OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
November 8, 2023
4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – November 8, 2023

DATE: November 1, 2023

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/Use of Statins in Members with Diabetes Mellitus (DM) – Appendix B

Action Item – Approval of 2024 DUR Board Meeting Dates – Appendix C

Action Item – Vote to Prior Authorize Elevidys (Delandistrogene Moxeparvovec-rokl) and Update the Approval Criteria for the Muscular Dystrophy Medications – Appendix D

Action Item – Vote to Prior Authorize Jesduvroq™ (Daprodustat) and Update the Approval Criteria for the Anemia Medications – Appendix E

Action Item – Vote to Prior Authorize Idacio® (Adalimumab-aacf), Litfulo™ (Ritlecitinib), Tofidence™ (Tocilizumab-bavi), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh) and Update the Approval Criteria for the Targeted Immunomodulator Agents– Appendix F

Action Item – Vote to Prior Authorize Veopoz™ (Pozelimab-bbfg) – Appendix G

Action Item – Vote to Prior Authorize Ojjaara (Momelotinib) – Appendix H

Action Item – Annual Review of Atopic Dermatitis (AD) Medications – Appendix I

Action Item – Annual Review of Injectable and Vaginal Progesterone Products – Appendix J

Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Elrexfio™ (Elranatamab-bcmm) and Talvey™ (Talquetamab-tgvs) – Appendix K

Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Symbicort Aerosphere® (Budesonide/Formoterol Fumarate) – Appendix L

30-Day Notice to Prior Authorize Sohonos™ (Palovarotene) – Appendix M

Annual Review of Vasomotor Symptom (VMS) Medications and 30-Day Notice to Prior Authorize Veozah™ (Fezolinetant) – Appendix N

Annual Review Review of Dry Eye Disease (DED) Medications and 30-Day Notice to Prior Authorize Miebo™ (Perfluorohexyloctane Ophthalmic Solution) and Vevye® (Cyclosporine Ophthalmic Solution) – Appendix O

Annual Review of Skysona® (Elivaldogene Autotemcel) – Appendix P

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – November 8, 2023 @ 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. Adams

DUR Board Members:

Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	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

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Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 919 6475 4191
Passcode: 95646190

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 11, 2023 DUR Board Meeting Minutes
   B. October 11, 2023 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/ Use of Statins in Members with Diabetes Mellitus (DM) – See Appendix B**
   A. Pharmacy Help Desk Activity for October 2023
   B. Medication Coverage Activity for October 2023
   C. Use of Statins in Members with DM

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

5. **Action Item – Approval of 2024 DUR Board Meeting Dates – See Appendix C**

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

6. **Action Item – Vote to Prior Authorize Elevidys (Delandistrogene Moxeparvovec-rokl) and Update the Approval Criteria for the Muscular Dystrophy Medications – See Appendix D**
   A. Market News and Updates
   B. Elevidys (Delandistrogene Moxeparvovec-rokl) Product Summary
   C. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Jesduvroq™ (Daprodustat) and Update the Approval Criteria for the Anemia Medications – See Appendix E**
   A. Market News and Updates
   B. Jesduvroq™ (Daprodustat) Product Summary
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Prior Authorize Idacio® (Adalimumab-aacf), Litfulo™ (Ritlecitinib), Tofidence™ (Tocilizumab-bavi), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh) and Update the Approval Criteria for the Targeted Immunomodulator Agents – See Appendix F**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Veopoz™ (Pozelimab-bbfg) – See Appendix G**
   A. Market News and Updates
   B. Veopoz™ (Pozelimab-bbfg) Product Summary
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Ojjaara (Momelotinib) – See Appendix H**
    A. Market News and Updates
    B. Ojjaara (Momelotinib) Product Summary
    C. College of Pharmacy Recommendations

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

11. **Action Item – Annual Review of Atopic Dermatitis (AD) Medications – See Appendix I**
    A. Current Prior Authorization Criteria
    B. Utilization of AD Medications
    C. Prior Authorization of AD Medications
    D. Market News and Updates
    E. College of Pharmacy Recommendations
    F. Utilization Details of AD Medications

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

12. **Action Item – Annual Review of Injectable and Vaginal Progesterone Products – See Appendix J**
    A. Current Prior Authorization Criteria

B. Utilization of Injectable and Vaginal Progesterone Products
C. Prior Authorization of Injectable and Vaginal Progesterone Products
D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Injectable and Vaginal Progesterone Products

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

13. **Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Elrexfio™ (Elranatamab-bcmm) and Talvey™ (Talquetamab-tgvs) – See Appendix K**

A. Current Prior Authorization Criteria
B. Utilization of Multiple Myeloma Medications
C. Prior Authorization of Multiple Myeloma Medications
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Multiple Myeloma Medications

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

14. **Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Symbicort Aerosphere® (Budesonide/Formoterol Fumarate) – See Appendix L**

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. College of Pharmacy Recommendations
F. Utilization Details of Asthma and COPD Maintenance Medications

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

15. **30-Day Notice to Prior Authorize Sohonos™ (Palovarotene) – See Appendix M**

A. Introduction
B. Sohonos™ (Palovarotene) Product Summary
C. College of Pharmacy Recommendations

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

16. **Annual Review of Vasomotor Symptom (VMS) Medications and 30-Day Notice to Prior Authorize Veozah™ (Fezolinetant) – See Appendix N**

A. Current Prior Authorization Criteria
B. Utilization of VMS Medications
C. Prior Authorization of VMS Medications
D. Market News and Updates
E. Veozah™ (Fezolinetant) Product Summary

F. College of Pharmacy Recommendations
G. Utilization Details of VMS Medications

Items to be presented Dr. Morgan, Dr. Muchmore, Chairman:

17. Annual Review of Dry Eye Disease (DED) Medications and 30-Day Notice to Prior Authorize Miebo™ (Perfluorohexyloctane Ophthalmic Solution) and Vevye® (Cyclosporine Ophthalmic Solution) – See Appendix O

A. Current Prior Authorization Criteria
B. Utilization of DED Medications
C. Prior Authorization of DED Medications
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of DED Medications

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

18. Annual Review of Skysona® (Elivaldogene Autotemcel) – See Appendix P

A. Current Prior Authorization Criteria
B. Utilization of Skysona® (Elivaldogene Autotemcel)
C. Prior Authorization of Skysona® (Elivaldogene Autotemcel)
D. College of Pharmacy Recommendations

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

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

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

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

A. Anticoagulants and Platelet Aggregation Inhibitors
B. Antidepressants
C. Lysosomal Storage Disease Medications
D. Skin Cancer Medications

*Future product and class reviews subject to change.

21. Adjournment

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING NOVEMBER 9, 2022

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

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Morgan Masterson, Pharm.D.; Clinical Pharmacist		X
Mattie Morgan, Pharm.D.; Pharmacy Resident	X	
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Jo'Nel Reynolds, 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
Emily Borders, Pharm.D., BCOP		X
Brooke Daugherty, Pharm. D., BCOP	X	
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.	X	
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.		X
Visiting Pharmacy Student(s): Kellie Tran	X	

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	
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:	
Brett Marchant, Biocon	Hayley Endicott, Gilead
Wendi Chandler	Robin Selsor, Aimmune
David Smith, Gilead	Amy Fay, Rhythm Pharmaceuticals
Amy DeStefanis, Rhythm Pharmaceuticals	Nima Nabavi, Amgen
Juan Roman, Rhythm Pharmaceuticals	Aaron Austin, Takeda
Shawana Crawford, Gilead	Shane Foster, Ferring
Cody Gerber, Rhythm Pharmaceuticals	Jamie Petkunas, Rhythm Pharmaceuticals
Melissa Abbott, Eisai	Roberto Pedraza, Vertex
Fred McClellan, Ascendis Pharma	Justin Springfield, Gilead
Brent Parker, Merck	Gary Parenteau, Dexcom
Nancy Njuguna, Gilead	Jennifer Davis, Gilead
Jeff Forshey, Rhythm Pharmaceuticals	Porscha Showers, Gilead
Kathrin Kucharski, Sarepta	JJ Roth, Mirum Pharmaceuticals
Mai Duong, Novartis	Jesse Richards, OU Health
Katie Asbill, Rhythm Pharmaceuticals	Todd Ness, AbbVie
David Prather, Novo Nordisk	Bob Atkins, Biogen
Ed Clasby, Medtronic	Ed Eldridge, Gilead

PRESENT FOR PUBLIC COMMENT:	
Dr. Jesse Richards, D.O., OU Health	Porscha Showers, Gilead
Mai Duong, Novartis	Kathrin Kucharski, Sarepta

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. Adams established the presence of a quorum.

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 7 DR. JESSE RICHARDS, D.O.
2B: AGENDA ITEM NO. 8 PORSCHA SHOWERS
2C: AGENDA ITEM NO. 11 MAI DUONG
2D: AGENDA ITEM NO. 12 KATHRIN KUCHARSKI

ACTION: NONE REQUIRED

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

3A: SEPTEMBER 13, 2023 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 PIPELINE UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR SEPTEMBER 2023
4B: MEDICATION COVERAGE ACTIVITY FOR SEPTEMBER 2023
4C: FALL PIPELINE UPDATE
Materials included in agenda packet; presented by Dr. O'Halloran, Dr. Reynolds
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE REBYOTA® (FECAL MICROBIOTA, LIVE-JSLM) AND VOWST™ (FECAL MICROBIOTA SPORES, LIVE-BRPK) AND UPDATE THE APPROVAL CRITERIA FOR ZINPLAVA™ (BEZLOTOXUMAB)
5A: MARKET NEWS AND UPDATES
5B: PRODUCT SUMMARIES
5C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE ORSERDU™ (ELACESTRANT) AND UPDATE THE APPROVAL CRITERIA FOR THE BREAST CANCER MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Daugherty
Dr. Walton moved to approve; seconded by Dr. Thomas
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: ANNUAL REVIEW OF IMCIVREE® (SETMELANOTIDE)
7A: CURRENT PRIOR AUTHORIZATION CRITERIA
7B: UTILIZATION OF IMCIVREE® (SETMELANOTIDE)
7C: PRIOR AUTHORIZATION OF IMCIVREE® (SETMELANOTIDE)
7D: MARKET NEWS AND UPDATES
7E: COLLEGE OF PHARMACY RECOMMENDATIONS
7F: UTILIZATION DETAILS OF IMCIVREE® (SETMELANOTIDE)
Materials included in agenda packet; presented by Dr. Teel
Dr. Hanner moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED BY MAJORITY APPROVAL; ONE BOARD MEMBER OPPOSED

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

AGENDA ITEM NO. 9: **ANNUAL REVIEW OF MYELOPROLIFERATIVE NEOPLASM MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE OJJAARA (MOMELOTINIB)**

9A: CURRENT PRIOR AUTHORIZATION CRITERIA
9B: UTILIZATION OF MYELOPROLIFERATIVE NEOPLASM MEDICATIONS
9C: PRIOR AUTHORIZATION OF MYELOPROLIFERATIVE NEOPLASM MEDICATIONS
9D: MARKET NEWS AND UPDATES
9E: OJJAARA (MOMELOTINIB) PRODUCT SUMMARY
9F: COLLEGE OF PHARMACY RECOMMENDATIONS
9G: UTILIZATION DETAILS OF MYELOPROLIFERATIVE NEOPLASM MEDICATIONS

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

AGENDA ITEM NO. 10: **ANNUAL REVIEW OF ANEMIA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE JESDUVROQ™ (DAPRODUSTAT)**

10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF ANEMIA MEDICATIONS
10C: PRIOR AUTHORIZATION OF ANEMIA MEDICATIONS
10D: MARKET NEWS AND UPDATES
10E: JESDUVROQ™ (DAPRODUSTAT) PRODUCT SUMMARY
10F: COLLEGE OF PHARMACY RECOMMENDATIONS
10G: 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. 11: **ANNUAL REVIEW OF TARGETED IMMUNOMODULATOR AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE IDACIO® (ADALIMUMAB-AACF), LITFULO™ (RITLECITINIB), TOFIDENCE™ (TOCILIZUMAB-BAVI), YUFLYMA® (ADALIMUMAB-AATY), AND YUSIMRY™ (ADALIMUMAB-AQVH)**

11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF TARGETED IMMUNOMODULATOR AGENTS
11C: PRIOR AUTHORIZATION OF TARGETED IMMUNOMODULATOR AGENTS
11D: MARKET NEWS AND UPDATES
11E: PRODUCT SUMMARIES
11F: COLLEGE OF PHARMACY RECOMMENDATIONS
11G: 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. 12: **ANNUAL REVIEW OF MUSCULAR DYSTROPHY MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ELEVIDYS (DELANDISTROGENE MOXEPARVOVEC-ROKL)**

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF MUSCULAR DYSTROPHY MEDICATIONS
12C: PRIOR AUTHORIZATION OF MUSCULAR DYSTROPHY MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: ELEVIDYS (DELANDISTROGENE MOXEPARVOVEC-ROKL) PRODUCT SUMMARY
12F: COLLEGE OF PHARMACY RECOMMENDATIONS
12G: UTILIZATION DETAILS OF MUSCULAR DYSTROPHY MEDICATIONS

Materials included in agenda packet; presented by Dr. Moss

ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF SPINAL MUSCULAR ATROPHY (SMA) MEDICATIONS
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF SMA MEDICATIONS
13C: PRIOR AUTHORIZATION OF SMA MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF SMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Reynolds
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

<u>AGENDA ITEM NO. 14:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE VEOPOZ™ (POZELIMAB-BBFG)
14A: INTRODUCTION
14B: VEOPOZ™ (POZELIMAB-BBFG) PRODUCT SUMMARY
14C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER

<u>AGENDA ITEM NO. 15:</u> 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

<u>AGENDA ITEM NO. 16:</u> FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
16A: ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS
16B: ATOPIC DERMATITIS MEDICATIONS
16C: INJECTABLE AND VAGINAL PROGESTERONE PRODUCTS
16D: MULTIPLE MYELOMA MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

<u>AGENDA ITEM NO. 17:</u> ADJOURNMENT
The meeting was adjourned at 5:56 pm.

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

Memorandum

Date: October 13, 2023

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 11, 2023

Recommendation 1: Fall 2023 Pipeline Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Rebyota™ (Fecal Microbiota, Live-jslm) and Vowst™ (Fecal Microbiota Spores, Live-brpk) and Update the Approval Criteria for Zinplava™ (Bezlotoxumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Rebyota™ (fecal microbiota, live-jslm) and Vowst™ (fecal microbiota spores, live-brpk) with the following criteria (shown in red):

Rebyota™ (Fecal Microbiota, Live-jslm) Approval Criteria:

1. An FDA approved indication for the prevention of recurrence of *Clostridium difficile* infection (CDI) in members 18 years of age or older; and
2. Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and
3. The most recent CDI episode must be confirmed by a positive stool test for *C. difficile* toxin; and
4. The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days); and

5. The prescriber must verify that administration of Rebyota™ will occur 24 to 72 hours following completion of antibiotic course for CDI treatment; and
6. Rebyota™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with expertise in the treatment of CDI; and
7. For members at high risk for recurrent CDI (e.g., age ≥65, immunocompromised, clinically severe CDI upon presentation), a patient specific, clinically specific reason why the member cannot use Zinplava™ (bezlotoxumab) must be provided; and
8. The member must not be using Rebyota™ in combination with Vowst™ (fecal microbiota spores, live-brpk) or Zinplava™ (bezlotoxumab); and
9. Initial approvals will be for 1 treatment course. A second treatment course may be considered following a confirmed treatment failure within 8 weeks.

Vowst™ (Fecal Microbiota Spores, Live-brpk) Approval Criteria:

1. An FDA approved indication for the prevention of recurrence of *Clostridium difficile* infection (CDI) in members 18 years of age or older; and
2. Member must have a diagnosis of at least 2 recurrent CDI episodes (≥3 total CDI episodes); and
3. The most recent CDI episode must be confirmed by a positive stool test for *C. difficile* toxin; and
4. The current CDI episode must be controlled (<3 unformed/loose stools/day for 2 consecutive days) following 10 to 21 days of antibiotic therapy; and
5. The prescriber must verify that administration of Vowst™ will occur 2 to 4 days following completion of antibiotic course for CDI treatment; and
6. The member must agree to bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution the day before the first dose of Vowst™; and
7. Vowst™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with the expertise in the treatment of CDI; and
8. A patient specific, clinically specific reason (beyond convenience) why the member cannot use Rebyota™ (fecal microbiota, live-jslm) must be provided; and
9. For members at high risk for recurrent CDI (e.g., age ≥65, immunocompromised, clinically severe CDI on presentation), a patient specific, clinically specific reason why the member cannot use Zinplava™ (bezlotoxumab) must be provided; and
10. The member must not be using Vowst™ in combination with Rebyota™ (fecal microbiota, live-jslm) or Zinplava™ (bezlotoxumab); and

11. A quantity limit of 12 capsules for 3 days for 1 treatment course will apply.

Additionally, the College of Pharmacy recommends updating the current approval criteria for Zinplava™ based on the FDA approved age expansion and to be more consistent with clinical practice (changes shown in red):

Zinplava™ (Bezlotoxumab) Approval Criteria:

1. An FDA approved diagnosis of Clostridium difficile infection (CDI) in members ~~18~~ 1 year of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence; and
    a. Prescriber must document the member has ≥1 of the following risk factor(s) for high risk of CDI recurrence:
        i. Age 65 years or older; or
        ii. One or more episodes of CDI within the 6 months prior to the episode under treatment; or
        iii. Need for ongoing therapy with concomitant antibiotics during treatment for CDI; or
        iv. Severe underlying medical disorders; or
        v. Immunocompromised; or
        vi. Clinically severe CDI (Zar score ≥2); and
2. Current or planned antibacterial drug for CDI must be provided on the prior authorization request to ensure medication is within standard of care; and
3. Prescriber must document that Zinplava™ (bezlotoxumab) will be administered while the member is receiving antibacterial drug treatment of CDI; and
4. Zinplava™ must be prescribed by, or in consultation with, a gastroenterologist, infectious disease specialist, or a specialist with expertise in the treatment of CDI; and
5. The member must not be using Zinplava™ in combination with Rebyota™ (fecal microbiota, live-jslm) or Vowst™ (fecal microbiota spores, live-brpk); 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. Approvals will be for 1 treatment course.

Recommendation 3: Vote to Prior Authorize Orserdu® (Elacestrant) and Update the Approval Criteria for the Breast Cancer Medications

MOTION CARRIED by unanimous approval.

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

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; and
5. Has progressed after at least 1 prior endocrine therapy.

The College of Pharmacy also recommends updating the approval criteria for Ibrance® (palbociclib), Talzenna® (talazoparib), Trodelvy® (sacituzumab govitecan-hziy), Tukysa® (tucatinib), and Verzenio® (abemaciclib) based on recent FDA approvals (changes and new criteria noted in red):

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

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

Talzenna® (Talazoparib) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of metastatic, castration-resistant prostate cancer; and
2. Disease is homologous recombination repair (HRR) gene-mutated; and
3. Used in combination with enzalutamide.

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

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

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

1. Diagnosis of RAS wild-type HER2-positve unresectable or metastatic CRC; and
2. Has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy; and
3. Used in combination with trastuzumab.

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 in advanced or metastatic breast cancer; or
        3. As monotherapy for disease progression following endocrine therapy and prior chemotherapy in metastatic breast cancer; ~~and~~ 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 ~~with Ki-67 ≥20%~~; and
    d. Used as adjuvant treatment in combination with endocrine therapy.

Additionally, the College of Pharmacy recommends updating the Tykerb® (lapatinib) approval criteria based on National Comprehensive Cancer Network (NCCN) recommendations for use in colorectal cancer (new criteria noted in red):

Tykerb® (Lapatinib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable, advanced, or metastatic disease; and
2. Member has human epidermal receptor 2 (HER2)-amplified disease; and
3. Member has wild-type RAS and BRAF disease; and
4. Member meets 1 of the following:
    a. Has tried at least 1 chemotherapy regimen; or
    b. Is not a candidate for intensive therapy, according to the prescriber; and
5. Used in combination with trastuzumab; and
6. Member has not been previously treated with a HER2-inhibitor.

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

Herceptin® (Trastuzumab), Herceptin Hylecta™ (Trastuzumab/ Hyaluronidase-oysk), 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), ~~Ontruzant® (trastuzumab-dttb)~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), Herceptin Hylecta™ (trastuzumab/hyaluronidase-oysk), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns)~~, or 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), ~~Ontruzant® (trastuzumab-dttb)~~, 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), 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, ~~or~~ 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), ~~Ontruzant® (trastuzumab-dttb)~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns)~~, or 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), ~~Ontruzant® (trastuzumab-dttb)~~, 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), 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), ~~Ontruzant® (trastuzumab-dttb)~~ and Trazimera® (trastuzumab-qyyp). Authorization of non-preferred trastuzumab products [Herceptin® (trastuzumab), ~~Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns)~~, or 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), ~~Ontruzant® (trastuzumab-dttb)~~, 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 Imcivree® (Setmelanotide)

MOTION CARRIED by majority approval; one Board member opposed.

