate certainty evidence) in favor of abrocitinib, dupilumab, tralokinumab, and upadacitinib in adults with moderate-to-severe AD
- **American Academy of Allergy, Asthma, and Immunology/American College of Allergy, Asthma, and Immunology (AAAAI/ACAAI):**
  - Updated guidelines were published for the management of AD in infants, children, and adults. These guidelines update the previous 2012 AAAAI/ACAAI guidelines. Key recommendations made for the treatment of AD include:
    - Strong recommendations (based on high certainty evidence) in favor of TCS and topical calcineurin inhibitors (TCI) in patients 3 months of age or older
    - Strong recommendations (based on high certainty evidence) in favor of dupilumab and tralokinumab in patients within the FDA approved age range for each product
    - Conditional recommendation (based on moderate certainty evidence) in favor of topical phosphodiesterase-4 (PDE4) inhibitors in patients 3 months of age or older
    - Conditional recommendations (based on low certainty evidence) in favor of abrocitinib and upadacitinib in patients 12 years of age or older
    - Conditional recommendation (based on low certainty evidence) against the use of topical Janus kinase (JAK) inhibitors in patients 12 years of age or older

Pipeline:

- **Delgocitinib:** Delgocitinib is a topical therapy that is being investigated for the treatment of chronic hand eczema. It is a pan-JAK inhibitor that is formulated as a topical cream. In September 2024, LEO Pharma announced that the FDA has accepted their New Drug Application (NDA) for delgocitinib for the treatment of adults with moderate-to-severe chronic hand eczema who have had an inadequate response to TCS or for whom TCS are not advisable.

- **Nemolizumab:** Nemolizumab is a monoclonal antibody designed to block interleukin (IL)-31 signaling, a cytokine with important roles in pruritus and skin inflammation. In February 2024, Galderma announced that the FDA has accepted their Biologics License Application (BLA) for nemolizumab for the treatment of adolescents and adults with moderate-to-severe AD. Nemolizumab was FDA approved in August 2024 for the treatment of adults with prurigo nodularis and is marketed under the brand name Nemluvio®.

Ebglyss™ (Lebrikizumab-lbkz) Product Summary[10,11,12]

Therapeutic Class: IL-13 antagonist

Indication(s): Treatment of adult and pediatric patients 12 years of age and older who weigh at least 40kg with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Ebglyss™ can be used with or without TCS.

How Supplied:
- 250mg/2mL solution in a single-dose prefilled pen
- 250mg/2mL solution in a single-dose prefilled syringe with needle shield

Dosing and Administration:
- Initial Dosing: 500mg [administered as (2) 250mg injections] at week 0 and week 2 followed by 250mg every 2 weeks until week 16 or later, when adequate clinical response is achieved
- Maintenance Dosing: 250mg every 4 weeks
- Administered by subcutaneous (sub-Q) injection into the abdomen, thigh, or back of the upper arm

Efficacy: The efficacy of Ebglyss™ was assessed primarily in 3 Phase 3 studies (ADvocate 1, ADvocate 2, and ADhere) which were randomized, double-blind, placebo-controlled studies. ADvocate 1 and ADvocate 2 were monotherapy trials which compared lebrikizumab monotherapy to placebo. ADhere compared combination therapy with lebrikizumab plus TCS to patients who received placebo plus TCS.
- Key Inclusion Criteria:
  - Chronic AD that has been present for ≥1 year
  - 12 years of age or older and weight ≥40kg
  - Eczema Area and Severity Index (EASI) score ≥16
  - Investigator Global Assessment (IGA) score ≥3
  - Body surface area (BSA) involvement ≥10%
  - History of inadequate response to treatment with topical medications