The College of Pharmacy, in collaboration with the Oklahoma Health Care Authority (OHCA) medical director team, recommend updating the Imcivree® (setmelanotide) approval criteria to be consistent with clinical practice and to be consistent with the current FDA approved label regarding renal function (changes shown in red):

Imcivree® (Setmelanotide) Approval Criteria:

1. An FDA approved indication of chronic weight management in adult and pediatric members 6 years of age and older with obesity due to 1 of following:
    a. Proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency; or
    b. Bardet-Biedl syndrome (BBS); and
2. For POMC-, PCSK1-, or LEPR-deficiency, diagnosis must be confirmed by molecular genetic testing to confirm homozygous variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (results of genetic testing must be submitted); and
3. For BBS, diagnosis must be confirmed by the following:

a. Molecular genetic testing to confirm homozygous or compound heterozygous variants in a BBS gene that are interpreted as pathogenic or likely pathogenic (results of genetic testing must be submitted); and
b. Clinical features of BBS supported by detailed clinical documentation of each feature (medical records/clinical documentation of each feature must be submitted), as follows:
    i. Four primary features (i.e., rod-cone dystrophy, polydactyly, obesity, learning disabilities, ~~hypogonadism in males~~ hypogonadotropic hypogonadism and/or genitourinary anomalies, renal anomalies); or
    ii. Three of the primary features previously listed in 3.b.i. plus two secondary features [i.e., speech disorder/delay, strabismus/cataracts/astigmatism, brachydactyly/syndactyly, developmental delay, ~~polyuria/polydipsia (nephrogenic diabetes insipidus)~~, ataxia/poor coordination/imbalance, mild spasticity (especially lower limbs), diabetes mellitus, dental crowding/hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, hepatic fibrosis]; and

4. Requests for Imcivree® for obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign or other types of obesity not related to POMC, PCSK1, or LEPR deficiency or BBS including obesity associated with other genetic syndromes, or general obesity will not be approved; and
5. Member is currently on a dietician-guided diet and exercise program and has previously failed a dietician-guided diet and exercise program alone; and
6. Member's baseline weight and body mass index (BMI) must be provided; and
7. Baseline BMI must be ≥30kg/m^2 for adults or ≥95th percentile on BMI-for-age growth chart assessment for children; and
8. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Imcivree® therapy and throughout treatment; and
9. Prescriber must verify member has been counseled on potential sexual adverse reactions and when to seek emergency medical care; and
10. Prescriber must verify member does not have ~~moderate, severe, or~~ end stage renal disease [estimated glomerular filtration rate (eGFR) <15~~60~~mL/min/1.73m^2] and must confirm the dose will be adjusted per package labeling for members with severe renal impairment (eGFR 15 to 29mL/min/1.73m^2); and
11. Prescriber must verify female member is not pregnant or breastfeeding; and

12. Prescriber must confirm member or caregiver has been trained on the proper storage and administration of Imcivree® prior to the first dose; and
13. For POMC-, PCSK1-, or LEPR-deficiency, initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; or
14. For BBS, approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member's current weight or BMI and member has achieved weight loss of ≥5% of baseline body weight or ≥5% of BMI; and
15. A quantity limit of 9mL per 30 days will apply.

Recommendation 5: Annual Review of Hepatitis C Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Zepatier® (elbasvir/grazoprevir) based on the FDA approved age expansion (changes shown in red):

Zepatier® (Elbasvir/Grazoprevir) Approval Criteria:

1. Member must be 12 ~~18~~ years of age or older or weigh at least 30kg; and
2. An FDA approved diagnosis of Chronic Hepatitis C (CHC) genotype-1 or genotype-4; and
3. Zepatier® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last 3 months; and
4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and
5. If the member has genotype-1a, testing results for the presence of virus with NS5A resistance-associated polymorphisms must be indicated on the prior authorization request; and
6. Member has chronic HCV infection defined by:
    a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or
    b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
        i. Positive (i.e., reactive) HCV antibody test and has a recent (within the last 3 months) detectable and quantifiable HCV RNA (>15 IU/mL); or
        ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

7. The following regimens and requirements based on genotype, polymorphisms, and prior treatment status will apply (all regimens apply to patients with and without cirrhosis, HIV/HCV co-infected patients, and patients with or without renal impairment):
    a. Genotype-1a, treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms:
        i. Zepatier® for 12 weeks
    b. Genotype-1a, treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms:
        i. Zepatier® with weight-based ribavirin for 16 weeks
    c. Genotype-1b, treatment-naïve or peginterferon alfa + ribavirin experienced:
        i. Zepatier® for 12 weeks
    d. Genotype-1a or -1b, peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, teleprevir) experienced:
        i. Zepatier® with weight-based ribavirin for 12 weeks
    e. Genotype-4, treatment-naïve:
        i. Zepatier® for 12 weeks
    f. Genotype-4, treatment-experienced:
        i. Zepatier® with weight-based ribavirin for 16 weeks
    g. New regimens will apply as approved by the FDA
8. Member must sign and submit the Hepatitis C Intent to Treat contract; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and
11. Prescriber must agree to counsel members on potential harms of illicit 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
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have decompensated cirrhosis or moderate-to-severe hepatic impairment (Child-Pugh B and C); and
14. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use two forms of non-hormonal birth control while on therapy (and for six months after therapy completion for ribavirin users); and
15. The prescriber must verify that the member's ALT levels will be monitored prior to treatment initiation, at treatment week eight, and as clinically indicated thereafter (patients receiving 16 weeks of therapy should receive additional ALT levels at treatment week 12); and

16. Member must not be taking the following medications: phenytoin, carbamazepine, rifampin, St. John's wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, bosentan, etravirine, elvitegravir/cobicstat/emtricitabine/tenofovir, or modafinil; and
17. 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
18. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.
21. Approvals for treatment regimen initiation for 12 or 16 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Recommendation 6: Annual Review of Myeloproliferative Neoplasm Medications and 30-Day Notice to Prior Authorize Ojjaara (Momelotinib)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER 2023.

Recommendation 7: Annual Review of Anemia Medications and 30-Day Notice to Prior Authorize Jesduvroq™ (Daprodustat)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER 2023.

Recommendation 8: Annual Review of Targeted Immunomodulator Agents and 30-Day Notice to Prior Authorize Idacio® (Adalimumab-aacf), Litfulo™ (Ritlecitinib), Tofidence™ (Tocilizumab-bavi), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER 2023.

Recommendation 9: Annual Review of Muscular Dystrophy Medications and 30-Day Notice to Prior Authorize Elevidys (Delandistrogene Moxeparvovec-rokl)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER 2023.

Recommendation 10: Annual Review of Spinal Muscular Atrophy (SMA) Medications

NO ACTION REQUIRED.

Recommendation 11: 30-Day Notice to Prior Authorize Veopoz™ (Pozelimab-bbfg)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN NOVEMBER 2023.

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

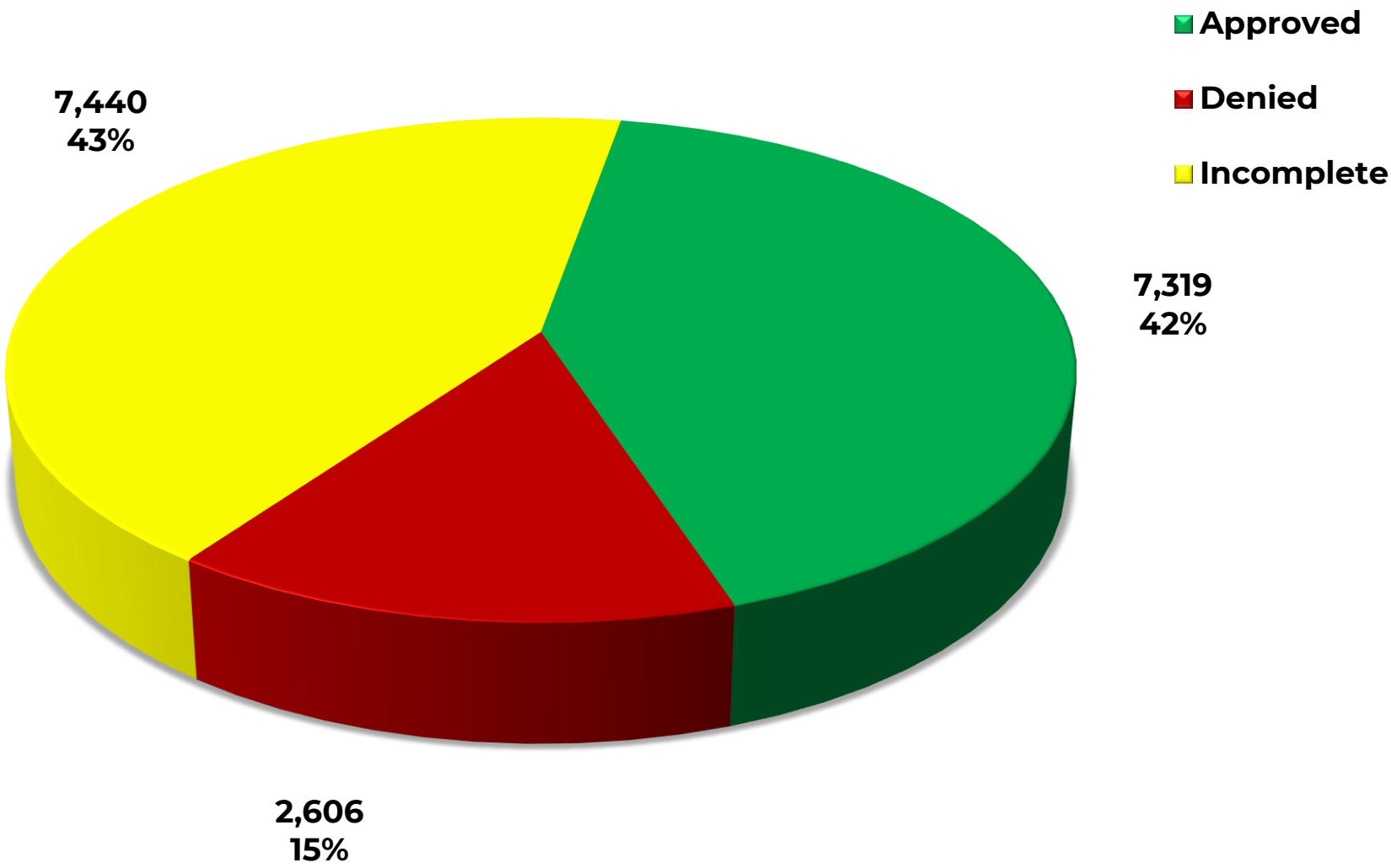
NO ACTION REQUIRED.

Recommendation 13: Future Business

NO ACTION REQUIRED.

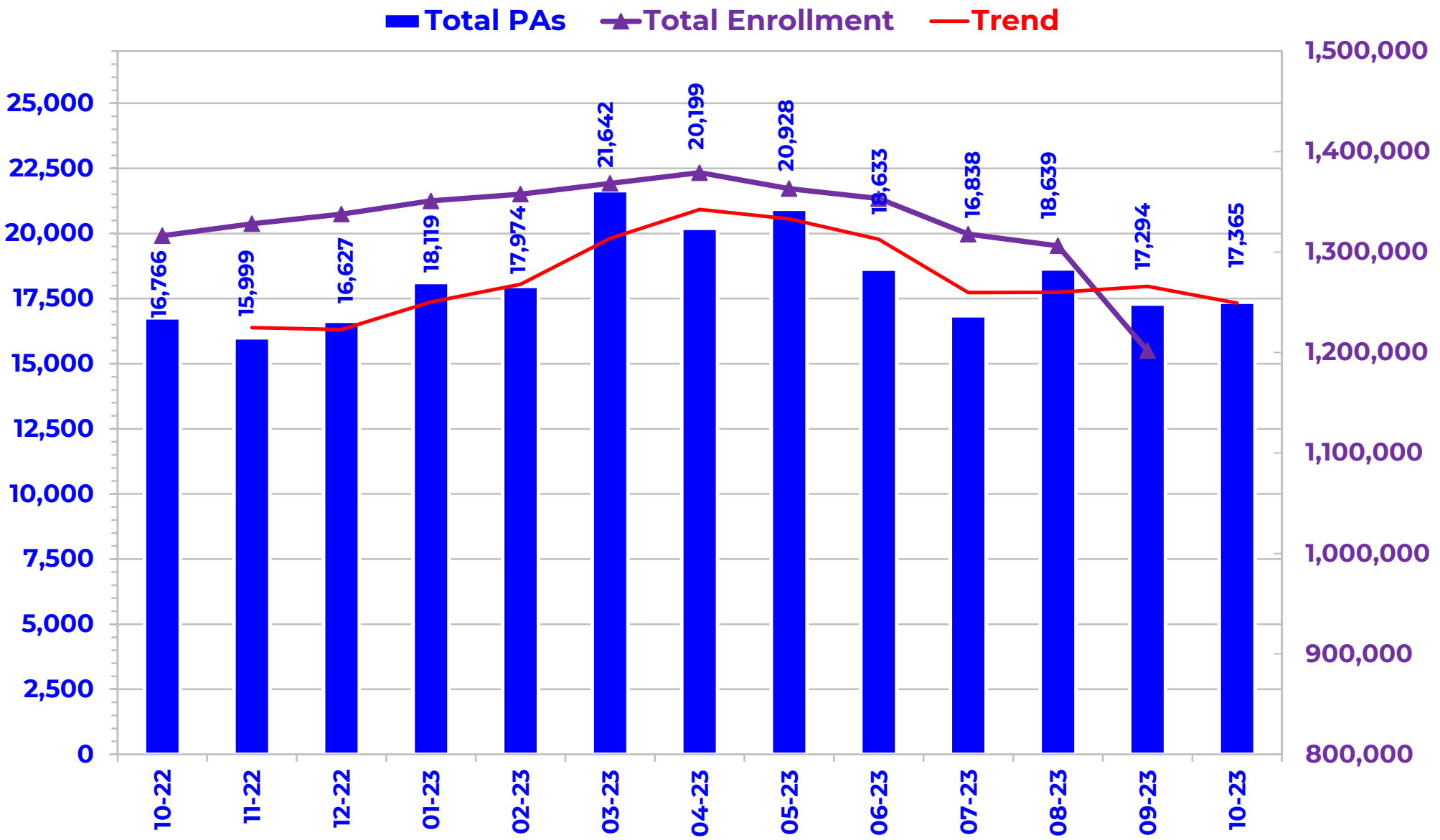
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: OCTOBER 2023



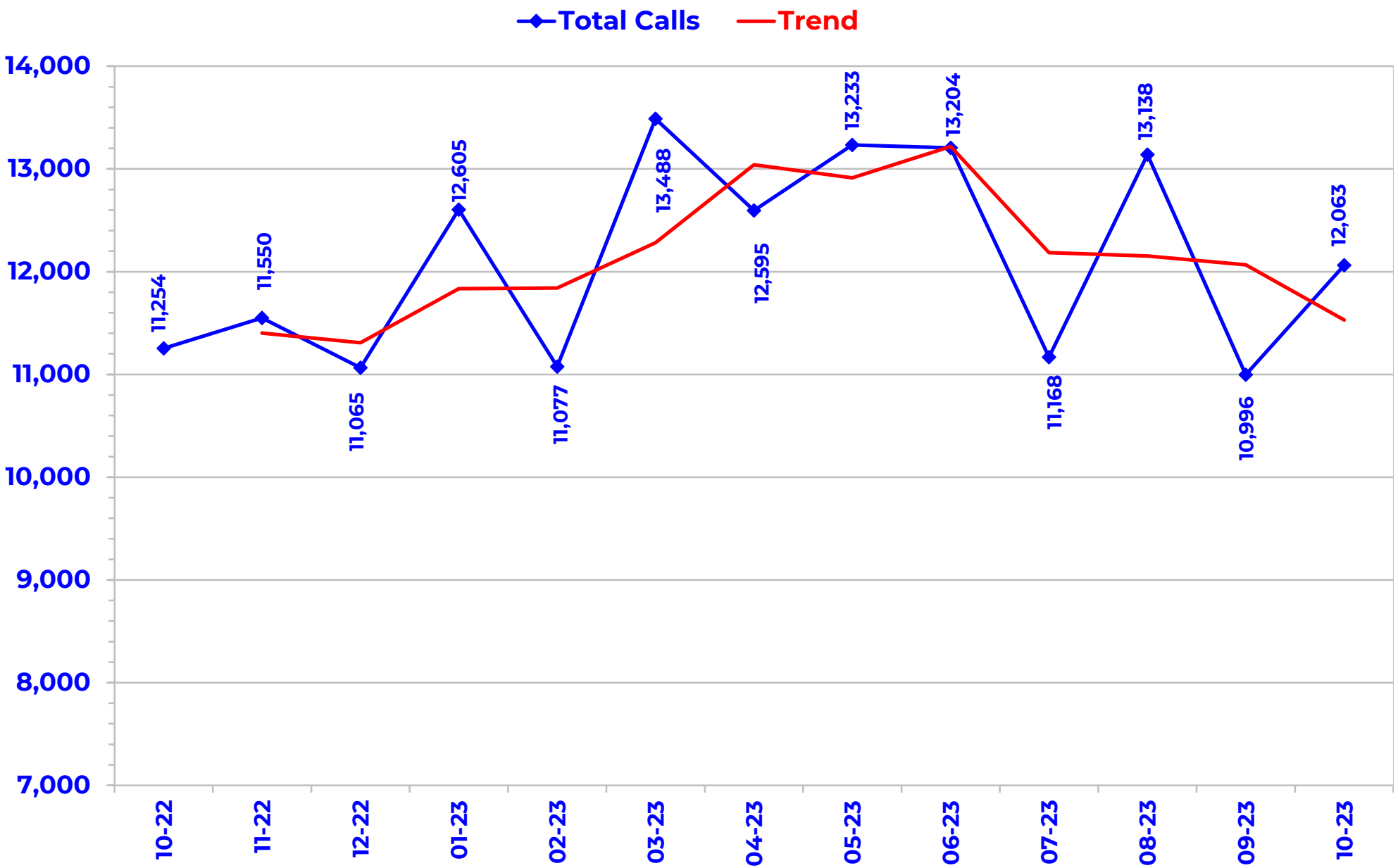
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: OCTOBER 2022 – OCTOBER 2023



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: OCTOBER 2022 – OCTOBER 2023



Prior Authorization Activity

10/1/2023 Through 10/31/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	182	62	8	112	357
Analgesic - NonNarcotic	18	0	4	14	0
Analgesic, Narcotic	420	167	42	211	116
Antiasthma	118	40	23	55	280
Antibiotic	47	17	5	25	272
Anticonvulsant	274	128	20	126	302
Antidepressant	481	125	74	282	309
Antidiabetic	2,187	593	628	966	357
Antigout	21	8	1	12	280
Antihemophilic Factor	10	7	0	3	268
Antihistamine	63	13	18	32	360
Antimalarial Agent	10	2	2	6	53
Antimigraine	758	143	210	405	258
Antineoplastic	367	236	21	110	176
Antiobesity	37	0	31	6	0
Antiparasitic	35	10	10	15	22
Antiparkinsons	17	3	9	5	361
Antiulcers	45	6	9	30	148
Antiviral	14	3	5	6	98
Anxiolytic	32	3	1	28	236
Atypical Antipsychotics	648	262	59	327	358
Benign Prostatic Hypertrophy	10	5	3	2	360
Biologics	466	262	46	158	323
Bladder Control	117	23	34	60	328
Blood Thinners	30	3	1	26	361
Botox	70	46	15	9	360
Buprenorphine Medications	121	47	15	59	121
Calcium Channel Blockers	14	2	1	11	269
Cardiovascular	161	81	15	65	345
Chronic Obstructive Pulmonary Disease	349	52	92	205	346
Constipation/Diarrhea Medications	403	96	109	198	207
Contraceptive	69	19	11	39	326
Corticosteroid	13	1	5	7	361
Dermatological	727	224	193	310	210
Diabetic Supplies	559	219	70	270	158
Diuretic	12	7	0	5	310
Endocrine & Metabolic Drugs	69	11	14	44	234
Erythropoietin Stimulating Agents	37	21	3	13	114
Estrogen Derivative	15	2	4	9	361
Fibric Acid Derivatives	10	1	1	8	361
Fibromyalgia	11	1	3	7	26