- Primary Endpoint(s):
  - Proportion of patients achieving an IGA score of 0 ("clear skin") or 1 ("almost clear skin") and at least a 2-point improvement from baseline at week 16
- Results:
  - ADvocate 1: Achieved by 43% of patients who received lebrikizumab vs. 13% of patients who received placebo [treatment difference: 30%; 95% confidence interval (CI): 22%, 38%]
  - ADvocate 2: Achieved by 33% of patients who received lebrikizumab vs. 11% of patients who received placebo (treatment difference: 22%; 95% CI: 14%, 30%)
  - ADhere: Achieved by 41% of patients who received lebrikizumab plus TCS vs. 22% of patients who received placebo plus TCS (treatment difference: 18%; 95% CI: 5%, 32%)

Cost Comparison: AD Injectable Products

Product	Cost Per mL	Cost Per 1st 16 Weeks*	Cost Per Year+
Ebglyss™ (lebrikizumab-lbkz) 250mg/2mL	**$1,750.00**	**$35,000.00**	**$66,500.00**
Adbry® (tralokinumab-ldrm) 300mg/2mL	$959.76	$17,275.68	$51,827.04
Dupixent® (dupilumab) 300mg/2mL	$916.32	$16,493.76	$49,481.28

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 first 16 weeks based on the initial FDA approved dosing for each product, including required loading doses.
+Cost per year based on the initial year of treatment, including required loading doses and the FDA approved maintenance dosing of 250mg every 4 weeks (for Ebglyss™) or 300mg every 2 weeks (for Adbry® and Dupixent®).

Cost Comparison: AD Oral Products

Product	Cost Per Tablet	Cost Per 30 Days*	Cost Per Year
Rinvoq® (upadacitinib) 30mg tablet	$207.21	$6,216.30	$74,595.60
Cibinqo® (abrocitinib) 200mg tablet	$185.58	$5,567.40	$66,808.80

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 based on the maximum FDA approved dose for AD for each product: 30mg once daily for Rinvoq® or 200mg once daily for Cibinqo®.

Recommendations

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 current body surface area (BSA) of atopic dermatitis involvement must be provided and must be ≥10%; 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 current body surface area (BSA) of atopic dermatitis involvement must be provided and must be ≥10%; 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 current body surface area (BSA) of atopic dermatitis involvement must be provided and must be ≥10%; 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 current body surface area (BSA) of atopic dermatitis involvement must be provided and must be ≥10%; 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.

Utilization Details of AD Medications: Fiscal Year 2024

Fee-For-Service Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INJECTABLE PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	2,929	601	$11,044,058.03	$3,770.59	4.87	50.20%
DUPIXENT INJ 300MG/2ML SYR	1,214	271	$4,325,967.35	$3,563.40	4.48	19.66%
DUPIXENT INJ 200MG/1.14ML SYR	903	183	$3,175,746.08	$3,516.88	4.93	14.43%
DUPIXENT INJ 200MG/1.14ML PEN	524	122	$1,921,948.97	$3,667.84	4.3	8.74%
ADBRY INJ 150MG/ML SYR	151	31	$539,569.13	$3,573.31	4.87	2.45%
SUBTOTAL	**5,721**	**1,132***	**$21,007,289.56**	**$3,671.96**	**5.05**	**95.48%**
TOPICAL PRODUCTS						
TACROLIMUS OIN 0.03%	1,147	809	$78,581.97	$68.51	1.42	0.36%
PIMECROLIMUS CREAM 1%	1,138	843	$166,293.31	$146.13	1.35	0.76%
TACROLIMUS OIN 0.1%	1,007	760	$73,055.07	$72.55	1.33	0.33%
EUCRISA OIN 2%	700	414	$528,079.22	$754.40	1.69	2.40%
OPZELURA CREAM 1.5%	17	13	$33,223.56	$1,954.33	1.31	0.15%
DOXEPIN HCL CREAM 5%	1	1	$571.81	$571.81	1	0.00%
SUBTOTAL	**4,010**	**2,694***	**$879,804.94**	**$219.40**	**1.49**	**4.00%**
ORAL PRODUCTS						
CIBINQO TAB 100MG	18	4	$98,296.26	$5,460.90	4.5	0.45%
CIBINQO TAB 200MG	3	1	$15,940.86	$5,313.62	3	0.07%
SUBTOTAL	**21**	**5***	**$114,237.12**	**$5,439.86**	**4.2**	**0.52%**
TOTAL	**9,752**	**3,396***	**$22,001,331.62**	**$2,256.08**	**2.87**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
HCL = hydrochloride; INJ = injection; OIN = ointment; SYR = syringe; TAB = tablet
Utilization data includes Dupixent® used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024