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Fish Oils	21	2	5	14	361
Gastrointestinal Agents	234	61	43	130	204
Genitourinary Agents	11	1	4	6	361
Glaucoma	25	9	0	16	103
Growth Hormones	213	148	22	43	137
Hematopoietic Agents	22	10	3	9	161
Hepatitis C	53	22	6	25	10
HFA Rescue Inhalers	22	3	1	18	138
Insomnia	133	6	33	94	197
Insulin	303	97	30	176	346
Miscellaneous Antibiotics	44	2	11	31	19
Multiple Sclerosis	90	44	9	37	253
Muscle Relaxant	57	4	8	45	192
Nasal Allergy	53	3	17	33	269
Neurological Agents	276	84	53	139	177
Neuromuscular Agents	20	11	3	6	233
NSAIDs	52	3	18	31	360
Ocular Allergy	23	6	2	15	222
Ophthalmic	37	5	7	25	181
Ophthalmic Anti-infectives	30	10	3	17	19
Ophthalmic Corticosteroid	14	1	3	10	361
Osteoporosis	37	13	5	19	360
Other*	421	135	68	218	286
Otic Antibiotic	26	0	0	26	0
Pediculicide	16	8	2	6	8
Respiratory Agents	49	32	2	15	318
Statins	52	12	9	31	189
Stimulant	3,165	1,752	133	1,280	325
Synagis	12	0	12	0	0
Testosterone	230	70	52	108	337
Thyroid	29	9	3	17	360
Topical Antifungal	55	6	12	37	140
Topical Corticosteroids	58	4	15	39	299
Vitamin	144	9	97	38	222
Pharmacotherapy	84	73	3	8	320
Emergency PAs	0	0	0	0	
Total	**15,158**	**5,606**	**2,509**	**7,043**	

* Includes any therapeutic category with less than 10 prior authorizations for the month.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Overrides					
Brand	33	17	1	15	212
Compound	17	13	0	4	13
Cumulative Early Refill	2	2	0	0	95
Diabetic Supplies	1	1	0	0	8
Dosage Change	406	381	2	23	18
High Dose	5	3	0	2	246
Ingredient Duplication	5	5	0	0	15
Lost/Broken Rx	105	86	10	9	21
MAT Override	307	252	6	49	81
NDC vs Age	339	246	30	63	274
NDC vs Sex	9	7	0	2	141
Nursing Home Issue	36	34	0	2	19
Opioid MME Limit	53	27	2	24	135
Opioid Quantity	50	37	2	11	117
Other	48	30	13	5	15
Quantity vs Days Supply	639	478	22	139	248
STBS/STBSM	22	18	2	2	95
Step Therapy Exception	47	26	5	16	316
Stolen	10	6	2	2	35
Temporary Unlock	1	1	0	0	6
Third Brand Request	72	43	0	29	17
Overrides Total	**2,207**	**1,713**	**97**	**397**	
Total Regular PAs + Overrides	**17,365**	**7,319**	**2,606**	**7,440**	

Denial Reasons	
Unable to verify required trials.	6,405
Does not meet established criteria.	2,658
Lack required information to process request.	1,147
Other PA Activity	
Duplicate Requests	1,728
Letters	47,760
No Process	7
Changes to existing PAs	4,215
Helpdesk Initiated Prior Authorizations	1,090
PAs Missing Information	894

* Includes any therapeutic category with less than 10 prior authorizations for the month.

Use of Statins in Members with Diabetes Mellitus (DM)

Oklahoma Health Care Authority
November 2023

Introduction[1,2,3]

Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality for individuals with DM, and an estimated $37.3 billion is spent annually on CV-related issues associated with DM. The American Diabetes Association (ADA) defines ASCVD as having either coronary heart disease (CHD), cerebrovascular disease, or peripheral arterial disease presumed to be of atherosclerotic origin. Subgroup analyses of patients with DM on statin therapy in larger clinical trials have shown significant primary and secondary prevention of ASCVD events and CHD death. Meta-analyses of data from over 18,000 patients with DM from 14 randomized trials of statin therapy have demonstrated a 9% proportional reduction in all-cause mortality and a 13% reduction in vascular mortality for each 1mmol/L (39mg/dL) reduction in low-density lipoprotein cholesterol (LDL-C).

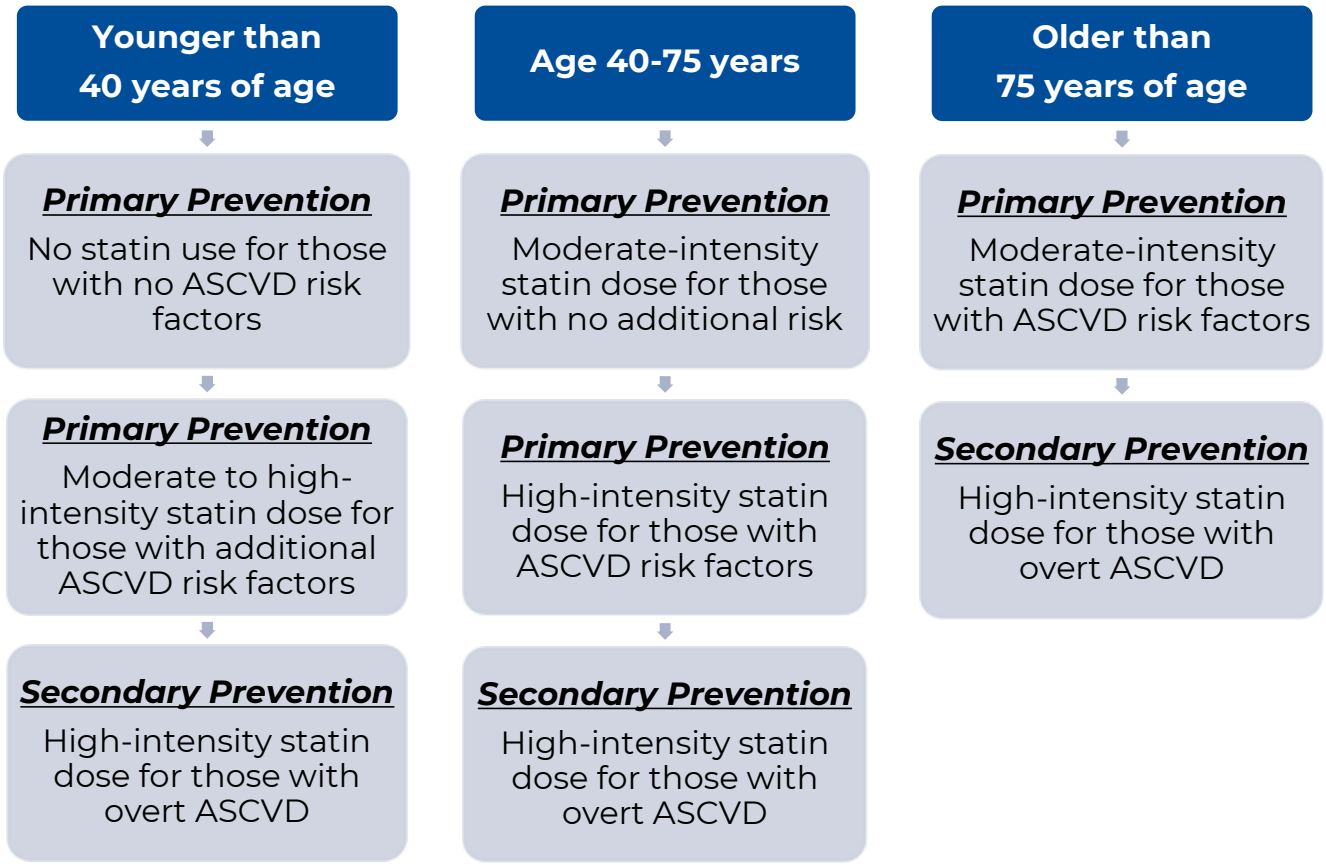
Statins are the drug of choice for LDL-C lowering. Depending on age and ASCVD risk factors, moderate-to-high intensity statins are generally recommended for prevention of ASCVD, while low-dose or low-intensity statin therapy is generally not recommended. High-intensity statin therapy will achieve approximately a ≥50% reduction in LDL-C, while moderate-intensity statin therapy will achieve a 30-49% reduction in LDL-C. For patients who are not able to tolerate the intended intensity of statin, the maximally tolerated dose should be used, which may include low-intensity statin therapy. Risk factors for ASCVD include hypertension, smoking, and overweight/obesity.

The 2023 ADA guidelines have been updated to reflect a few changes from previous years. The recommendations are still divided into 3 different age groups (younger than 40 years of age, 40-75 years of age, and older than 75 years of age) and have specific recommendations for primary prevention (patients without ASCVD) and secondary prevention (patients with ASCVD). For primary prevention in patients with DM aged 40–75 years with ASCVD risk factors, it is now recommended to target an LDL-C <70mg/dL; prior years did not specify an LDL-C goal for this category. For those with diabetes and ASCVD, an LDL-C of <55mg/dL should be targeted regardless of the patient's age. Previously, the addition of non-statin LDL-lowering therapies was recommended for secondary prevention in very high-risk patients with ASCVD who are already on high-intensity (and maximally tolerated) statin

therapy and have an LDL-C level ≥70mg/dL; however, this is now a recommendation for primary prevention as well. The non-statin LDL-lowering therapies include ezetimibe, PCSK9 inhibitors, and bempedoic acid. The guideline also addresses DM risk with statin use. Several studies have reported a modestly increased risk of incident DM with statin use which may be limited to those with risk factors for DM. An analysis of 1 of the initial studies suggest that although statin use was associated with DM risk, the CV event rate reduction with statins far outweighed the risk of incident DM even for patients at highest risk for DM.

Figure 1 below is a summary of the current recommendations for statin treatment for patients with either Type 1 DM (T1DM) or Type 2 DM (T2DM).

Figure 1: ADA Statin Treatment Recommendations



Mailing Summary

In August 2022, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) sent an educational letter to 122 providers regarding 7,152 unique members with a diagnosis of DM and who were not on statin therapy for primary or secondary prevention of ASCVD as directed by the

ADA guidelines. ASCVD was defined as having an ICD-10 code of either chronic ischemic heart disease, peripheral vascular disease, or other cerebrovascular disease in the member's medical claims history. Statin use for primary prevention for members younger than 40 years of age or older than 75 years of age was not assessed since the number of ASCVD risk factors could not be calculated from the available claims data. Depending on the number of ASCVD risk factors, statin therapy may or may not be recommended, so these members were not included in the analysis. The purpose of the educational mailing was to encourage providers to evaluate evidence-based prescribing practices for SoonerCare members with DM and who may benefit from lipid lowering therapies for primary or secondary ASCVD prevention.

Mailing Results

In October 2023, 14 months after the letters were sent out, a post-mailing claims analysis was performed. The claims analysis found 2,637 (37%) members included in the mailing had a paid claim for a statin medication after the letter was sent. Additionally, 268 members had a paid claim for other LDL-lowering therapies. Pharmacy claims not billed to SoonerCare (e.g., cash claims, office samples, commercial insurance) were not included in the claims analysis.

Statin Use in SoonerCare Members with DM in Calendar Year 2022 (CY22)

During CY22, there were a total of 33,843 unique members in the SoonerCare population with a diagnosis of either T1DM or T2DM who were 20 years of age or older and had a paid claim for a diabetes medication, which is a 47% increase from CY21. Of these members, 19% had a diagnosis of ASCVD in the member's medical claims history, as previously defined using specific ICD-10 codes. When evaluating members with DM with ASCVD, 24% of these members were not on statin therapy for secondary prevention of ASCVD, which has decreased from 27% in CY21. For primary prevention in members between the age of 40-75 years with DM without ASCVD, 24% of these members were not on statin therapy, compared to 44% during CY21. As with the previous analysis, statin use for primary prevention for members younger than 40 years of age or older than 75 years of age was not assessed because the number of ASCVD risk factors could not be calculated from the available claims data.

The following figure (Figure 2) is a summary of the data for SoonerCare members with DM during CY22. The age of the member was determined as the current age at the beginning of the year.

Figure 2: DM in the SoonerCare Population (CY22)

Data Point	Number of Members
Number of members with DM* 20 years of age and older	33,843
Number of members with DM* without ASCVD	27,550
Number of members with DM* with ASCVD	6,293
Number of members with DM* with ASCVD on a statin	4,806
Number of members with DM* with ASCVD not on a statin	1,487
Number of members with DM* without ASCVD not on statin and between 40-75 years of age	8,143

ASCVD = atherosclerotic cardiovascular disease; DM = diabetes mellitus
*Includes both Type 1 and Type 2 DM and a paid claim for a diabetes medication

Conclusions

The post-mailing claims analysis showed that 37% of members included in the mailing now have a paid claim for a statin medication for primary or secondary prevention of ASCVD as recommended in the ADA guidelines. Additionally, 3.7% of members had a paid claim for other LDL-lowering therapies that may be appropriate.

The post-mailing analysis did have some limitations such as not including pharmacy claims not billed to SoonerCare. Due to prescription limits and the lower cost of statin therapies, members could potentially be obtaining the medication through cash pay, commercial insurance, or Indian Health Services. Only pharmacy claims billed to SoonerCare were included in the analysis.

Overall, the purpose of this mailing was not to see all of the members started on therapy with a statin medication, but rather to ensure the providers were evaluating these members for appropriate therapy. As of October 2023, there are currently 9,630 unique SoonerCare members with a diagnosis of DM who are not receiving treatment with a statin medication for primary or secondary prevention of ASCVD. The number of members with DM who may benefit from primary or secondary prevention is expected to continue to increase, and the COP will continue to work with OHCA to improve the quality of care for SoonerCare members with DM needing primary or secondary prevention of ASCVD. New interventions will be implemented where appropriate, and results will be reported to the DUR Board when available.

[1] Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2019; 73(24):3168-3209. doi: 10.1016/j.jacc.2018.11.002.

[2] American Diabetes Association Professional Practice Committee. 10. Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes-2023. *Diabetes Care* 2023; 46(1):S158-S190. doi: 10.2337/dc23-S010.

[3] Joseph JJ, Deedwania P, Acharya T, et al. Comprehensive Management of Cardiovascular Risk Factors for Adults with Type 2 Diabetes: A Scientific Statement from the American Heart Association. *Circulation* 2022; 145(9):722-759. doi: 10.1161/CIR.0000000000001040.

Appendix C

2024 Drug Utilization Review (DUR) Board Meeting Dates

Oklahoma Health Care Authority
November 2023

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

January 10, 2024

February 14, 2024

March 13, 2024

April 10, 2024

May 8, 2024

June 12, 2024

July 10, 2024

August 14, 2024

September 11, 2024

October 9, 2024

November 13, 2024

December 11, 2024

Appendix D

Vote to Prior Authorize Elevidys (Delandistrogene Moxeparvovec-rokl) and Update the Approval Criteria for the Muscular Dystrophy Medications

Oklahoma Health Care Authority
November 2023

Market News and Updates[1]

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

- **June 2023:** The FDA approved Elevidys (delandistrogene moxeparvovec-rokl) under the accelerated approval pathway for the treatment of pediatric patients 4 years through 5 years of age with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene. It is the first gene therapy for the treatment of DMD. DMD is a genetic condition that is caused by a defective gene that results in the reduction or absence of dystrophin, a protein that helps keep muscle cells intact. Elevidys is a recombinant gene therapy designed to deliver a gene into the body that encodes the Elevidys micro-dystrophin protein that contains selected domains of the dystrophin protein present in normal cells. The accelerated approval is based on an increase in Elevidys micro-dystrophin protein expression in skeletal muscle in patients treated with Elevidys.

Elevidys (Delandistrogene Moxeparvovec-rokl) Product Summary[2]

Therapeutic Class: Adeno-associated virus (AAV) vector-based gene therapy

Indication(s): Treatment of ambulatory pediatric patients 4 through 5 years of age with DMD with a confirmed mutation in the *DMD* gene

- This indication is approved under accelerated approval based on expression of Elevidys micro-dystrophin in skeletal muscle observed in patients treated with Elevidys. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

How Supplied: Suspension for intravenous (IV) infusion with a nominal concentration of 1.33×10^{13} vector genomes (vg)/mL

Dosing and Administration:

- Elevidys is a single dose IV infusion which should be delivered over 1-2 hours at a rate of less than 10mL/kg/hr.
- Patients should be selected for treatment with Elevidys with anti-AAVrh74 total binding antibody titers <1:400.

- The recommended dosage is 1.33 x 10^{14} vg per kg of body weight.
- Treatment should be postponed in patients with concurrent infections until the infection has resolved.
- Patient's liver function, platelet counts, and troponin-I levels should be assessed before infusion.
- One day prior to infusion, a corticosteroid regimen should be initiated and continued for a minimum of 60 days. The dose should be modified for patients with liver abnormalities.

Cost: The Wholesale Acquisition Cost (WAC) for Elevidys is $3.2 million for the one-time treatment, regardless of the weight-based dose required.

Recommendations

The College of Pharmacy recommends the prior authorization of Elevidys (delandistrogene moxeparvovec-rokl) with the following criteria (shown in red):

Elevidys (Delandistrogene Moxeparvovec-rokl) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD) with a confirmed mutation in the *DMD* gene (results of genetic testing must be submitted); and
2. Member must be 4 years through 5 years of age; and
3. Prescriber must attest the member is ambulatory and the results of 1 of the following tests must be submitted:
    a. North Star Ambulatory Assessment (NSAA); or
    b. 6-minute walk test (6MWT); or
    c. 10-meter walk test (10mWT); or
    d. Ascend 4 Steps; or
    e. Time to Rise (TTR); or
    f. 100-meter timed test; and
4. Elevidys must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Member's baseline anti-AAVrh74 total binding antibody titers must be <1:400; and
6. Member must not have any deletion in exon 8 and/or exon 9 in the *DMD* gene; and
7. If the member has a deletion in the *DMD* gene in exon 1 to 17 and/or exons 59 to 71, the prescriber must verify the member will be monitored for a severe immune-mediated myositis reaction; and
8. Member must not have any active infections and if the member does have an active infection, the prescriber must verify Elevidys infusion will be postponed until infection has resolved; and

9. Prescriber must verify the member will initiate a corticosteroid regimen 1 day prior to the infusion of Elevidys and continue for a minimum of 60 days to reduce the risk of an immune response as specified in the package labeling; and
10. Prescriber must verify liver function tests (LFTs) (e.g., GGT, total bilirubin) will be performed prior to Elevidys administration and will be monitored weekly for the first 3 months following Elevidys infusion then as clinically indicated; and
11. Prescriber must verify troponin-I will be monitored before the Elevidys infusion and weekly for the first month following infusion then as clinically indicated; and
12. Prescriber must verify that platelet counts will be monitored before the Elevidys infusion and weekly for the first 2 weeks following infusion then as clinically indicated; and
13. Member will not be approved for concomitant treatment with exon skipping therapy (e.g., Amondys 45, Exondys 51, Viltepso®, Vyondys 53) following Elevidys infusion (current authorizations for exon skipping therapy will be discontinued upon Elevidys approval); and
14. Member's current weight (kg) taken within the past 3 weeks must be provided on the request to ensure accurate weight-based dosing according to package labeling; and
15. Approvals will be for 1 dose per member per lifetime.

Additionally, the College of Pharmacy recommends the following change to the Amondys 45 (casimersen), Exondys 51 (eteplirsen), Viltepso® (viltolarsen), and Vyondys 53 (golodirsen) approval criteria based on the FDA approval of Elevidys (delandistrogene moxeparvovec-rokl) (changes shown in red):

Amondys 45 (Casimersen), Exondys 51 (Eteplirsen), Viltepso® (Viltolarsen), and Vyondys 53 (Golodirsen) Approval Criteria:

1. An FDA approved diagnosis of Duchenne muscular dystrophy (DMD); and
2. Member must have a confirmed mutation of the *DMD* gene that is amenable to exon skipping for the requested medication (results of genetic testing must be submitted); and
3. Member must not have previously received Elevidys (delandistrogene moxeparvovec-rokl); and
4. Must be prescribed by a neurologist or specialist with expertise in the treatment of DMD (or an advanced care practitioner with a supervising physician who is a neurologist or specialist with expertise in the treatment of DMD); and
5. Prescriber must verify the member's renal function will be appropriately assessed prior to initiation of therapy and monitored during treatment; and

6. Member must be on a stable dose of a corticosteroid (at least 3 months in duration) or a patient-specific, clinically significant reason why corticosteroids are not appropriate for the member must be provided; and
7. A baseline assessment must be provided using at least 1 of the following exams as functionally appropriate:
    a. 6-minute walk test (6MWT); or
    b. Forced vital capacity percent predicted (FVCpp); and
8. The requested exon-skipping therapy will not be approved for concurrent use with any other exon-skipping therapies for DMD; and
9. Initial authorizations will be for the duration of 6 months, at which time the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
10. Subsequent approvals will be for the duration of 1 year. For yearly approvals, the prescriber must verify the member is responding to the medication as demonstrated by clinically significant improvement or maintenance of function from pretreatment baseline status using the same exam as performed at baseline assessment; and
11. 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.