Aetna Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INJECTABLE PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	188	98	$733,440.36	$3,901.28	1.92	44.71%
DUPIXENT INJ 300MG/2ML SYR	92	52	$353,433.85	$3,841.67	1.77	21.55%
DUPIXENT INJ 200MG/1.14MG PEN	57	28	$213,356.04	$3,743.09	2.04	13.01%
DUPIXENT INJ 200MG/1.14ML SYR	55	26	$203,540.35	$3,700.73	2.12	12.41%
ADBRY INJ 150MG/ML SYR	14	7	$50,067.14	$3,576.22	2	3.05%
SUBTOTAL	**406**	**206***	**$1,553,837.74**	**$3,827.19**	**1.97**	**94.72%**
TOPICAL PRODUCTS						
TACROLIMUS OIN 0.03%	101	86	$5,686.86	$56.31	1.17	0.35%
TACROLIMUS OIN 0.1%	91	79	$5,982.76	$65.74	1.15	0.36%
PIMECROLIMUS CREAM 1%	74	65	$8,728.95	$117.96	1.14	0.53%
EUCRISA OIN 2%	55	48	$47,130.46	$856.92	1.15	2.87%
OPZELURA CREAM 1.5%	4	3	$7,915.54	$1,978.89	1.33	0.48%
SUBTOTAL	**325**	**271***	**$75,444.57**	**$232.14**	**1.2**	**4.60%**
ORAL PRODUCTS						
CIBINQO TAB 100MG	2	1	$11,157.46	$5,578.73	2	0.68%
SUBTOTAL	**2**	**1***	**$11,157.46**	**$5,578.73**	**2**	**0.68%**
TOTAL	**733**	**444***	**$1,640,439.77**	**$2,237.98**	**1.65**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; OIN = ointment; SYR = syringe; TAB = tablet
Utilization data includes Dupixent® used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.
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.

Humana Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INJECTABLE PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	265	129	$1,020,882.55	$3,852.39	2.05	53.73%
DUPIXENT INJ 200MG/1.14ML SYR	70	34	$259,179.68	$3,702.57	2.06	13.64%
DUPIXENT INJ 300MG/2ML SYR	69	41	$257,735.12	$3,735.29	1.68	13.56%
DUPIXENT INJ 200MG/1.14ML PEN	61	33	$228,482.51	$3,745.61	1.85	12.03%
ADBRY INJ 150MG/ML SYR	7	4	$26,953.08	$3,850.44	1.75	1.42%
SUBTOTAL	**472**	**236***	**$1,793,232.94**	**$3,799.22**	**2**	**94.38%**
TOPICAL PRODUCTS						
TACROLIMUS OIN 0.1%	110	94	$7,697.54	$69.98	1.17	0.41%
PIMECROLIMUS CREAM 1%	101	85	$14,014.18	$138.75	1.19	0.74%
TACROLIMUS OIN 0.03%	82	74	$4,744.91	$57.86	1.11	0.25%
EUCRISA OIN 2%	68	54	$57,293.33	$842.55	1.26	3.02%
OPZELURA CREAM 1.5%	6	5	$11,885.46	$1,980.91	1.2	0.63%
SUBTOTAL	**367**	**303***	**$95,635.42**	**$260.59**	**1.21**	**5.03%**
ORAL PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CIBINQO TAB 200MG	2	1	$11,157.46	$5,578.73	2	0.59%
SUBTOTAL	**2**	**1***	**$11,157.46**	**$5,578.73**	**2**	**0.59%**
TOTAL	**841**	**503***	**$1,900,025.82**	**$2,259.25**	**1.67**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; OIN = ointment; SYR = syringe; TAB = tablet
Utilization data includes Dupixent® used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.
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.