[1] U.S. Food and Drug Administration (FDA). FDA Approves First Gene Therapy for Treatment of Certain Patients with Duchene Muscular Dystrophy. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treatment-certain-patients-duchenne-muscular-dystrophy. Issued 06/22/2023. Last accessed 10/12/2023.
[2] Elevidys Prescribing Information. Sarepta Therapeutics, Inc. Available online at: https://www.elevidys.com/downloads/elevidys-pi.pdf. Last revised 06/2023. Last accessed 10/12/2023.

Appendix E

Vote to Prior Authorize Jesduvroq™ (Daprodustat) and Update the Approval Criteria for the Anemia Medications

Oklahoma Health Care Authority
November 2023

Market News and Updates[1,2,3]

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

- **January 2023:** The FDA approved a supplemental Biologics License Application (sBLA) to expand the indication for Enjaymo® (sutimlimab-jome) to include patients with or without a history of transfusions. Enjaymo® was previously FDA approved for the treatment of hemolysis in adults with cold agglutinin disease in those with a red blood cell (RBC) transfusion in the last 6 months.
- **February 2023:** The FDA approved Jesduvroq™ (daprodustat), the first oral treatment for anemia due to chronic kidney disease (CKD), in patients who have been on dialysis for at least 4 months.
- **August 2023:** Reblozyl® (luspatercept-aamt) received a label expansion to include patients with anemia who are erythropoiesis stimulating agent (ESA) naïve with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular RBC transfusions. The new expansion places Reblozyl® as a potential first-line treatment option for these patients.

Jesduvroq™ (Daprodustat) Product Summary[4]

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

Indication(s): Treatment of anemia due to CKD in adults on dialysis for at least 4 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; or
    - In patients not on dialysis

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

Dosing and Administration:

- Jesduvroq™ should be taken once daily, with or without food.
- The maximum recommended dose is 24mg once daily.
- Jesduvroq™ may be administered without regard to concomitant administration of iron or phosphate binders or the timing or type of dialysis.
- The lowest dose needed to reduce the need for RBC transfusions should be used.
- The recommended starting dose will vary based on patients' hemoglobin levels and if switching from an ESA.
- Refer to the full *Prescribing Information* for the recommended starting dose, titration, and monitoring recommendations.

Cost: The Wholesale Acquisition Cost (WAC) of Jesduvroq™ is $31.28 per 8mg tablet, resulting in a monthly cost of $2,815.20 and $33,782.40 per year, based on the maximum recommended dose of 24mg once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Jesduvroq™ (daprodustat) with the following criteria (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; 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.

Additionally, the College of Pharmacy recommends updating the Enjaymo® (sutimlimab-jome) and Reblozyl® (luspatercept-aamt) approval criteria based on the new FDA approved label expansions (changes shown in red):

Enjaymo® (Sutimlimab-jome) Approval Criteria:

1. An FDA approved diagnosis of primary cold agglutin disease confirmed by the following:
    a. Chronic hemolysis; and
    b. Positive direct antiglobulin (Coombs) test for C3d; and
    c. Cold agglutin titer of ≥64 at 4° Celsius; and
2. Member must have 1 or more symptoms associated with cold agglutinin disease (i.e., symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, a major adverse vascular event); and
3. ~~Member has a history of at least 1 documented red blood cell (RBC) transfusion within 6 months of initiation; and~~
4. Member has a hemoglobin (Hgb) level ≤10g/dL; and
5. Member has a bilirubin level above the normal reference range; and
6. Enjaymo® must be prescribed by a hematologist (or an advanced care practitioner with a supervising physician who is a hematologist); and
7. Member has not received rituximab within 3 months of initiation and will not be using rituximab concomitantly with Enjaymo®; and
8. Prescriber must verify the member has been vaccinated against encapsulated bacteria (e.g., *Neisseria meningitides, Streptococcus pneumoniae, Haemophilus influenzae*) at least 2 weeks prior to initiation of treatment; and
9. Enjaymo® must be administered in a health care setting by a health care provider prepared to manage anaphylaxis; and
10. The prescriber must agree to monitor the member for at least 2 hours following the initial infusion for signs or symptoms of an infusion and/or

hypersensitivity reaction and for 1 hour following completion of subsequent infusions; and

11. Prescriber must verify the member has no chronic systemic infections [e.g., hepatitis B, hepatitis C, human immunodeficiency virus (HIV)]; and
12. 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
13. Initial approvals will be for 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to therapy, as confirmed by at least 1 of the following:
    a. Member has an increase in Hgb level of ≥2g/dL from baseline; or
    b. Member has had normalization of Hgb level to ≥12g/dL; or
    c. Member has had a decreased number of RBC transfusions since initiation of therapy.

Reblozyl® (Luspatercept-aamt) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. An FDA approved indication of 1 of the following:
    a. Treatment of adult members with very low-to-intermediate risk MDS with ring sideroblasts (MDS-RS) or myelodysplastic/ myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with anemia failing an erythropoiesis-stimulating agent (ESA) and requiring ≥2 red blood cell (RBC) units over 8 weeks; or
    b. Treatment of adult members with very low-to-intermediate risk MDS with anemia who are ESA-naïve and who required ≥2 RBC units within the last 8 weeks; and
2. For MDS-RS or MDS/MPN-RS-T:
    a. Member must have had an inadequate response to prior treatment with an ESA, be intolerant of ESAs, or have a serum erythropoietin level >200U/L; and
    b. Member must not have been previously treated with a disease modifying agent for the treatment of MDS; and
    c. Prescriber must verify the member does not have deletion 5q (del 5q); and
3. Complete blood counts (CBC) and verification that levels are acceptable to the prescriber and in accordance with package labeling; and
4. Reblozyl® must be prescribed by, or in consultation with, a hematologist, oncologist, or a specialist with expertise in treatment of MDS (or an advanced care practitioner with a supervising physician who is a hematologist, oncologist, or specialist with expertise in treating MDS); and
5. 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 6 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 1.75mg/kg or if unacceptable toxicity occurs at any time. Subsequent approvals will be for 1 year if the prescriber documents the member is responding well to treatment.

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[1] Sanofi. FDA Approves Expanded Label of Enjaymo® (Sutimlimab-jome) to Include Long-term Safety and Efficacy for People with Cold Agglutinin Disease. Available online at: https://www.news.sanofi.us/2023-01-15-FDA-approves-expanded-label-of-Enjaymo-R-sutimlimab-jome-to-include-long-term-safety-and-efficacy-for-people-with-cold-agglutinin-disease. Issued 01/25/2023. Last accessed 10/18/2023.

[2] U.S. FDA. FDA Approves First Oral Treatment for Anemia Caused by Chronic Kidney Disease for Adults on Dialysis. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-treatment-anemia-caused-chronic-kidney-disease-adults-dialysis. Issued 02/01/2023. Last accessed 10/18/2023.

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Appendix F

Vote to Prior Authorize Idacio® (Adalimumab-aacf), Litfulo™ (Ritlecitinib), Tofidence™ (Tocilizumab-bavi), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh) and Update the Approval Criteria for the Targeted Immunomodulator Agents

Oklahoma Health Care Authority
November 2023

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

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

- **March 2021:** The FDA approved Actemra® (tocilizumab) for a new indication to slow the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).
- **December 2021:** The FDA approved Yusimry™ (adalimumab-aqvh) as a new biosimilar to Humira® (adalimumab) for the treatment of all eligible Humira® indications.
- **June 2022:** The FDA approved Olumiant® (baricitinib) for a new indication for the treatment of adults with severe alopecia areata.
- **December 2022:** The FDA approved Idacio® (adalimumab-aacf) as a new biosimilar to Humira® (adalimumab) for the treatment of all eligible Humira® indications.
- **February 2023:** The FDA approved Kevzara® (sarilumab) for a new indication for the treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate a corticosteroid taper.
- **May 2023:** The FDA approved Yuflyma® (adalimumab-aaty) as a new biosimilar to Humira® (adalimumab) for the treatment of 8 different Humira® indications.
- **June 2023:** The FDA approved Litfulo™ (ritlecitinib) for the treatment of adults and adolescents 12 years of age and older with severe alopecia areata.
- **August 2023:** The FDA approved Ilaris® (canakinumab) for a new indication for the treatment of gout flares in adults in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

- **September 2023:** The FDA approved a new subcutaneous (sub-Q) formulation of Entyvio® (vedolizumab) for maintenance treatment of adults with moderately-to-severely active ulcerative colitis (UC) after at least 2 intravenous (IV) doses of vedolizumab. The sub-Q formulation will be available as a 108mg/0.68mL prefilled syringe or pen and the recommended dosing is 108mg every 2 weeks.
- **September 2023:** The FDA approved Tofidence™ (tocilizumab-bavi) as the first biosimilar to Actemra® (tocilizumab) for the treatment of adult patients with moderately-to-severely active rheumatoid arthritis (RA) who have had inadequate response to 1 or more disease-modifying anti-rheumatic drugs (DMARDs), the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA), and the treatment of patients 2 years of age and older with active systemic juvenile idiopathic arthritis (sJIA). Tofidence™ will be available as a solution for IV infusion in 80mg/4mL, 200mg/10mL, and 400mg/20mL single-dose vials (SDVs).

Litfulo™ (Ritlecitinib) Product Summary[13]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of severe alopecia areata in adults and adolescents 12 years of age and older

- Limitations of Use: Not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants

How Supplied: 50mg oral capsule

Dosing: 50mg orally once daily

Cost: The Wholesale Acquisition Cost (WAC) of Litfulo™ is $134.62 per capsule, resulting in an estimated cost of $3,769.36 per 28 days and $49,001.68 per year based on the recommended dose of 50mg once daily.

Recommendations

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

1. Creation of a new Special Prior Authorization (PA) Tier based on net cost; and
2. Updating the Tier-2 and Tier-3 approval criteria to be consistent with clinical practice to require the recommended clinical monitoring for all Tiers; and

3. Prior authorization and placement of Litfulo™ into the Special PA Tier and moving Olumiant® to the Special PA Tier with additional approval criteria for the diagnosis of alopecia areata; and
4. Prior authorization and placement of Idacio®, Yuflyma®, and Yusimry™ into the Special PA Tier based on net cost; and
5. Prior authorization and placement of Tofidence™ into the Special PA Tier with additional criteria for use of a biosimilar product; and
6. Moving Actemra® to the Special PA Tier and adding new approval criteria for the diagnosis of SSc-ILD; and
7. Moving Ilaris® to the Special PA Tier and adding new approval criteria for the diagnosis of gout flare; and
8. Adding new approval criteria for Kevzara® for the diagnosis of PMR; and
9. Moving all current Humira® and Enbrel® biosimilar products (Abrilada™, Amjevita™, Cyltezo®, Erelzi®, Eticovo™, Hadlima™, Hulio®, and Hyrimoz®), as well as Cosentyx®, Ilumya®, Rinvoq®, Skyrizi®, Sotyktu™, Stelara®, Taltz®, and Tremfya® from Tier-3 to the Special PA Tier based on net cost; and
10. Moving Inflectra®, Riabni®, Ruxience®, and Truxima® from Tier-3 to Tier-2 based on net cost; and
11. Updating the Entyvio® approval criteria based on the new sub-Q formulation and to add Inflectra® as a Tier-2 trial option; and
12. Removing the additional approval criteria for Xeljanz® and Xeljanz XR® based on net cost and to be consistent with other Tier-3 medications; and
13. Placing Arcalyst®, Benlysta®, Lupkynis®, Saphnelo®, Spevigo®, and Tavneos® into the Special PA Tier based on net cost.

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
6-mercaptopurine	adalimumab (Humira®)⁺	abatacept (Orencia®, Orencia® ClickJect™)¤	**adalimumab-aacf (Idacio®)±**
azathioprine	anakinra (Kineret®)	~~**adalimumab-adaz (Hyrimoz®)±**~~	**adalimumab-aaty (Yuflyma®)±**
hydroxychloroquine	apremilast (Otezla®)ß	~~**adalimumab-adbm (Cyltezo®)±**~~	**adalimumab-adaz (Hyrimoz®)±**
leflunomide	etanercept (Enbrel®)	~~**adalimumab-afzb (Abrilada™)±**~~	**adalimumab-adbm (Cyltezo®)±**
mesalamine	**infliximab-dyyb (Inflectra®)±**	~~**adalimumab-atto (Amjevita™)±**~~	**adalimumab-afzb (Abrilada™)±**
methotrexate	rituximab (Rituxan®)~	~~**adalimumab-bwwd (Hadlima™)±**~~	**adalimumab-aqvh (Yusimry™)±**
minocycline	**rituximab-abbs (Truxima®)±**	~~**adalimumab-fkjp (Hulio®)±**~~	**adalimumab-atto (Amjevita™)±**

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
NSAIDs	**rituximab-arrx (Riabni®)±**	~~**baricitinib (Olumiant®)**~~	**adalimumab-bwwd (Hadlima™)±**
oral corticosteroids	**rituximab-pvvr (Ruxience®)±**	brodalumab (Siliq®)**	**adalimumab-fkjp (Hulio®)±**
sulfasalazine		~~**canakinumab (Ilaris®)¥**~~	**anifrolumab-fnia (Saphnelo®)****
		certolizumab pegol (Cimzia®)	**avacopan (Tavneos®)****
		~~**deucravacitinib (Sotyktu™)**~~	**baricitinib (Olumiant®)€**
		~~**etanercept-szzs (Erelzi®)±**~~	**belimumab (Benlysta®)****
		~~**etanercept-ykro (Eticovo™)±**~~	**canakinumab (Ilaris®)¥**
		golimumab (Simponi®, Simponi Aria®)	**deucravacitinib (Sotyktu™)**
		~~**guselkumab (Tremfya®)**~~	**etanercept-szzs (Erelzi®)±**
		infliximab (Remicade®)±	**etanercept-ykro (Eticovo™)±**
		infliximab-axxq (Avsola®)±	**guselkumab (Tremfya®)**
		~~**infliximab-dyyb (Inflectra®)±**~~	**ixekizumab (Taltz®)**
		infliximab-abda (Renflexis®)±	**rilonacept (Arcalyst®)****
		~~**ixekizumab (Taltz®)**~~	**risankizumab-rzaa (Skyrizi®)**
		~~**risankizumab-rzaa (Skyrizi®)**~~	**ritlecitinib (Litfulo™)€**
		~~**rituximab-abbs (Truxima®)±**~~	**secukinumab (Cosentyx®)**
		~~**rituximab-arrx (Riabni®)±**~~	**spesolimab-sbzo (Spevigo®)****
		~~**rituximab-pvvr (Ruxience®)±**~~	**tildrakizumab-asmn (Ilumya®)**
		sarilumab (Kevzara®)§	**tocilizumab (Actemra®)₸**
		~~**secukinumab (Cosentyx®)**~~	**tocilizumab-bavi (Tofidence™)±**
		~~**tildrakizumab-asmn (Ilumya®)**~~	**upadacitinib (Rinvoq®)#**
		~~**tocilizumab (Actemra®)₸**~~	**ustekinumab (Stelara®)**
		tofacitinib (Xeljanz®, Xeljanz® XR, Xeljanz® oral solution)**	**voclosporin (Lupkynis®)****
		~~**upadacitinib (Rinvoq®)#**~~	

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
		~~**ustekinumab (Stelara®)**~~	
		vedolizumab (Entyvio®)**	

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. ~~**Appropriate laboratory monitoring must be verified by the prescriber prior to approval.**~~
‡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), ~~**or**~~ 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).
ᵀUnique 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).
**Unique criteria applies to this medication for approval.

Targeted Immunomodulator Agents Tier-2 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 trial of at least 1 Tier-1 medication (appropriate to the member's disease state) in the last 90 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
4. Prior stabilization on the Tier-2 medication documented within the last 100 days.

Targeted Immunomodulator Agents Tier-3 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. Recent trials (within the last 360 days) of 1 Tier-1 medication (appropriate to the member's disease state) and at least 2 Tier-2 medications (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 Tier-3 medication documented within the last 100 days; or
5. A unique FDA-approved indication not covered by Tier-2 medications (unique approval criteria may apply).

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 trial (within the last 360 days) of 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), ~~and~~ Hyrimoz® (Adalimumab-adaz), Idacio® (Adalimumab-aacf), Yuflyma® (Adalimumab-aaty), and Yusimry™ (Adalimumab-aqvh) Approval Criteria:

1. Member must meet ~~Tier-3 trial requirements~~ Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use Humira® (adalimumab) 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) Approval Criteria [Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Diagnosis]:

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

3. Medication must be prescribed by, or in consultation with, a pulmonologist or pulmonary specialist (or an advanced care practitioner with a supervising physician who is a pulmonologist or pulmonary specialist); and
4. Approvals will be for subcutaneous administration using the FDA approved dosing of 162mg once weekly.

Avsola® (Infliximab-axxq), ~~and~~ Remicade® (Infliximab), and Renflexis® (Infliximab-abda) Approval Criteria:

1. Member must meet Tier-3 trial requirements; and
2. A patient-specific, clinically significant reason why the member cannot use Inflectra® (infliximab-dyyb) ~~and Renflexis® (infliximab-abda)~~ 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.

Entyvio® (Vedolizumab) Approval Criteria:

1. An FDA approved diagnosis:
   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® sub-Q administration, member must have received at least 2 initial IV doses of Entyvio®; 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.

Erelzi® (Etanercept-szza) and Eticovo™ (Etanercept-ykro) Approval Criteria:

1. Member must meet ~~Tier 3 trial requirements~~ Special Prior Authorization (PA) approval criteria; and
2. A patient-specific, clinically significant reason why the member cannot use Enbrel® (etanercept) 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.

Ilaris® (Canakinumab) Approval Criteria [Gout Flare Diagnosis]:

1. An FDA approved indication for the treatment of gout flare; and
2. Member must have had ≥3 gout flares in the previous year; and
3. Member must meet 1 of the following:
    a. Inadequate response or intolerance to recent trials of oral colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroids (oral, intraarticular, and/or intramuscular) used for the treatment of previous gout flare(s); or
    b. Colchicine, NSAIDs, and corticosteroids are contraindicated for the member (specific information regarding contraindication must be submitted); and
4. A patient-specific, clinically significant reason why the member cannot use Kineret® (anakinra) must be provided; and
5. Approvals will be for (1) 150mg dose at a time. Subsequent approvals will require documentation that the member responded well to previous treatment with Ilaris®; and
6. Approvals will not be granted more often than once every 12 weeks.

Kevzara® (Sarilumab) Approval Criteria [Polymyalgia Rheumatica (PMR) Diagnosis]:

1. An FDA approved diagnosis of PMR; and
2. Member must be 18 years of age or older; and
3. Prescriber must verify member has had an inadequate response to corticosteroids or cannot tolerate corticosteroid taper; and
4. Prescriber must verify Kevzara® will be used in combination with a tapering course of corticosteroids, unless contraindicated.

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 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 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
10. 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
11. Concurrent use with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants will not be approved; and
12. Prescriber must verify female members are not breastfeeding; and
13. 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
14. Initial approvals will be for a duration of 24 weeks of treatment; and
15. 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).

~~**Riabni™ (Rituximab-arrx), Ruxience® (Rituximab-pvvr), and Truxima® (Rituximab-abbs) Approval Criteria:**~~

~~1. Member must meet Tier 3 trial requirements; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use Rituxan® (rituximab) 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.~~

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) 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.