OK Complete Health Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INJECTABLE PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	231	120	$903,258.65	$3,910.21	1.93	50.55%
DUPIXENT INJ 300MG/2ML SYR	85	48	$305,975.37	$3,599.71	1.77	17.12%
DUPIXENT INJ 200MG/1.14ML SYR	69	39	$255,428.42	$3,701.86	1.77	14.30%
DUPIXENT INJ 200MG/1.14ML PEN	49	26	$183,745.10	$3,749.90	1.88	10.28%
ADBRY INJ 150MG/ML SYR	8	4	$30,803.52	$3,850.44	2	1.72%
SUBTOTAL	**442**	**233***	**$1,679,211.06**	**$3,799.12**	**1.9**	**93.98%**
TOPICAL PRODUCTS						
TACROLIMUS OIN 0.03%	93	77	$5,733.11	$61.65	1.21	0.32%
PIMECROLIMUS CREAM 1%	80	69	$10,347.02	$129.34	1.16	0.58%
TACROLIMUS OIN 0.1%	74	67	$4,388.20	$59.30	1.1	0.25%
EUCRISA OIN 2%	69	57	$55,742.30	$807.86	1.21	3.12%
OPZELURA CREAM 1.5%	13	9	$25,739.68	$1,979.98	1.44	1.44%
SUBTOTAL	**329**	**273***	**$101,950.31**	**$309.88**	**1.21**	**5.71%**
ORAL PRODUCTS						
CIBINQO TAB 50MG	1	1	$5,578.73	$5,578.73	1	0.31%
SUBTOTAL	**1**	**1***	**$5,578.73**	**$5,578.73**	**1**	**0.31%**
TOTAL	**772**	**474***	**$1,786,740.10**	**$2,314.43**	**1.63**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; OIN = ointment; SYR = syringe; TAB = tablet
Utilization data includes Dupixent® used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.
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 10/2024. Last accessed 10/05/2024.
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Appendix M

Fiscal Year 2024 Annual Review of Sohonos® (Palovarotene)

Oklahoma Health Care Authority
November 2024

Current Prior Authorization Criteria

Sohonos® (Palovarotene) Approval Criteria:

1. An FDA approved diagnosis of fibrodysplasia ossificans progressiva (FOP); and
    a. Diagnosis must be confirmed by genetic testing identifying a pathogenic R206H mutation in the *ACVR1* gene (results of genetic testing must be submitted); and
2. Member must be:
    a. 8 years of age or older for female members; or
    b. 10 years of age or older for male members; and
3. For members younger than 14 years of age, member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing in accordance with package labeling; and
4. Must be prescribed by a geneticist or other specialist with expertise in the treatment of FOP; and
5. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test within 1 week prior to therapy initiation; and
6. Prescriber must verify female members of reproductive potential are not breastfeeding and will use effective contraception at least 1 month prior to initiating treatment with Sohonos® and for 1 month after the last dose of Sohonos®; and
7. Prescriber must verify the member does not have severe renal impairment (creatinine clearance <30mL/min) or moderate or severe hepatic impairment (Child-Pugh B or C); and
8. Member must not be taking any of the following medications concomitantly with Sohonos®:
    a. Strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); or
    b. Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone); or
    c. Vitamin A at doses higher than the recommended daily allowance (RDA); or
    d. Other oral retinoids (e.g., acitretin, isotretinoin, tretinoin); or
    e. Tetracyclines (e.g., doxycycline, minocycline, tetracycline); and