~~**Xeljanz® (Tofacitinib) Approval Criteria:**~~

~~1. Member must meet Tier 3 approval criteria; and~~
~~2. Member must have a negative tuberculosis test, successful treatment of active tuberculosis, or close evaluation and appropriate treatment of latent tuberculosis; and~~
~~3. Severe hepatic impairment has been ruled out; and~~
~~4. Approval will be for 12 weeks, after which time, prescriber must confirm performance of the following tests (and verification that the results are acceptable to prescriber) for further approval:~~
   ~~a. Lymphocytes; and~~
   ~~b. Neutrophils; and~~
   ~~c. Hemoglobin; and~~
   ~~d. Liver enzymes; and~~
   ~~e. Lipid panel; and~~
~~5. Subsequent approvals will be for the duration of 1 year. Yearly approvals require performance of repeat tuberculosis test.~~

~~**Xeljanz® XR [Tofacitinib Extended-Release (ER)] Approval Criteria:**~~

~~1. Member must meet Tier 3 approval criteria and all Xeljanz® approval criteria; and~~
~~2. A patient-specific, clinically significant reason why the member cannot take the twice daily formulation of Xeljanz® must be provided.~~

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[7] Pfizer, Inc. FDA Approves Pfizer's Litfulo™ (Ritlecitinib) for Adults and Adolescents with Severe Alopecia Areata. Available online at: https://www.pfizer.com/news/press-release/press-release-detail/fda-approves-pfizers-litfulotm-ritlecitinib-adults-and. Issued 06/23/2023. Last accessed 10/24/2023.
[8] Ilaris® (Canakinumab) – New Indication. *OptumRx®*. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/clinical-updates/clinicalupdate_Ilaris_2023-0829.pdf. Issued 08/25/2023. Last accessed 10/24/2023.
[9] Takeda. U.S. FDA Approves Subcutaneous Administration of Takeda's Entyvio® (Vedolizumab) for Maintenance Therapy in Moderately to Severely Active Ulcerative Colitis. Available online at: https://www.takeda.com/newsroom/newsreleases/2023/US-FDA-Approves-Subcutaneous-Administration-of-Takeda-ENTYVIO-vedolizumab-for-Maintenance-Therapy-in-Moderately-to-Severely-Active-Ulcerative-Colitis/. Issued 09/27/2023. Last accessed 10/24/2023.
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[13] Litfulo™ (Ritlecitinib) Prescribing Information. Pfizer, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215830s000lbl.pdf. Last revised 06/2023. Last accessed 10/24/2023.

Appendix G

Vote to Prior Authorize Veopoz™ (Pozelimab-bbfg)

Oklahoma Health Care Authority
November 2023

Market News and Updates[1]

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

- **August 2023:** The FDA approved Veopoz™ (pozelimab-bbfg) for the treatment of CD55-deficient protein-losing enteropathy (PLE), also known as complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease, in adult and pediatric patients 1 year of age or older.

Veopoz™ (Pozelimab-bbfg) Product Summary[2]

Therapeutic Class: Complement inhibitor

Indication(s): Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient PLE, also known as CHAPLE disease

How Supplied: 400mg/2mL single dose vial (SDV)

Dosing and Administration:

- Loading Dose: 30mg/kg intravenous (IV) infusion
- Maintenance Dose: 10mg/kg subcutaneous (sub-Q) injection once weekly starting on day 8
  - Dose may be increased to 12mg/kg once weekly if there is inadequate clinical response after at least 3 weekly doses
  - Maximum maintenance dosage is 800mg once weekly
- Meningococcal vaccination should be completed or updated at least 2 weeks prior to administering the first dose, unless the risks of delaying therapy outweigh the risk of developing a meningococcal infection.

Cost: The Wholesale Acquisition Cost (WAC) of Veopoz™ is $17,307.69 per mL, or $34,615.38 per 400mg/2mL SDV, resulting in an estimated cost of $276,923.04 per month and $3,599,999.52 per year, based on the maximum recommended maintenance dose of 800mg once weekly.

Recommendations

The College of Pharmacy recommends the prior authorization of Veopoz™ (pozelimab-bbfg) with the following criteria (shown in red):

Veopoz™ (Pozelimab-bbfg) Approval Criteria:

1. An FDA approved diagnosis of CD55-deficient protein-losing enteropathy (PLE) confirmed by all of the following:
   a. Genetic testing identifying biallelic pathogenic mutations in the *CD55* gene (results of genetic testing must be submitted); and
   b. A history of PLE; and
2. Member has active disease defined by hypoalbuminemia (serum albumin concentration ≤3.2g/dL) with 1 or more of the following signs or symptoms within the last 6 months: abdominal pain, diarrhea, peripheral edema, or facial edema; and
3. Member must be 1 year of age or older; and
4. Prescriber must verify the member has received the meningococcal vaccine 2 weeks prior to treatment unless urgent treatment is needed; and
5. Veopoz™ must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or other specialist with expertise in the treatment of CD55-deficient PLE; and
6. The prescriber must verify that Veopoz™ will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a normalization of serum albumin or documentation of a positive clinical response to therapy.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for CD55-Deficient Protein-Losing Enteropathy (CHAPLE Disease). Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-treatment-cd55-deficient-protein-losing-enteropathy-chaple-disease. Issued 08/18/2023. Last accessed 10/18/2023.

[2] Veopoz™ (Pozelimab-bbfg) Prescribing Information. Regeneron Pharmaceuticals. Available online at: https://www.regeneron.com/downloads/veopoz_fpi.pdf. Last revised 08/2023. Last accessed 10/18/2023.

Appendix H

Vote to Prior Authorize Ojjaara (Momelotinib)

Oklahoma Health Care Authority
November 2023

Market News and Updates[1]

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

- **September 2023:** The FDA approved Ojjaara (momelotinib) for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

Ojjaara (Momelotinib) Product Summary[2]

Therapeutic Class: Kinase inhibitor

Indication(s): Treatment of intermediate or high-risk MF, including primary MF or secondary MF (post-PV and post-ET), in adults with anemia

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

Dose: 200mg once daily, with or without food

Cost: The Wholesale Acquisition Cost (WAC) of Ojjaara is $896.67 per tablet, resulting in a cost of approximately $26,900 per month or $322,800 per year based on recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Ojjaara (momelotinib) with the following criteria (shown in red):

Ojjaara (Momelotinib) Approval Criteria [Myelofibrosis (MF) Diagnosis]:

1. Diagnosis of intermediate or high-risk disease (including MF, polycythemia vera, or post-essential thrombocythemia); and
2. Presence of anemia.

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[1] GlaxoSmithKline. Ojjaara (Momelotinib) Approved in the US as the First and Only Treatment Indicated for Myelofibrosis Patients with Anaemia. Available online at: https://www.gsk.com/en-gb/media/press-releases/ojjaara-momelotinib-approved-in-the-us-as-the-first-and-only-treatment-indicated-for-myelofibrosis-patients-with-anaemia/. Issued 09/15/2023. Last accessed 10/24/2023.
[2] Ojjaara (Momelotinib) Prescribing Information. GlaxoSmithKline. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216873s000lbl.pdf. Last revised 09/2023. Last accessed 10/24/2023.

Appendix I

Fiscal Year 2023 Annual Review of Atopic Dermatitis (AD) Medications

Oklahoma Health Care Authority
November 2023

Current Prior Authorization Criteria

Approval criteria for Dupixent® (dupilumab injection) for indications other than AD can be found in the Fiscal Year 2023 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications report, which is also being presented at the November 2023 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 2023 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 18 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 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 2023

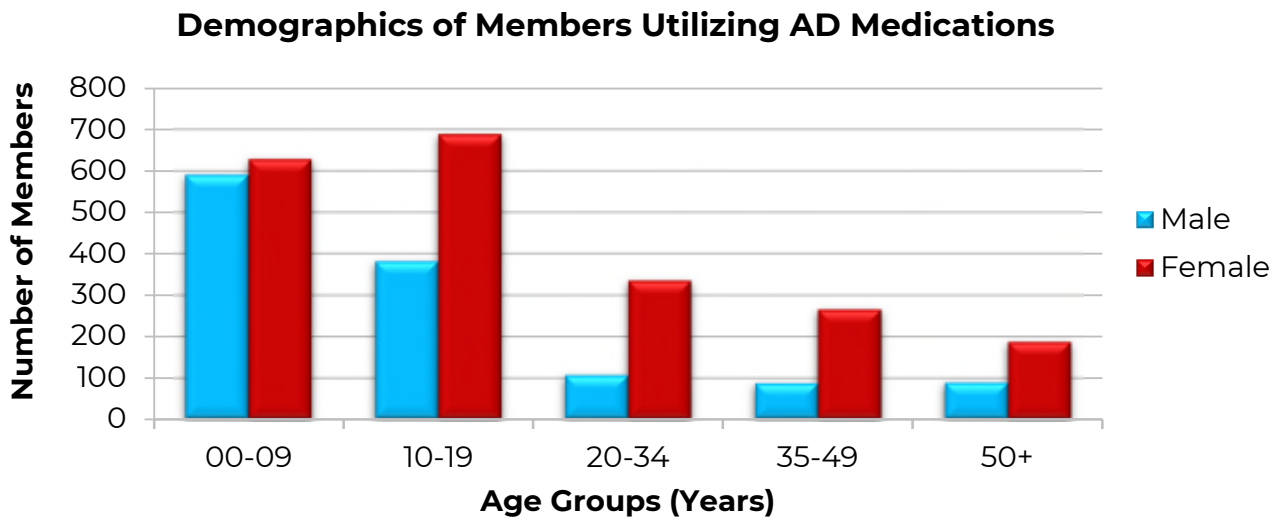
Comparison of Fiscal Years

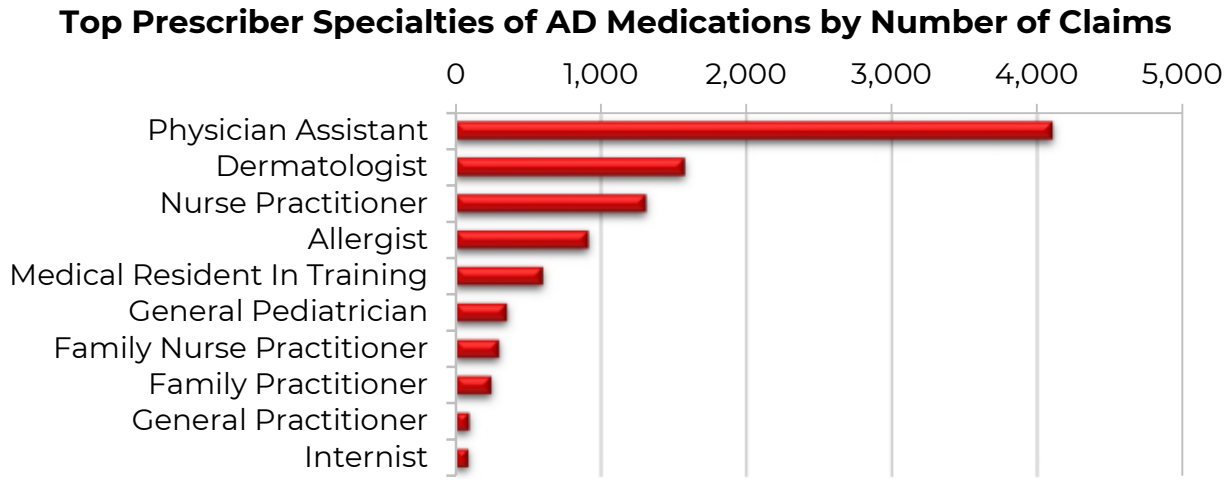
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	2,431	6,427	$10,367,672.88	$1,613.14	$53.40	203,426	194,138
2023	3,345	9,908	$19,086,691.12	$1,926.39	$62.09	266,721	307,387
% Change	**37.60%**	**54.20%**	**84.10%**	**19.40%**	**16.30%**	**31.10%**	**58.30%**
Change	**914**	**3,481**	**$8,719,018.24**	**$313.25**	**$8.69**	**63,295**	**113,249**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Utilization data includes Dupixent® used for all diagnoses and does not differentiate between AD diagnoses and other diagnoses, for which use may be appropriate.

- Aggregate drug rebates collected during fiscal year 2023 for AD medications totaled $3,965,093.04.[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.

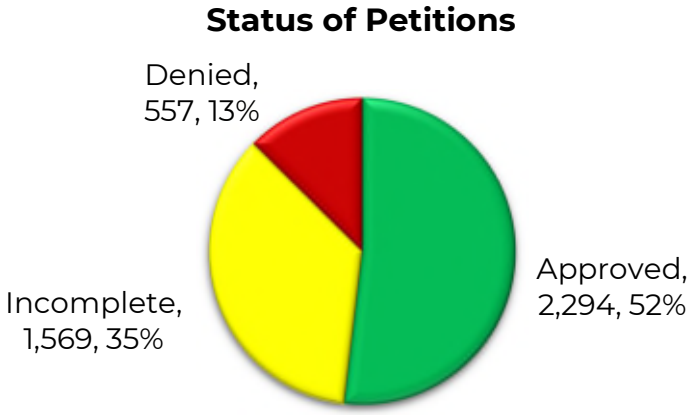
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.





Prior Authorization of AD Medications

There were 4,420 prior authorization requests submitted for AD medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



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

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):

- **February 2023:** The FDA approved Cibinqo™ (abrocitinib) for an age expansion in patients 12 years of age and older with refractory moderate-to-severe AD whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Previously, Cibinqo™ was FDA approved for use only in adult patients.
- **April 2023:** The FDA approved an expanded dosing regimen for Eucrisa® (crisaborole) in patients with mild-to-moderate AD. For patients who achieve a clinical effect with initial twice daily dosing of Eucrisa®, the dosing frequency may be decreased to once daily application. Eucrisa® is indicated for the treatment of mild-to-moderate AD in patients 3 months of age and older.

Guideline Update(s):

- **July 2023:** The American Academy of Dermatology (AAD) published updated guidelines for the management of AD in adults with topical therapies. 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. Some of the key recommendations made for topical treatment of adult patients with AD include:

  Strong Recommendations Based on High Certainty of Evidence:
  - Tacrolimus 0.03% or 0.1% is recommended for adults with AD
  - Pimecrolimus 1% is recommended for adults with mild-to-moderate AD
  - Topical corticosteroids (TCS) are recommended for adults with AD
  - Intermittent use of medium potency TCS are recommended as maintenance therapy (2 times per week) to reduce disease flares and relapse
  - Crisaborole is recommended for adults with mild-to-moderate AD

  Strong Recommendation Based on Moderate Certainty of Evidence:
  - Ruxolitinib cream is recommended for adults with mild-to-moderate AD

Pipeline:

- **Delgocitinib:** Delgocitinib is a topical therapy that is being investigated for the treatment of chronic hand eczema. It is a pan-Janus kinase (JAK) inhibitor that is formulated as a topical cream. In October 2023, LEO Pharma announced positive results from the Phase 3 DELTA 2 study of delgocitinib in adults with moderate-to-severe chronic hand eczema. Delgocitinib is also being evaluated for the treatment of frontal fibrosing alopecia.
- **Lebrikizumab:** Lebrikizumab is an investigational monoclonal antibody designed to bind IL-13 with high affinity, resulting in inhibition of signaling pathways thought to be responsible for multiple aspects of the pathophysiology of AD, including skin barrier dysfunction, itching, skin thickening, and infection. Positive Phase 3 results in patients with AD were reported previously. In October 2023, the FDA issued a Complete Response Letter (CRL) to a Biologic License Application (BLA) for lebrikizumab for the treatment of moderate-to-severe AD due to issues related to a third-party contracted manufacturer. The concerns were not related to the clinical data or safety of lebrikizumab. Eli Lilly intends to work with the third-party manufacturer and the FDA to address the CRL for potential FDA approval.
- **Nemolizumab:** Nemolizumab is an investigational monoclonal antibody designed to block IL-31 signaling, a cytokine with important roles in pruritus and skin inflammation. In October 2023, Galderma announced positive results from the Phase 3 ARCADIA 1 and ARCADIA 2 studies in patients with moderate-to-severe AD which demonstrated reductions in itch and skin lesions in patients with AD. Nemolizumab is also being evaluated for the treatment of prurigo nodularis.

Recommendations

The College of Pharmacy recommends updating the Cibinqo™ (abrocitinib) and Rinvoq® (upadacitinib) approval criteria based on the FDA approved age expansion for Cibinqo™ (changes shown in red):

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 ~~18~~ 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.

Utilization Details of AD Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INJECTABLE PRODUCTS						
DUPIXENT INJ 300MG/2ML PEN	2,242	403	$7,678,441.74	$3,424.82	5.56	40.23%
DUPIXENT INJ 300MG/2ML SYR	1,554	267	$5,212,577.40	$3,354.30	5.82	27.31%
DUPIXENT INJ 200MG/1.14ML SYR	1,096	177	$3,673,074.15	$3,351.35	6.19	19.24%
DUPIXENT INJ 200MG/1.14ML PEN	249	54	$879,579.79	$3,532.45	4.61	4.61%
ADBRY INJ 150MG/ML SYR	101	21	$350,427.69	$3,469.58	4.81	1.84%
DUPIXENT INJ 100MG/0.67ML SYR	3	1	$10,188.72	$3,396.24	3	0.05%
SUBTOTAL	**5,245**	**923**	**$17,804,289.49**	**$3,394.53**	**5.68**	**93.28%**
TOPICAL PRODUCTS						
PIMECROLIMUS CRE 1%	1,373	984	$220,254.41	$160.42	1.4	1.15%
TACROLIMUS OIN 0.1%	1,102	785	$89,478.11	$81.20	1.4	0.47%
EUCRISA OIN 2%	1,088	561	$798,026.25	$733.48	1.94	4.18%
TACROLIMUS OIN 0.03%	1,062	742	$77,609.66	$73.08	1.43	0.41%
OPZELURA CRE 1.5%	31	13	$59,837.86	$1,930.25	2.38	0.31%
SUBTOTAL	**4,656**	**3,085**	**$1,245,206.29**	**$267.44**	**1.51**	**6.52%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORAL PRODUCTS						
CIBINQO TAB 100MG	7	3	$37,195.34	$5,313.62	2.33	0.19%
SUBTOTAL	**7**	**3**	**$37,195.34**	**$5,313.62**	**2.33**	**0.19%**
TOTAL	**9,908**	**3,345***	**$19,086,691.12**	**$1,926.39**	**2.96**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CRE = cream; 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 2023 = 07/01/2022 to 06/30/2023

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[12] Galderma. EADV 2023: Phase III Trials Demonstrate Nemolizumab's Efficacy and Rapid Onset of Action in Atopic Dermatitis and Prurigo Nodularis. Available online at: https://www.galderma.com/news/galderma-eadv-2023-phase-iii-trials-demonstrate-nemolizumabs-efficacy-and-rapid-onset-action. Issued 10/11/2023. Last accessed 10/25/2023.

Appendix J

Fiscal Year 2023 Annual Review of Injectable and Vaginal Progesterone Products

Oklahoma Health Care Authority
November 2023

Current Prior Authorization Criteria

Crinone® (Progesterone Vaginal Gel) Approval Criteria:

1. Current singleton pregnancy; and
2. Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and
3. Cervical length of ≤20mm; and
4. Gestational age between 20 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. A patient-specific, clinically significant reason why the member cannot use Endometrin® (progesterone vaginal insert) must be provided; and
6. Authorizations will be given for treatment through 36 weeks, 6 days of gestation; and
7. Crinone® will not be approved for use with assisted reproductive technology (ART) for female infertility.

Endometrin® (Progesterone Vaginal Insert) Approval Criteria:

1. Current singleton pregnancy; and
2. Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and
3. Cervical length of ≤20mm; and
4. Gestational age between 20 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. Authorizations will be given for treatment through 36 weeks, 6 days of gestation; and
6. Endometrin® will not be approved for use with assisted reproductive technology (ART) for female infertility.

Hydroxyprogesterone Caproate 250mg/mL Injection (Generic Delalutin®/Delta-Lutin®) Approval Criteria:

1. An FDA approved indication of 1 of the following in non-pregnant women:
   a. For the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); or
   b. For the management of amenorrhea (primary and secondary) or abnormal uterine bleeding due to hormonal imbalance in the

absence of organic pathology, such as submucous fibroids or uterine cancer; or
    c. As a test for endogenous estrogen production or for the production of secretory endometrium and desquamation; and
2. The quantity approved will be patient-specific depending on member's diagnosis, maximum recommended dosage, and manufacturer packaging; and
3. Requests for the prevention of preterm birth in pregnant women with a history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation will not be approved for generic Delalutin®/Delta-Lutin® and should be resubmitted for authorization consideration of Makena® (hydroxyprogesterone caproate).

Makena® [Hydroxyprogesterone Caproate Intramuscular (IM) Injection and Subcutaneous (Sub-Q) Auto-Injector] Approval Criteria:

1. Documented history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation; and
2. Current singleton pregnancy; and
3. Gestational age between 16 weeks, 0 days and 26 weeks, 6 days of gestation; and
4. Authorizations will be for once weekly administration by a health care professional through 36 weeks, 6 days of gestation; and
5. For Makena® sub-Q auto-injector:
    a. Initial dose must be administered by a health care professional; and
    b. Member and caregiver must be trained by a health care professional on sub-Q administration and storage of Makena® sub-Q auto-injector; and
    c. A patient-specific, clinically significant reason why Makena® IM injection cannot be used must be provided.* (*The manufacturer of Makena® has currently provided a supplemental rebate to make the sub-Q auto-injector available with the current Makena® criteria; however, use of Makena® sub-Q auto-injector will require a reason why Makena® IM injection cannot be used if the manufacturer chooses not to participate in supplemental rebates.)

When it is determined to be appropriate to use the compounded hydroxyprogesterone caproate product, this product is covered through SoonerCare as a medical-only benefit without a prior authorization requirement.