9. If concurrent use with a moderate CYP3A4 inhibitor (e.g., ciprofloxacin, diltiazem, erythromycin, imatinib, fluconazole, fluvoxamine, verapamil) is required, prescriber must agree to reduce the Sohonos® dose as recommended in the package labeling; and
10. Prescriber must verify the member or member's caregiver has been counseled on all warnings and precautions related to Sohonos®, including the risks of embryo-fetal toxicity, premature epiphyseal closure, metabolic bone disorders, psychiatric disorders, and night blindness; and
11. The request must specify if it is for a chronic daily dose or a flare-up dose; and
12. Chronic Daily Dose Approvals: Initial approvals will be for the duration of 6 months for the appropriate dose based on member age or weight. For additional approval consideration after 6 months, the prescriber must verify the member is tolerating and responding well to the medication. Subsequent approvals will be for the duration of 1 year; and
13. Flare-Up Dose Approvals: Initial approvals will be for the duration of 12 weeks for the appropriate doses based on member age or weight. After 12 weeks, flare-up dosing may be approved in additional 4-week increments if the prescriber documents the flare-up symptoms have not resolved at the end of the 12-week period; and
14. Member will not be approved for the chronic daily dose and flare-up dosing at the same time.

Utilization of Sohonos® (Palovarotene): Fiscal Year 2024

There was no SoonerCare utilization of Sohonos® (palovarotene) during fiscal year 2024.

Prior Authorization of Sohonos® (Palovarotene)

There were no prior authorization requests submitted for Sohonos® (palovarotene) during fiscal year 2024.

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

Anticipated Patent Expiration(s):

- Sohonos® (palovarotene): June 2037

Pipeline:

- **Garetosmab (REGN2477):** Garetosmab is an investigational antibody that blocks the activity of Activin A, a protein implicated in the pathophysiology of fibrodysplasia ossificans progressiva (FOP). In January 2020, Regeneron Pharmaceuticals announced positive Phase 2 results from a double-blind, placebo-controlled trial evaluating 44 patients with FOP. Compared to the placebo group, the garetosmab

group experienced a 24.6% reduction in new and existing bone lesions, although this was not statistically significant (P=0.07). However, in an open-label, crossover addition to the study, the endpoints were prospectively changed to solely examine the reduction of new bone lesions. The results of this analysis showed that patients who crossed over from the placebo group to the garetosmab group experienced a statistically significant reduction in new bone lesions when compared to their historical placebo data (-40.9%; P=0.0027). A global Phase 3 trial evaluating the safety and efficacy of garetosmab is ongoing. In 2017, the U.S. Food and Drug Administration (FDA) granted Fast Track and Orphan Drug designations to garetosmab.

Recommendations

The College of Pharmacy does not recommend any changes to the current Sohonos® (palovarotene) prior authorization criteria at this time.

[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 10/2024. Last accessed 10/24/2024.
[2] International Fibrodysplasia Ossificans Progressiva Association. Optima Trial (Garetosmab). Available online at: https://www.ifopa.org/regn2477. Last accessed 10/24/2024.
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Appendix N

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: October 11, 2024

FDA Approves New Treatment for Hemophilia A or B

The FDA approved Hympavzi™ (marstacimab-hncq) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A without factor VIII (FVIII) inhibitors or hemophilia B without factor IX (FIX) inhibitors (neutralizing antibodies).

Hemophilia A and hemophilia B are genetic bleeding disorders caused by dysfunction or deficiency of FVIII or FIX, respectively. Patients with these hemophilias are unable to clot properly and may bleed for a longer time than normal after injury or surgery. They may also have spontaneous bleeding in muscles, joints, and organs, which can be life-threatening. These bleeding episodes are typically managed by either on-demand, episodic treatment or prophylaxis using products containing FVIII or FIX, or a product that mimics a factor.