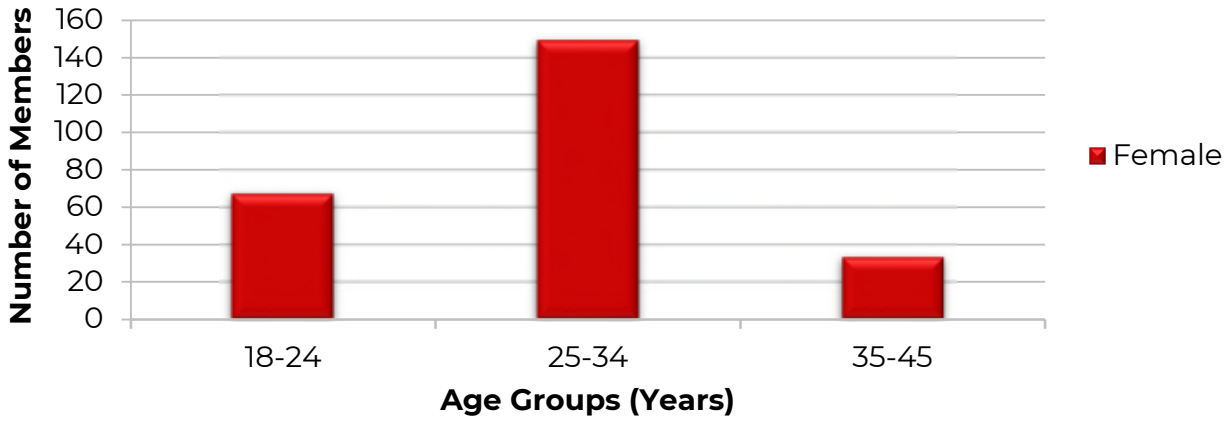
Utilization of Injectable and Vaginal Progesterone Products: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

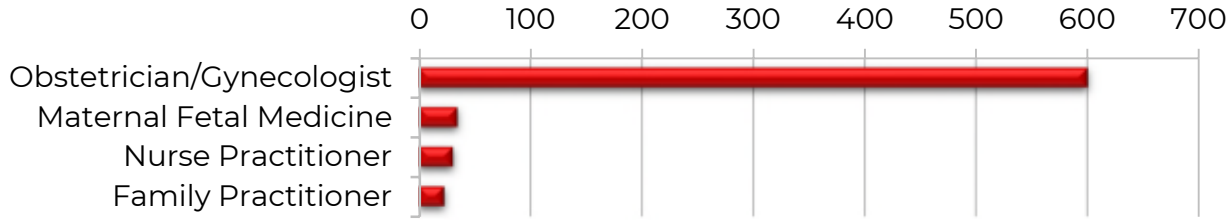
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	362	1,131	$2,778,526.28	$2,456.70	$89.06	5,086	31,198
2023	245	690	$1,737,712.52	$2,518.42	$91.90	3,124	18,909
% Change	**-32.30%**	**-39.00%**	**-37.50%**	**2.50%**	**3.20%**	**-38.60%**	**-39.40%**
Change	**-117**	**-441**	**-$1,040,813.76**	**$61.72**	**$2.84**	**-1,962**	**-12,289**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: The compounded hydroxyprogesterone caproate product is billed by medical claims only and not reflected in the pharmacy claims data. In fiscal year 2023, there was no medical claim utilization for the compounded hydroxyprogesterone caproate product.

Demographics of Members Utilizing Injectable and Vaginal Progesterone Products



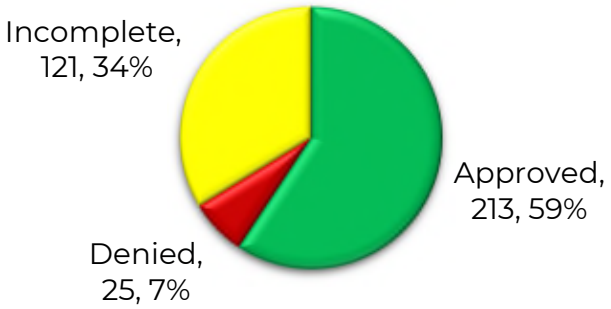
Top Prescriber Specialties of Injectable and Vaginal Progesterone Products by Number of Claims



Prior Authorization of Injectable and Vaginal Progesterone Products

There were 359 prior authorization requests submitted for 227 unique members for injectable and vaginal progesterone products during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1,2,3]

News:

- **April 2023:** The U.S. Food and Drug Administration (FDA) withdrew the approval of Makena® (hydroxyprogesterone caproate injection) and its generics based on the results of the confirmatory trial, which did not show a reduction in preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

Guideline Update(s):

- **April 2023:** Following the FDA withdrawal of hydroxyprogesterone caproate injection, the American College of Obstetricians and Gynecologists (ACOG) issued a Practice Advisory with updated clinical guidance on the use of progesterone supplementation for the prevention of recurrent preterm birth. Hydroxyprogesterone caproate injection is no longer recommended for the primary prevention of preterm birth in patients with a history of spontaneous preterm birth. Vaginal progesterone may be considered for patients with a history of preterm birth, singleton gestation, and a shortened cervix. However, vaginal progesterone has not been proven effective in the absence of a shortened cervix and should not be considered an alternative to hydroxyprogesterone caproate injection.

Recommendations

The College of Pharmacy recommends the removal of coverage and of the prior authorization criteria for Makena® (hydroxyprogesterone caproate injection) and compounded hydroxyprogesterone caproate based on the FDA withdrawal of approval for this medication and the updated ACOG recommendations (changes shown in red):

~~**Makena® [Hydroxyprogesterone Caproate Intramuscular (IM) Injection and Subcutaneous (Sub-Q) Auto-Injector] Approval Criteria:**~~

~~1. Documented history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation; and~~
~~2. Current singleton pregnancy; and~~
~~3. Gestational age between 16 weeks, 0 days and 26 weeks, 6 days of gestation; and~~
~~4. Authorizations will be for once weekly administration by a health care professional through 36 weeks, 6 days of gestation; and~~
~~5. For Makena® sub-Q auto-injector:~~
~~a. Initial dose must be administered by a health care professional; and~~
~~b. Member and caregiver must be trained by a health care professional on sub-Q administration and storage of Makena® sub-Q auto-injector; and~~
~~c. A patient-specific, clinically significant reason why Makena® IM injection cannot be used must be provided.* (*The manufacturer of Makena® has currently provided a supplemental rebate to make the sub-Q auto-injector available with the current Makena® criteria; however, use of Makena® sub-Q auto-injector will require a reason why Makena® IM injection cannot be used if the manufacturer chooses not to participate in supplemental rebates.)~~

~~When it is determined to be appropriate to use the compounded hydroxyprogesterone caproate product, this product is covered through SoonerCare as a medical-only benefit without a prior authorization requirement.~~

Additionally, the College of Pharmacy recommends the following changes to the injectable and vaginal progesterone products based on the FDA withdrawal of Makena® (hydroxyprogesterone caproate injection) and updated ACOG recommendations (changes shown in red):

Hydroxyprogesterone Caproate 250mg/mL Injection (Generic Delalutin®/Delta-Lutin®) Approval Criteria:

1. An FDA approved indication of 1 of the following in non-pregnant women:
    a. For the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); or

b. For the management of amenorrhea (primary and secondary) or abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer; or
c. As a test for endogenous estrogen production or for the production of secretory endometrium and desquamation; and

2. The quantity approved will be patient-specific depending on member's diagnosis, maximum recommended dosage, and manufacturer packaging; and
3. Requests for the prevention of preterm birth in pregnant women with a history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation will not be approved for generic Delalutin®/Delta-Lutin®. ~~and should be resubmitted for authorization consideration of Makena® (hydroxyprogesterone caproate).~~

Crinone® (Progesterone Vaginal Gel) Approval Criteria:

1. Current singleton pregnancy; and
2. ~~Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and~~
3. Cervical length of ≤ ~~20~~ 25mm; and
4. Gestational age between ~~20~~ 16 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. A patient-specific, clinically significant reason why the member cannot use Endometrin® (progesterone vaginal insert) must be provided; and
6. Authorizations will be given for treatment through 36 weeks, 6 days of gestation; and
7. Crinone® will <u>not</u> be approved for use with assisted reproductive technology (ART) for female infertility.

Endometrin® (Progesterone Vaginal Insert) Approval Criteria:

1. Current singleton pregnancy; and
2. ~~Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and~~
3. Cervical length of ≤ ~~20~~ 25mm; and
4. Gestational age between ~~20~~ 16 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. Authorizations will be given for treatment through 36 weeks, 6 days of gestation; and
6. Endometrin® will <u>not</u> be approved for use with assisted reproductive technology (ART) for female infertility.

Utilization Details of Injectable and Vaginal Progesterone Products: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYPROGESTERONE INJECTABLE PRODUCTS						
MAKENA INJ 275MG	462	168	$1,410,906.24	$3,053.91	2.75	81.19%
HYDROXYPROG INJ 250MG/ML	217	76	$322,994.22	$1,488.45	2.86	18.59%
SUBTOTAL	**679**	**241***	**$1,733,900.46**	**$2,553.61**	**2.82**	**99.78%**
PROGESTERONE VAGINAL PRODUCTS						
ENDOMETRIN SUP 100MG	11	4	$3,812.06	$346.55	2.75	0.22%
SUBTOTAL	**11**	**4***	**$3,812.06**	**$346.55**	**2.75**	**0.22%**
TOTAL	**690**	**245***	**$1,737,712.52**	**$2,518.42**	**2.82**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
HYDROXYPROG = hydroxyprogesterone; INJ = injection; SUP = suppository
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena. Available online at: https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena. Issued 04/06/2023. Last accessed 10/02/2023.
[2] U.S. FDA. Makena (Hydroxyprogesterone Caproate Injection) Information. Available online at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information. Issued 04/06/2023. Last accessed 10/02/2023.
[3] American College of Obstetricians and Gynecologists (ACOG). Updated Clinical Guidance for the Use of Progesterone Supplementation for the Prevention of Recurrent Preterm Birth. Available online at: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/04/updated-guidance-use-of-progesterone-supplementation-for-prevention-of-recurrent-preterm-birth. Issued 04/2023. Last accessed 10/02/2023.

Appendix K

Fiscal Year 2023 Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Elrefxio™ (Elranatamab-bcmm) and Talvey™ (Talquetamab-tgvs)

Oklahoma Health Care Authority
November 2023

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.

Blenrep (Belantamab Mafodotin-blmf) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM) in adults; and
2. Member has received ≥4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor (PI), and an immunomodulatory agent; and
3. Prescriber must verify the member will receive eye exams, including visual acuity and slit lamp ophthalmic examinations, with each cycle (every 3 weeks).

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 protease 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.

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.

Pepaxto® (Melphalan Flufenamide) Approval Criteria [Multiple Myeloma Diagnosis]:

1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and
2. Member has received at least 4 prior lines of therapy (including being refractory to at least 1 proteasome inhibitor, 1 immunomodulatory agent, and 1 CD-38 directed monoclonal antibody); and
3. Members who are new to treatment with Pepaxto® will generally not be approved.

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.

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.

Utilization of Multiple Myeloma Medications: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1	10	$111,739.10	$11,173.91	$399.07	30	280
2023	4	15	$177,311.05	$11,820.74	$422.17	45	420
% Change	**300.00%**	**50.00%**	**58.70%**	**5.80%**	**5.80%**	**50.00%**	**50.00%**
Change	**3**	**5**	**$65,571.95**	**$646.83**	**$23.10**	**15**	**140**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	12	125	$997,396.00	$7,979.17	10.42
2023	28	227	$2,213,181.10	$9,749.70	8.11
% Change	**133.33%**	**81.60%**	**121.90%**	**22.19%**	**-22.17%**
Change	**16**	**102**	**$1,215,785.10**	**$1,770.53**	**-2.31**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Multiple Myeloma Medications

- Due to the limited number of members utilizing multiple myeloma medications during fiscal year 2023, detailed demographic information could not be provided.

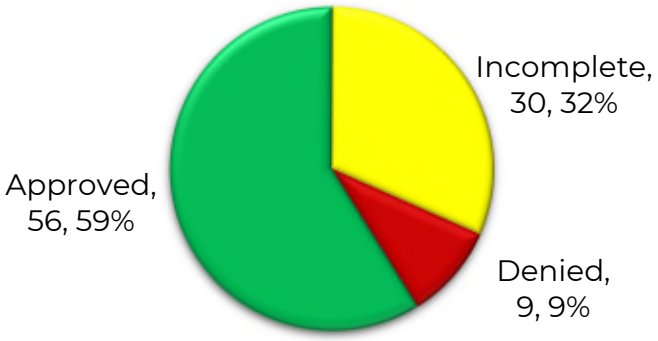
Top Prescriber Specialties of Multiple Myeloma Medications by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for multiple myeloma medications during fiscal year 2023 was hematology/oncology.

Prior Authorization of Multiple Myeloma Medications

There were 95 prior authorization requests submitted for multiple myeloma medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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):

- **August 2023:** The FDA granted accelerated approval to Talvey™ (talquetamab-tgvs) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

- **August 2023:** The FDA granted accelerated approval to Elrexfio™ (elranatamab-bcmm) for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).

News:

- **November 2022:** GSK, the manufacturer of Blenrep (belantamab mafodotin-blmf) announced it initiated the process for withdrawing the FDA's accelerated approval for the medication based on results from a Phase 3 confirmatory trial.
- **December 2022:** The FDA requested withdrawal of its accelerated approval for Pepaxto® (melphalan flufenamide) based on results from a Phase 3 confirmatory trial.

Elrexfio™ (Elranatamab-bcmm) Product Summary[6]

Therapeutic Class: Bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

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

How Supplied:

- 76mg/1.9mL single-dose vial (SDV)
- 44mg/1.1mL SDV

Dosing and Administration: Administered as a subcutaneous (sub-Q) injection according to the following schedule:

- Step-up Dosing: 12mg on day 1, 32mg on day 4, and 76mg on day 8
- Weekly Dosing: 76mg once weekly starting 1 week after the previous dose
- Biweekly (Every 2 Weeks) Dosing: 76mg every 2 weeks starting on week 24 and thereafter (only for patients who received at least 24 weeks of treatment and achieved at least a partial response and maintained this response for at least 2 months)

Cost: The Wholesale Acquisition Cost (WAC) for Elrexfio™ is $6,868.80 per milliliter, resulting in a cost of $7,555.68 for each step-up dose or $13,050.72 for each 76mg dose. The cost of treatment for the first 24 weeks (including step-up dosing) would be $315,277.92. For patients who respond and continue to biweekly dosing, the estimated cost would be $26,101.44 per 28 days.

Talvey™ (Talquetamab-tgvs) Product Summary[7]

Therapeutic Class: Bispecific GPRC5D-directed CD3 T-cell engager

Indication(s): Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

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

How Supplied:

- 3mg/1.5mL SDV
- 40mg/1mL SDV

Dosing and Administration: Administered as a sub-Q injection according to either the weekly or biweekly dosing schedule:

- Weekly Dosing Schedule:
  - Step-up Dosing: 0.01mg/kg on day 1, 0.06mg/kg on day 4, 0.4mg/kg on day 7
  - Weekly Dosing: 0.4mg/kg once weekly starting 1 week after the previous dose
- Biweekly (Every 2 Weeks) Dosing Schedule:
  - Step-up Dosing: 0.01mg/kg on day 1, 0.06mg/kg on day 4, 0.4mg/kg on day 7, 0.8mg/kg on day 10
  - Biweekly Dosing: 0.8mg/kg every 2 weeks starting 2 weeks after the previous dose

Cost: The WAC for Talvey™ is $777 for the 3mg/1.5mL SDV and $10,360 for the 40mg/mL SDV. For an 80kg adult using the weekly dosing schedule, the estimated cost would be $777 for the first step-up dose, $1,554 for the second step-up dose, and $10,360 for each subsequent dose. The cost of treatment for the first 24 weeks (including step-up dosing) would be $240,611. For patients who continue weekly dosing, the estimated cost would be $41,440 per 28 days.

Recommendations

The College of Pharmacy recommends the prior authorization of Elrexfio™ (elranatamab-bcmm) and Talvey™ (talquetamab-tgvs) with the following criteria (shown in red):

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.

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.

Additionally, the College of Pharmacy recommends removal of coverage and of the prior authorization criteria for Blenrep (belantamab mafodotin-blmf) and Pepaxto® (melphalan flufenamide) based on the FDA withdrawal of approval for these medications (changes shown in red):

~~**Blenrep (Belantamab Mafodotin-blmf) Approval Criteria [Multiple Myeloma Diagnosis]:**~~

1. ~~Diagnosis of relapsed or refractory multiple myeloma (RRMM) in adults; and~~
2. ~~Member has received ≥4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor (PI), and an immunomodulatory agent; and~~
3. ~~Prescriber must verify the member will receive eye exams, including visual acuity and slit lamp ophthalmic examinations, with each cycle (every 3 weeks).~~

~~**Pepaxto® (Melphalan Flufenamide) Approval Criteria [Multiple Myeloma Diagnosis]:**~~

1. ~~Diagnosis of relapsed or refractory multiple myeloma (RRMM); and~~

2. ~~Member has received at least 4 prior lines of therapy (including being refractory to at least 1 proteasome inhibitor, 1 immunomodulatory agent, and 1 CD-38 directed monoclonal antibody); and~~
3. ~~Members who are new to treatment with Pepaxto® will generally not be approved.~~

Utilization Details of Multiple Myeloma Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IXAZOMIB PRODUCTS						
NINLARO CAP 3MG	14	3	$165,864.64	$11,847.47	4.67	93.54%
NINLARO CAP 4MG	1	1	$11,446.41	$11,446.41	1	6.46%
TOTAL	**15**	**4***	**$177,311.05**	**$11,820.74**	**3.75**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9144 DARATUM/HYALURON INJ	187	23	$1,579,044.60	$8,444.09	8.13
J9145 DARATUMUMAB INJ	34	4	$296,946.00	$8,733.71	8.5
J9176 ELOTUZUMAB INJ	5	1	$14,595.00	$2,919.00	5
Q2055 IDECABTAGENE VICLEUCEL INJ	1	1	$322,595.50	$322,595.50	1
TOTAL	**227**	**28**	**$2,213,181.10**	**$9,749.70**	**8.11**

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 2023 = 07/01/2022 to 06/30/2023

[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 10/2023. Last accessed 10/10/2023.
[2] U.S. FDA. FDA Grants Accelerated Approval to Talquetamab-Tgvs for Relapsed or Refractory Multiple Myeloma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-talquetamab-tgvs-relapsed-or-refractory-multiple-myeloma. Issued 08/09/2023. Last accessed 10/10/2023.
[3] U.S. FDA. FDA Grants Accelerated Approval to Elranatamab-Bcmm for Multiple Myeloma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-elranatamab-bcmm-multiple-myeloma. Issued 08/14/2023. Last accessed 10/10/2023.
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[5] Oncopeptides AB. Oncopeptides Provides Update on Pepaxto© US Marketing Authorization. Available online at: https://www.prnewswire.com/news-releases/oncopeptides-provides-update-on-pepaxto-us-marketing-authorization-301697061.html. Issued 12/07/2022. Last accessed 10/13/2023.
[6] Elrexfio™ (Elranatamab-bcmm) Prescribing Information. Pfizer, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761345Orig1s000lbl.pdf. Last revised 08/2023. Last accessed 10/10/2023.
[7] Talvey™ (Talquetamab-tgvs) Prescribing Information. Janssen Biotech, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761342s000lbl.pdf. Last revised 08/2023. Last accessed 10/10/2023.

Appendix L

Fiscal Year 2023 Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Symbicort Aerosphere® (Budesonide/Formoterol Fumarate)

Oklahoma Health Care Authority
November 2023

Current Prior Authorization Criteria: Asthma and COPD Maintenance Medications

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
budesonide (Pulmicort Flexhaler®)	beclomethasone dipropionate (QVAR® RediHaler®)
budesonide/formoterol (Symbicort®) – **Brand Preferred**	fluticasone furoate (Arnuity® Ellipta®)
ciclesonide (Alvesco®)	fluticasone furoate/vilanterol (Breo® Ellipta®)
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 50mcg (Asmanex® HFA)
	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.
αDoes 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 and formulations other than Asmanex® HFA 50mcg.
◊ Includes 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.

Arnuity® Ellipta® (Fluticasone Furoate) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be at or above the minimum age indicated, and
3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) is not appropriate for the member must be provided.

Asmanex® HFA (Mometasone Furoate) 50mcg and 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. Asmanex® HFA 50mcg: Member must be between 5 and 11 years of age; or
    b. 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.

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 18 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.

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.

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)	
tiotropium inhalation powder (Spiriva® HandiHaler®)	aclidinium inhalation powder (Tudorza® PressAir®)
tiotropium soft mist inhaler (Spiriva® Respimat®)	glycopyrrolate inhalation solution (Lonhala® Magnair®)

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
	revefenacin inhalation solution (Yupelri®)
	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 for at least the past 12 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 years 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 for at least the past 12 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 pruritis 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 for at least the past 12 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 6months. 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 for at least the past 12 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 for at least the past 12 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. Tezspire® must be administered by a health care provider prepared to manage anaphylaxis; and
7. 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
8. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
9. 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 been on medium-to-high dose inhaled corticosteroids (ICS) (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose) for at minimum the past 12 months; and

7. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
8. Xolair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
9. 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
10. 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
11. Initial approvals will be for the duration of 12 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. 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
7. 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
8. 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
9. 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. Xolair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
11. 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
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.

Utilization of Asthma and COPD Maintenance Medications: Fiscal Year 2023

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

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	38,610	121,151	$40,238,438.63	$332.13	$9.41	3,395,413	4,275,497
2023	43,397	142,564	$46,536,810.12	$326.43	$9.25	4,014,123	5,031,133
% Change	**12.4%**	**17.7%**	**15.7%**	**-1.7%**	**-1.7%**	**18.2%**	**17.7%**
Change	**4,787**	**21,413**	**$6,298,371.49**	**-$5.70**	**-$0.16**	**618,710**	**755,636**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note, the above utilization data does not include asthma-indicated monoclonal antibodies.

- Aggregate drug rebates collected during fiscal year 2023 for the asthma and COPD maintenance medications totaled $42,381,780.41[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)

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	509	3,301	$10,453,504.96	$3,166.77	$109.30	10,795	95,642
2023	931	5,734	$19,439,653.73	$3,390.24	$110.45	19,748	176,008
% Change	**82.9%**	**73.7%**	**86.0%**	**7.1%**	**1.1%**	**82.9%**	**84.0%**
Change	**422**	**2,433**	**$8,986,148.77**	**$223.47**	**$1.15**	**8,953**	**80,366**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note, the above utilization data includes Xolair®, Nucala, and Dupixent® used for all diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

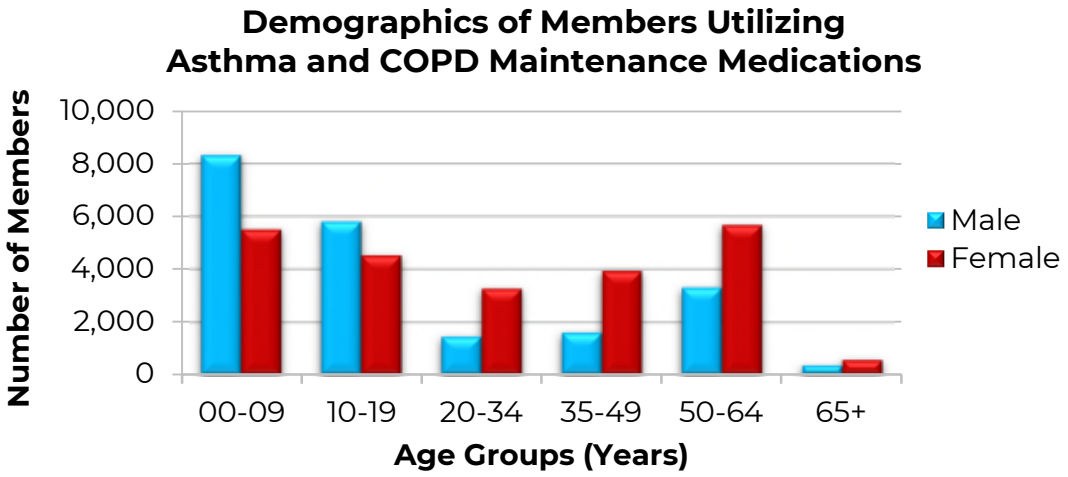
- Aggregate drug rebates collected during fiscal year 2023 for the asthma-indicated monoclonal antibodies totaled $4,205,558.21[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

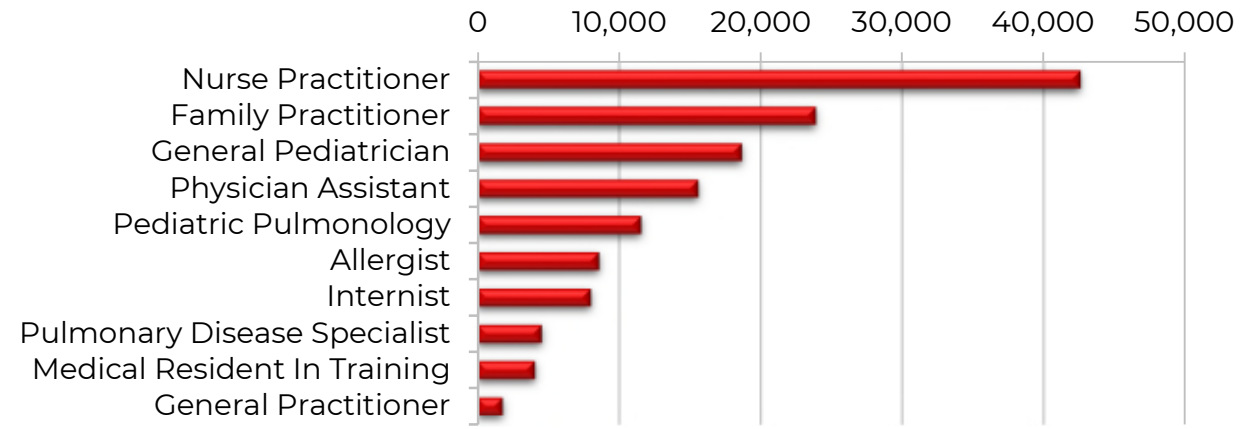
Comparison of Fiscal Years: Asthma-Indicated Monoclonal Antibodies (Medical Claims)

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	32	291	$699,901.60	$2,405.16	9.1
2023	57	473	$1,079,441.05	$2,282.12	8.3
% Change	**78.1%**	**62.5%**	**54.2%**	**-5.1%**	**-8.8%**
Change	**25**	**182**	**$679,539.45**	**-$123.04**	**-0.8**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note, the above utilization data includes Xolair® and Nucala used for all diagnoses and does not differentiate between asthma diagnoses and other diagnoses, for which use may be appropriate.

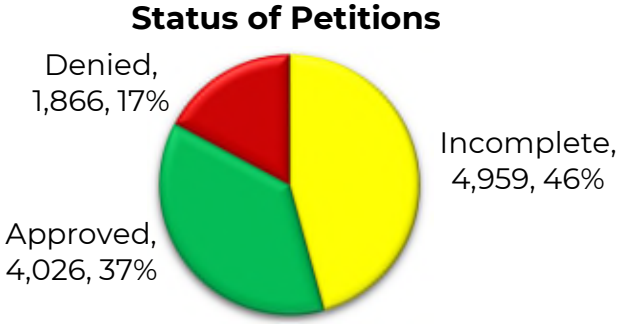
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.





Prior Authorization of Asthma and COPD Maintenance Medications

There were 10,851 prior authorization requests submitted for asthma and COPD maintenance medications during fiscal year 2023. Of those prior authorization requests, 3,021 were submitted for monoclonal antibody medications. The following chart shows the status of the submitted petitions for fiscal year 2023.



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

Anticipated Patent Expiration(s):

- Daliresp® (roflumilast oral tablet): March 2024
- Tudorza® Pressair® (aclidinium inhalation powder): March 2029
- Duaklir® Pressair® (aclidinium/formoterol inhalation powder): March 2029
- Symbicort® (budesonide/formoterol inhalation aerosol): October 2029
- Spiriva® HandiHaler® (tiotropium inhalation powder): April 2030
- Striverdi® Respimat® (olodaterol inhalation spray): October 2030
- Stiolto® Respimat® (tiotropium/olodaterol inhalation spray): October 2030
- Breo® Ellipta® (fluticasone furoate/vilanterol inhalation powder): October 2030
- Incruse® Ellipta® (umeclidinium inhalation powder): October 2030
- Arnuity® Ellipta® (fluticasone furoate inhalation powder): October 2030
- Anoro® Ellipta® (umeclidinium/vilanterol inhalation powder): November 2030
- Trelegy® Ellipta® (fluticasone furoate/umeclidinium/vilanterol inhalation powder): November 2030
- Bevespi Aerosphere® (glycopyrrolate/formoterol inhalation aerosol): March 2031
- Breztri Aerosphere® (budesonide/glycopyrrolate/formoterol aerosol): March 2031
- Spiriva® Respimat® (tiotropium soft mist inhaler): April 2031
- QVAR® RediHaler® (beclomethasone inhalation aerosol): January 2032
- AirDuo RespiClick® (fluticasone propionate/salmeterol inhalation powder): April 2035
- AirDuo® Digihaler® (fluticasone propionate/salmeterol inhalation powder): June 2039
- ArmonAir® Digihaler® (fluticasone propionate inhalation powder): June 2039

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

- **April 2021:** The FDA approved a supplemental Biologics License Application (sBLA) for Xolair® (omalizumab) prefilled syringe for self-administration in appropriate patients for all indications. Before starting self-administration, patients should have no history of anaphylaxis and should be observed by a health care provider for at least 3 injections and have no allergic reactions.
- **February 2023:** The FDA approved Tezspire® (tezepelumab-ekko) for self-administration with a pre-filled, single use pen in patients 12 years of age or older. Tezspire® was first FDA approved in December 2021 and

was initially only recommended to be administered by a health care provider.

- **April 2023:** The FDA approved Symbicort Aerosphere® (budesonide/formoterol) for the maintenance treatment of patients with COPD. Symbicort Aerosphere® is not indicated for the treatment of asthma. The new formulation utilizes the Aerosphere® inhalation device that is a pressurized metered dose inhaler. The launch of Symbicort Aerosphere® is still pending.
- **May 2023:** Breo® Ellipta® (fluticasone furoate/vilanterol) was FDA approved for an age expansion for the maintenance treatment of asthma in patients 5 years of age or older. Along with the age expansion, a new strength of 50mcg/25mcg was also approved. Breo® Ellipta® was previously FDA approved for those 18 years of age or older for the maintenance treatment of asthma and COPD.
- **July 2023:** An Abbreviated New Drug Application (ANDA) was approved by the FDA for Breyna™ (budesonide/formoterol), the first generic version of Symbicort® (budesonide/formoterol). It will be available in 80mcg/4.5mcg and 160mg/4.5mcg strengths.
- **August 2023:** The Xolair® *Prescribing Information* has been revised to include the autoinjector in the list of dosage forms and includes updates to the administration section to include this new formulation.

Guidelines Update(s):

- **Global Initiative for Asthma (GINA) Guideline Update:** The GINA guidelines have been updated for 2023. Some notable updates include:
  - Inhaled corticosteroid + short-acting beta$_2$ agonist (ICS+SABA) for as needed use in adults and adolescents has been added to Track 2.
  - ICS-formoterol remains the preferred treatment approach in Track 1 for adults and adolescents despite the addition of ICS+SABA as an option.
  - Details about doses have been included where relevant, including in the treatment steps and asthma action plans.
  - Mepolizumab has been added to the treatment options for patients 6 to 11 years of age with severe eosinophilic asthma after specialist referral and optimization of treatment.
  - Updated guidance has been added on managing severe asthma including the recommendation of biologic therapy only if asthma is severe and if existing treatment has been optimized.
  - Additional details have been added on doses for as needed ICS-formoterol and ICS-SABA on written action plans with references customized for maintenance and reliever therapy (MART) with ICS-formoterol.

- **Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guideline Update:** GOLD released *The Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease* for 2023. Some notable updates and additions include:
    - The ABCD Assessment Tool has been revised to the ABE Assessment Tool to recognize the clinical relevance of exacerbations, independent of level of symptoms. Groups C and D have now been combined into Group E to include all patients with ≥2 moderate exacerbations or ≥1 severe exacerbation regardless of their modified Medical Research Council (mMRC) or COPD assessment test (CAT) scores.
    - Changes to initial pharmacological treatment updates include:
        - Group B patients should be initiated with a long-acting $beta_2$ agonist + long-acting muscarinic agonist (LABA+LAMA) (prior recommendations stated a LABA or a LAMA should be initiated in this group).
        - Group E patients are recommended to be initiated on a LABA+LAMA. In 2022, Group C was recommended to start on a LAMA and Group D on a LAMA or LABA+LAMA based on severity. Triple therapy is recommended if eosinophils are ≥300cells/mcL.
    - Changes to follow-up pharmacological treatment include:
        - ICS+LABA dual therapy is no longer encouraged in any group as an option during dyspnea or exacerbations.

News:

- **April 2023:** Lonhala® Magnair® (glycopyrrolate inhalation solutions) has been discontinued by the manufacturer.
- **June 2023:** Brand name Flovent® HFA and Flovent® Diskus are being discontinued by the manufacturer. The last date they will be available to order is December 31, 2023. The generic formulations will still be available.
- **August 2023:** A generic equivalent formulation of Spiriva® (tiotropium bromide) has been launched in the United States for the treatment of COPD.

Pipeline:

- **Dupixent® (Dupilumab):** Dupixent® had positive results in a Phase 3 trial for adults on maximal standard-of-care inhaled therapy with uncontrolled COPD and evidence of type 2 inflammation. Dupixent® showed a 30% reduction in moderate or severe acute COPD exacerbations over 52 weeks. A second Phase 3 trial is currently ongoing with results expected in 2024.

- **Ensifentrine:** Ensifentrine is an inhaled dual inhibitor of phosphodiesterase 3 (PDE3) and PDE4 enzymes that combines bronchodilator and non-steroidal anti-inflammatory activities into 1 compound. The FDA accepted an NDA and is currently reviewing ensifentrine for the maintenance treatment of patients with COPD. A Prescription Drug User Fee Act (PDUFA) date has been set for June 26, 2024.
- **Xolair® (Omalizumab):** Xolair® is currently in Phase 3 of the OUtMATCH trial assessing the efficacy for patients with multiple food allergies. The trial includes patients diagnosed with a peanut allergy or with allergies to 2 of the following: milk, cashew, egg, wheat, hazelnuts, or walnuts. Phase 3 assesses treatment duration, and patients will be followed for 56 months with results expected to be reported in 2023. The estimated completion date will be in August 2026.

Recommendations

The College of Pharmacy recommends the following changes to the Tezspire® (tezepelumab-ekko) and Xolair® (omalizumab) approval criteria based on the new FDA approved label expansions (changes shown in red):

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 resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly for at least the past 12 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 been on medium-to-high dose inhaled corticosteroids (ICS) (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose) for at minimum the past 12 months; 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 12 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.

Additionally, the College of Pharmacy recommends the following changes to the maintenance asthma and COPD medications Product Based Prior Authorization (PBPA) category (changes noted in red in the following PBPA Tier charts and criteria):

1. Updating the Breo® Ellipta® approval criteria based on the new FDA approved age expansion and making it brand preferred based on net cost; and

2. Prior authorization of Breyna™ (budesonide/formoterol fumarate) with the following criteria; and
3. Prior authorization of Symbicort Aerosphere® (budesonide/formoterol fumarate) and placement into Tier-2 with the following additional criteria; and
4. Moving Arnuity® Ellipta® (fluticasone furoate) and Asmanex® HFA 50mcg (mometasone furoate) to Tier-1 based on net costs; and
5. Moving Tudorza® PressAir® and Incruse® Ellipta® to Tier-1 based on net costs; and
6. Making Spiriva® Handihaler® brand preferred based on net costs; and
7. The removal of Lonhala® Magnair® due to product discontinuation.

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 (Arnuity® Ellipta®)**~~
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 50mcg (Asmanex® HFA)**~~
	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 and formulations other than Asmanex® HFA 50mcg.~~
[◊] Includes all strengths other than Dulera® 50mcg/5mcg.

~~Arnuity® Ellipta® (Fluticasone Furoate) Approval Criteria:~~

~~1. An FDA approved diagnosis of asthma; and~~
~~2. Member must be at or above the minimum age indicated, and~~
~~3. A patient-specific, clinically significant reason why Flovent® (fluticasone propionate) is not appropriate for the member must be provided.~~

~~**Asmanex® HFA (Mometasone Furoate) 50mcg and**~~ **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. Asmanex® HFA 50mcg: Member must be between 5 and 11 years of age; or~~
   b. 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.

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 patients 5 ~~18~~ 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 a prior authorization).

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.

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®)	~~**aclidinium inhalation powder (Tudorza® PressAir®)**~~
tiotropium inhalation powder (Spiriva® HandiHaler®) – **Brand Preferred**	~~**glycopyrrolate inhalation solution (Lonhala® Magnair®)**~~
tiotropium soft mist inhaler (Spiriva® Respimat®)	revefenacin inhalation solution (Yupelri®)
umeclidinium inhalation powder (Incruse® Ellipta®)	~~**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 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ICS/LABA COMBINATION PRODUCTS					
TIER-1 UTILIZATION					
SYMBICORT AER 160/4.5MCG	17,588	5,507	$7,526,264.06	$427.92	3.19
ADVAIR HFA AER 115/21MCG	8,662	2,919	$3,430,942.99	$396.09	2.97
FLUTIC/SALME AER 250/50MCG	7,847	3,135	$1,038,704.59	$132.37	2.5
SYMBICORT AER 80/4.5MCG	6,151	2,483	$2,163,492.57	$351.73	2.48
ADVAIR DISKUS AER 250/50MCG	5,353	2,171	$2,279,178.99	$425.78	2.47
DULERA AER 200/5MCG	3,300	964	$1,154,742.05	$349.92	3.42
ADVAIR HFA AER 45/21MCG	2,481	881	$778,667.39	$313.85	2.82
ADVAIR HFA AER 230/21MCG	2,450	813	$1,354,865.93	$553.01	3.01
FLUTIC/SALME AER 100/50MCG	2,322	994	$239,551.41	$103.17	2.34
FLUTIC/SALME AER 500/50MCG	2,160	771	$488,030.22	$225.94	2.8
DULERA AER 100/5MCG	2,109	677	$699,843.62	$331.84	3.12
ADVAIR DISKUS AER 500/50MCG	1,895	702	$1,138,644.74	$600.87	2.7
ADVAIR DISKUS AER 100/50MCG	1,541	714	$507,942.76	$329.62	2.16

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FLUTIC/SALME AER 115/21MCG	848	616	$245,806.49	$289.87	1.38
FLUTIC/SALME AER 230/21MCG	272	198	$109,990.12	$404.38	1.37
FLUTIC/SALME AER 45/21MCG	251	178	$58,977.11	$234.97	1.41
BUDES/FORMOT AER 80/4.5MCG	215	95	$46,312.48	$215.41	2.26
WIXELA INHUB AER 250/50MCG	35	15	$4,108.15	$117.38	2.33
WIXELA INHUB AER 100/50MCG	32	9	$2,707.35	$84.60	3.56
WIXELA INHUB AER 500/50MCG	6	4	$1,160.34	$193.39	1.5
BUDES/FORMOT AER 160/4.5MCG	3	1	$23.85	$7.95	3
FLUTIC/SALME INH 55/14MCG	1	1	$118.30	$118.30	1
SUBTOTAL	**65,522**	**23,848**	**$23,270,075.51**	**$355.15**	**2.75**
TIER-2 UTILIZATION					
BREO ELLIPTA INH 200/25MCG	131	33	$54,559.61	$416.49	3.97
BREO ELLIPTA INH 100/25MCG	128	32	$52,336.72	$408.88	4
DULERA AER 50/5MCG	65	33	$22,304.23	$343.14	1.97
FLUTIC/VILAN INH 100/25MCG	56	15	$12,579.75	$224.64	3.73
FLUTIC/VILAN INH 200/25MCG	37	16	$10,661.14	$288.14	2.31
SUBTOTAL	**417**	**129**	**$152,441.45**	**$365.57**	**3.23**
ICS/LABA TOTAL	**65,939**	**23,977**	**$23,422,516.96**	**$355.21**	**2.75**
INDIVIDUAL COMPONENT ICS PRODUCTS					
TIER-1 UTILIZATION					
FLUTICASONE HFA AER 110MCG	10,936	5,304	$2,038,922.71	$186.44	2.06
FLUTICASONE HFA AER 44MCG	10,586	5,197	$1,475,784.35	$139.41	2.04
FLOVENT HFA AER 110MCG	9,615	4,799	$2,582,533.37	$268.59	2
FLOVENT HFA AER 44MCG	9,165	4,619	$1,852,614.01	$202.14	1.98
BUDESONIDE SUS 0.5MG/2ML	3,816	1,906	$214,197.46	$56.13	2
BUDESONIDE SUS 0.25MG/2ML	3,138	2,027	$210,914.71	$67.21	1.55
FLOVENT HFA AER 220MCG	1,217	622	$520,286.03	$427.52	1.96
FLUTICASONE HFA AER 220MCG	1,169	596	$333,893.18	$285.62	1.96
PULMICORT INH 90MCG	921	457	$200,173.82	$217.34	2.02
PULMICORT INH 180MCG	710	367	$209,865.90	$295.59	1.93
ASMANEX HFA AER 100MCG	658	273	$130,699.15	$198.63	2.41
FLOVENT DISKUS AER 100MCG	544	238	$122,830.11	$225.79	2.29
FLOVENT DISKUS AER 50MCG	415	175	$85,658.50	$206.41	2.37
ALVESCO AER 80MCG	384	187	$108,635.70	$282.91	2.05
BUDESONIDE SUS 1MG/2ML	363	152	$119,044.10	$327.95	2.39
FLOVENT DISKUS AER 250MCG	274	90	$89,063.92	$325.05	3.04
ASMANEX HFA AER 200MCG	227	88	$57,370.24	$252.73	2.58
ALVESCO AER 160MCG	171	51	$46,566.83	$272.32	3.35
ASMANEX 60 AER 220MCG	159	61	$43,010.33	$270.51	2.61
ASMANEX 30 AER 220MCG	117	41	$26,187.19	$223.82	2.85
ASMANEX 120 AER 220MCG	70	27	$29,353.50	$419.34	2.59
ASMANEX 30 AER 110MCG	58	20	$11,919.38	$205.51	2.9
PULMICORT SUS 0.25MG/2ML	1	1	$272.87	$272.87	1