Hympavzi™ is a new type of drug that, rather than replacing a clotting factor, works by reducing the amount, and therefore, the activity of, the naturally occurring anticoagulation protein called tissue factor pathway inhibitor. This increases the amount of thrombin, an enzyme that is critical in blood clotting, that is generated. This is expected to reduce or prevent the frequency of bleeding episodes.

Hympavzi™'s approval is based on an open-label, multi-center study in 116 adult and pediatric male patients with either severe hemophilia A or severe hemophilia B, both without inhibitors. For the first 6 months of this study, patients received treatment with replacement factor either on-demand (33 patients) or prophylactically (83 patients). These patients then received Hympavzi™ prophylaxis for 12 months. The primary measure of efficacy of Hympavzi™ was the annualized bleeding rates of treated bleeds. In the patients receiving on-demand factor replacement during the first 6 months of the study, the estimated annualized bleeding rate was 38 compared to the estimated annualized bleeding rate during treatment with Hympavzi™ of 3.2, showing that Hympavzi™ was superior to on-demand factor replacement. In the initial six-month period during which patients received prophylactic factor replacement, the estimated annualized bleeding rate was 7.85 and was 5.08 during the subsequent 12 months on Hympavzi™ prophylaxis, showing that Hympavzi™ provided similar bleeding rates.

Hympavzi™ comes with warnings and precautions about circulating thromboembolic events, hypersensitivity, and embryofetal toxicity. The most common side effects of Hympavzi™ are injection site reactions, headache, and pruritus.

The FDA granted Hympavzi™ Orphan Drug designation for this application. The FDA granted the approval of Hympavzi™ to Pfizer Inc.

FDA NEWS RELEASE

For Immediate Release: October 7, 2024

FDA Authorizes Marketing of First Home Flu and COVID-19 Combination Test Outside of Emergency Use Authorities

The FDA granted marketing authorization for the Healgen® Rapid Check COVID-19/Flu A&B Antigen Test. The test, authorized for use without a prescription, is for use by individuals experiencing respiratory symptoms and uses a nasal swab sample to deliver at-home results in approximately 15 minutes for COVID-19 and influenza. The test detects proteins from both SARS-CoV-2 and influenza A and B.

This is the first over-the-counter (OTC) test that can detect influenza to be granted marketing authorization using a traditional premarket review pathway, which enables the test to be marketed in the absence of an applicable emergency use declaration. Other OTC flu/COVID tests are currently available under emergency use authorization.

The test is for use by individuals 14 years of age or older taking and testing their own sample, or individuals 2 years of age and older with a sample taken and tested by an adult. The FDA reviewed data from a study of individuals with signs and symptoms of COVID-19 and influenza, which showed that this test correctly identified 99% of negative and 92% of positive SARS-CoV-2 samples, 99.9% of negative Flu A and B samples, and 92.5% and 90.5% of positive Flu A and Flu B samples, respectively. Validation data for the test was gathered through the Independent Test Assessment Program (ITAP), a National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx®) Tech program, in collaboration with the FDA. ITAP was launched in 2021 to accelerate test evaluation to support the FDA's regulatory review and the availability of high-quality, accurate, and reliable diagnostic tests to the public.

As with all rapid antigen tests, which generally have lower sensitivity than molecular tests, there is a risk of false negative test results. Individuals who test negative and continue to experience symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2, flu or another respiratory infection and should seek follow up care with their health care provider. Individuals who test positive for SARS-CoV-2 or flu should take appropriate precautions to avoid spreading the virus and should seek follow-up care with their physician or health care provider.

Current Drug Shortages Index (as of October 30, 2024):

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***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***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 Injection	***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***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 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***
Epinephrine Injection, Syringes	***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***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
Indocyanine Green Injection	***Currently in Shortage***
Isoniazid Tablet	***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***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Peritoneal Dialysis Solution	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***

Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
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 14.6% Injection	***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***
Vecuronium Bromide Injection	***Currently in Shortage***