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ASMANEX HFA AER 50MCG	1	1	$189.72	$189.72	1
SUBTOTAL	**54,715**	**27,299**	**$10,509,987.08**	**$192.09**	**2**
TIER-2 UTILIZATION					
QVAR REDIHALER AER 80MCG	39	10	$11,186.67	$286.84	3.9
ARNUITY ELLIPTA INH 100MCG	13	7	$3,420.26	$263.10	1.86
QVAR REDIHALER AER 40MCG	10	4	$2,036.19	$203.62	2.5
ARNUITY ELLIPTA INH 200MCG	4	3	$1,202.36	$300.59	1.33
ARNUITY ELLIPTA INH 50MCG	1	1	$61.21	$61.21	1
SUBTOTAL	**67**	**25**	**$17,906.69**	**$267.26**	**2.68**
ICS TOTAL	**54,782**	**27,324**	**$10,527,893.77**	**$192.18**	**2**
INDIVIDUAL COMPONENT LAMA PRODUCTS					
TIER-1 UTILIZATION					
SPIRIVA SPR 2.5MCG	7,396	2,070	$3,574,405.85	$483.29	3.57
SPIRIVA CAP HANDIHALER 18MCG	5,987	2,004	$4,339,241.92	$724.78	2.99
SPIRIVA AER 1.25MCG	4,032	1,164	$1,884,679.44	$467.43	3.46
SUBTOTAL	**17,415**	**5,238**	**$9,798,327.21**	**$562.64**	**3.32**
TIER-2 UTILIZATION					
INCRUSE ELPT INH 62.5MCG	83	22	$35,360.26	$426.03	3.77
YUPELRI SOL 175MCG/3ML	82	33	$125,931.31	$1,535.75	2.48
TUDORZA PRES AER 400MCG/ACT	31	7	$20,520.63	$661.96	4.43
LONHALA MAGNAIR SOL 25MCG	12	4	$14,741.62	$1,228.47	3
SUBTOTAL	**208**	**66**	**$196,553.82**	**$944.97**	**3.15**
LAMA TOTAL	**17,623**	**5,304**	**$9,994,881.03**	**$567.15**	**3.32**
INDIVIDUAL COMPONENT LABA PRODUCTS					
TIER-1 UTILIZATION					
SEREVENT DISKUS AER 50MCG	841	349	$414,539.30	$492.91	2.41
SUBTOTAL	**841**	**349**	**$414,539.30**	**$492.91**	**2.41**
TIER-2 UTILIZATION					
ARFORMOTEROL NEB 15MCG/2ML	97	32	$24,995.32	$257.68	3.03
FORMOTEROL NEB 20MCG/2ML	77	22	$52,242.52	$678.47	3.5
BROVANA NEB 15MCG	11	3	$11,565.61	$1,051.42	3.67
PERFOROMIST NEB 20MCG	8	2	$8,693.68	$1,086.71	4
STRIVERDI AER 2.5MCG	2	2	$504.22	$252.11	1
SUBTOTAL	**195**	**61**	**$98,001.35**	**$502.57**	**3.2**
LABA TOTAL	**1,036**	**410**	**$512,540.65**	**$494.73**	**2.53**
LABA/LAMA/ICS COMBINATION PRODUCTS					
TRELEGY AER 100/62.5/25MCG	1,083	257	$823,059.88	$759.98	4.21
TRELEGY AER 200/62.5/25MCG	882	200	$625,729.58	$709.44	4.41
BREZTRI AEROSPHERE 160/9/4.8MCG	434	108	$292,787.33	$674.63	4.02
SUBTOTAL	**2,399**	**565**	**$1,741,576.79**	**$725.96**	**4.25**
LABA/LAMA COMBINATION PRODUCTS					
ANORO ELLIPTA AER 62.5/25MCG	382	77	$192,579.04	$504.13	4.96
STIOLTO AER 2.5/2.5MCG	97	34	$58,903.77	$607.26	2.85

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BEVESPI AER 9/4.8MCG	33	9	$17,768.57	$538.44	3.67
SUBTOTAL	**512**	**120**	**$269,251.38**	**$525.88**	**4.27**
PDE4 ENZYME INHIBITOR PRODUCTS					
ROFLUMILAST TAB 500MCG	103	27	$6,557.80	$63.67	3.81
DALIRESP TAB 500MCG	92	21	$34,399.95	$373.91	4.38
DALIRESP TAB 250MCG	55	9	$18,336.16	$333.38	6.11
ROFLUMILAST TAB 250MCG	23	12	$8,855.63	$385.03	1.92
SUBTOTAL	**273**	**69**	**$68,149.54**	**$249.63**	**3.96**
TOTAL	**142,564**	**43,397***	**$46,536,810.12**	**$326.43**	**3.29**

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 2023 = 07/01/2022 to 06/30/2023

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

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DUPILUMAB PRODUCTS					
DUPIXENT INJ 300MG/2ML PEN	2,243	403	$7,681,920.10	$3,424.84	5.57
DUPIXENT INJ 300MG/2ML SYR	1,554	267	$5,212,577.40	$3,354.30	5.82
DUPIXENT INJ 200MG/1.14ML SYR	1,096	177	$3,673,074.15	$3,351.35	6.19
DUPIXENT INJ 200MG/1.14ML PEN	249	54	$879,579.79	$3,532.45	4.61
DUPIXENT INJ 100MG/0.67ML SYR	3	1	$10,188.72	$3,396.24	3
SUBTOTAL	**5,145**	**902**	**$17,457,340.16**	**$3,393.07**	**5.7**
OMALIZUMAB PRODUCTS					
XOLAIR INJ 150MG/ML	204	36	$639,293.56	$3,133.79	5.67
XOLAIR INJ 75MG/0.5ML	85	14	$100,548.88	$1,182.93	6.07
XOLAIR SOL 150MG	20	3	$15,207.41	$760.37	6.67
SUBTOTAL	**309**	**53**	**$755,049.85**	**$2,443.53**	**5.83**
MEPOLIZUMAB PRODUCTS					
NUCALA INJ 100MG/ML	62	12	$248,221.90	$4,003.58	5.17
NUCALA INJ 100MG	52	9	$171,039.44	$3,289.22	5.78
NUCALA INJ 40MG/0.4ML	11	2	$15,371.57	$1,397.42	5.5
SUBTOTAL	**125**	**23**	**$434,632.91**	**$3,477.06**	**5.43**
BENRALIZUMAB PRODUCTS					
FASENRA PEN INJ 30MG/ML	89	26	$485,396.97	$5,453.90	3.42
FASENRA INJ 30MG/ML	35	11	$189,565.43	$5,416.16	3.18
SUBTOTAL	**124**	**37**	**$674,962.40**	**$5,443.25**	**3.35**
TEZEPELUMAB-EKKO PRODUCTS					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TEZSPIRE SOL 210MG	31	6	$117,668.41	$3,795.76	5.17
SUBTOTAL	**31**	**6**	**$117,668.41**	**$3,795.76**	**5.17**
TOTAL	**5,734**	**931***	**$19,439,653.73**	**$3,390.24**	**6.16**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; SOL = solution
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
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.

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
OMALIZUMAB INJ (J2357)	409	44	$832,824.15	$2,036.24	9.3
MEPOLIZUMAB INJ (J2812)	29	5	$85,327.00	$2,942.31	5.8
BENRALIZUMAB INJ (J0517)	23	6	$116,289.00	$5,056.04	3.83
TEZEPELUMAB-EKKO INJ (J2356)	12	2	$45,000.90	$3,750.10	6
TOTAL	**473⁺**	**57***	**$1,079,441.05**	**$2,282.12**	**8.3**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
INJ = injection
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
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.

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Appendix M

30-Day Notice to Prior Authorize Sohonos™ (Palovarotene)

Oklahoma Health Care Authority
November 2023

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

Fibrodysplasia ossificans progressiva (FOP) is a rare genetic disorder of connective tissue that is characterized by the development of abnormal bone formation outside of the skeleton, known as heterotopic ossification. During this process, muscle and connective tissue is progressively replaced by bone, leading to eventual loss of mobility as joints are affected. Heterotopic ossification can occur spontaneously or as a result of any soft tissue trauma, including from intramuscular (IM) vaccinations, falls, or surgical procedures. Patients with FOP are usually born with bilateral hallux valgus malformations, which can be the first clinical sign of the condition. Patients with FOP experience recurrent flare-up of painful soft-tissue swelling which is followed by increased heterotopic ossification in that area. Areas in the neck, back, chest, arms, and legs are usually affected first. As the disorder progresses, additional areas such as the hips, ankles, and wrists can be affected. Over time, joints can become completely immobilized leading to loss of ambulation or need for a wheelchair, feeding difficulties when the jaw is affected, and respiratory difficulties. By the third decade of life, most patients require a wheelchair and assistance performing activities of daily living. Patients can also experience other complications such as hearing loss and thoracic insufficiency syndrome, which is a significant cause of mortality in patients with FOP, characterized by pneumonia, hypoxemia, pulmonary hypertension, and right-sided heart failure.

FOP is estimated to occur in approximately 1 in 1 million people, with 400 patients with FOP expected to live in the United States. Males and females appear to be equally affected. FOP is caused by a gain-of-function pathogenic mutation in the *ACVR1* gene, which is inherited in an autosomal dominant fashion; however, most cases of FOP occur due to *de novo* mutations rather than being inherited from a parent. FOP is diagnosed based on a combination of clinical findings and genetic testing to confirm a pathogenic variant in the *ACVR1* gene.

Management of FOP involves avoiding any situations which can lead to soft-tissue trauma, such as IM injections, arterial punctures, falls, biopsies, and all elective surgical procedures. Additional precautions are required during dental care or any situation that could precipitate a flare-up. Historically,

treatment has been supportive and could include the use of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, mast cell stabilizers, and leukotriene inhibitors. In August 2023, the U.S. Food and Drug Administration (FDA) approved Sohonos™ (palovarotene) to reduce the volume of new heterotopic ossification in adults and pediatric patients 8 years of age and older (for females) or 10 years of age and older (for males) with FOP. Sohonos™ is the first and only FDA approved medication for FOP.

Sohonos™ (Palovarotene) Product Summary[7]

Therapeutic Class: Retinoid

Indication(s): Reduction in the volume of new heterotopic ossification in adults and children 8 years of age and older for females and 10 years of age and older for males with FOP

How Supplied: 1mg, 1.5mg, 2.5mg, 5mg, and 10mg oral capsules

Dosing and Administration: Dosing includes a chronic daily dose, which can be increased for flare-up symptoms:

- Adults and Pediatric Patients 14 Years of Age and Older:
  - Daily Dose: 5mg daily
  - Flare-Up Dose: 20mg daily for 4 weeks then 10mg daily for 8 weeks, then return to 5mg daily dose
    - If during flare-up treatment, the patient experiences marked worsening of the original flare-up site or another flare-up at a new location, the 12-week flare-up dosing should be re-started at 20mg daily.
    - If flare-up symptoms have not resolved at the end of the 12-week period, the 10mg daily dose may be extended in 4-week intervals and continued until the flare-up symptoms resolve. If new flare-up symptoms occur after the 5mg daily dose is resumed, flare-up dosing may be restarted.
- Pediatric Patients 8-13 Years of Age (for Females) or 10-13 Years of Age (for Males):

Weight	Daily Dose	Week 1-4 Flare-Up Dose	Week 5-12 Flare-Up Dose
10kg to 19.9kg	2.5mg	10mg	5mg
20kg to 39.9kg	3mg	12.5mg	6mg
40kg to 59.9kg	4mg	15mg	7.5mg
≥ 60kg	5mg	20mg	10mg

- Dosage reductions may be required for adverse reactions and drug interactions.

Cost: The Wholesale Acquisition Cost (WAC) of Sohonos™ is $342 per milligram ($1,710 per 5mg capsule or $3,420 per 10mg capsule). For a member who is 14 years of age or older, this results in an estimated cost of $47,880 per 28 days for the 5mg chronic daily dose. The cost of the 12-week flare-up dosing for this member would be $383,040 per 12-week flare episode. If the member experiences an average of (2) 12-week flares per year, the estimated annual cost would be $1,101,240 per year based on recommended dosing.

Recommendations

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

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.

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Appendix N

Fiscal Year 2023 Annual Review of Vasomotor Symptom (VMS) Medications and 30-day Notice to Prior Authorize Veozah™ (Fezolinetant)

Oklahoma Health Care Authority
November 2023

Current Prior Authorization Criteria

Bijuva® (Estradiol/Progesterone Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause in women with an intact uterus; and
2. A patient-specific, clinically significant reason why the member cannot use all other available estrogen/progestin products indicated for vasomotor symptoms of menopause must be provided; and
3. A quantity limit of 30 capsules (1 pack) per 30 days will apply.

Brisdelle® (Paroxetine Mesylate 7.5mg) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause; and
2. Approvals for Brisdelle® will not be granted for psychiatric indications; and
3. Members must not have any of the contraindications for use of Brisdelle®; and
4. Two previous trials with either a selective serotonin reuptake inhibitor (SSRI) or a selective serotonin norepinephrine reuptake inhibitor (SNRI) or both, or a patient-specific, clinically significant reason why a SSRI or SNRI is not appropriate for the member must be provided; and
5. Authorization requires a patient-specific, clinically significant reason why paroxetine 10mg is not appropriate for the member; and
6. A quantity limit of 30 capsules per 30 days will apply.

Duavee® (Conjugated Estrogens/Bazedoxifene) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms associated with menopause or for prevention of postmenopausal osteoporosis; and
2. Member must be a female with an intact uterus; and
3. For the treatment of moderate-to-severe vasomotor symptoms associated with menopause:
    a. Member must have at least 7 moderate-to-severe hot flushes per day or at least 50 per week prior to treatment; and
4. For the prevention of postmenopausal osteoporosis:

   a. A trial of Fosamax® (alendronate), Actonel® (risedronate), Boniva® (ibandronate), or Reclast® (zoledronic acid) used compliantly for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
   b. Contraindication to, hypersensitivity to, or intolerable adverse effects with all bisphosphonates indicated for prevention of postmenopausal osteoporosis; and
5. Member must not have any of the contraindications for use of Duavee®; and
6. Members older than 65 years of age will generally not be approved without supporting information; and
7. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
8. A quantity limit of 30 tablets per 30 days will apply.

Elestrin® (Estradiol 0.06% Gel) Approval Criteria:

1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause; and
2. Member must not have any contraindications for use of Elestrin®; and
3. A patient-specific, clinically significant reason why other topical estradiol formulations (e.g., Divigel®) are not appropriate for the member must be provided; and
4. Members older than 65 years of age will generally not be approved without supporting information; and
5. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and
6. A quantity limit of 52 grams per 30 days will apply.

Utilization of VMS Medications: Fiscal Year 2023

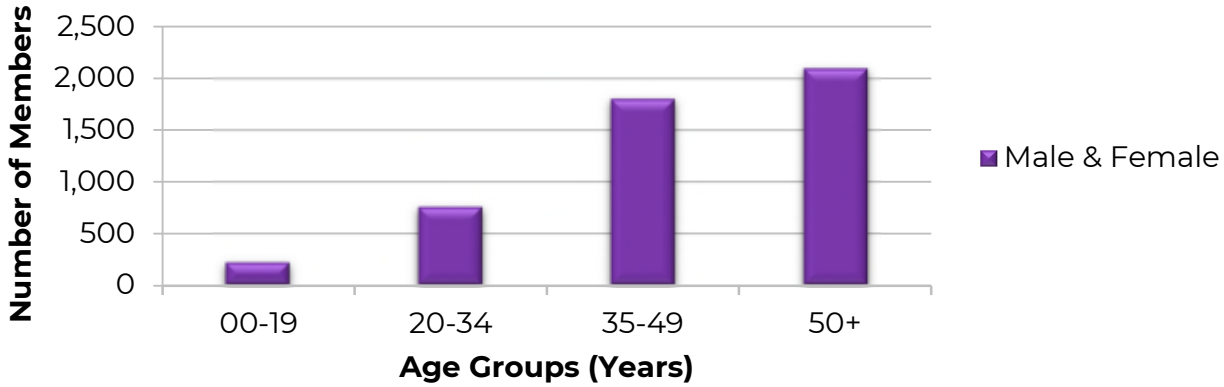
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	3,684	13,719	$1,047,685.87	$76.37	$1.70	596,503	617,533
2023	4,858	19,569	$1,410,326.06	$72.07	$1.60	871,390	882,610
% Change	**31.90%**	**42.60%**	**34.60%**	**-5.60%**	**-5.90%**	**46.10%**	**42.90%**
Change	**1,174**	**5,850**	**$362,640.19**	**-$4.30**	**-$0.10**	**274,887**	**265,077**

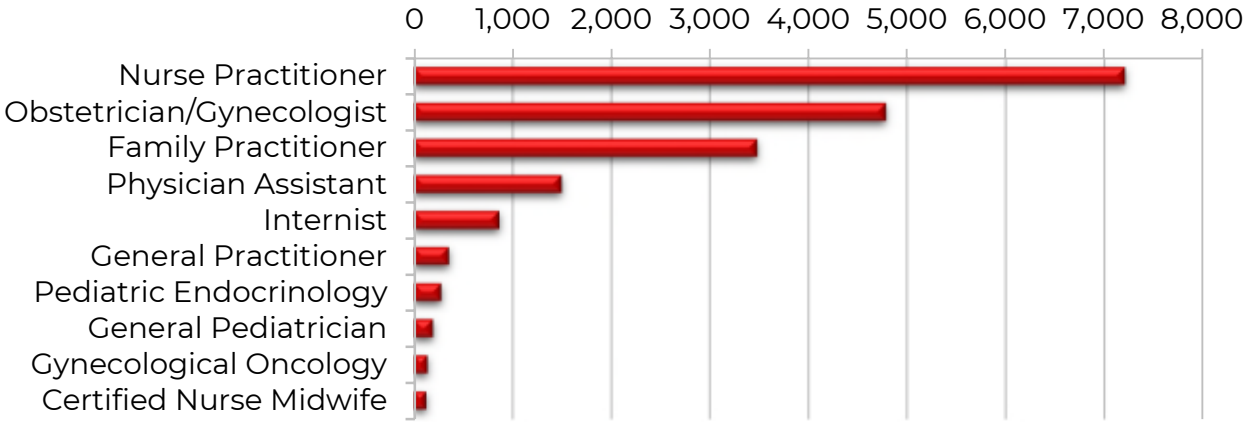
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

- Aggregate drug rebates collected during fiscal year 2023 for the VMS medications totaled $967,815.11.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing VMS Medications



Top Prescriber Specialties of VMS Medications by Number of Claims

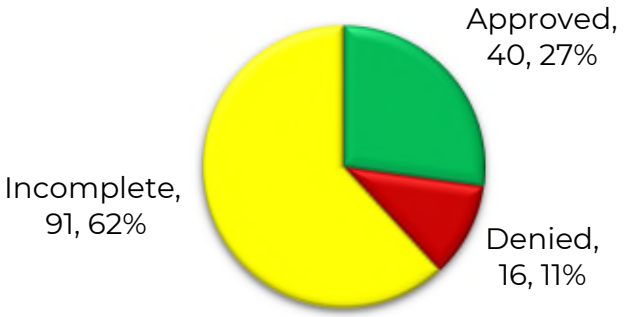


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Prior Authorization of VMS Medications

There were 147 prior authorization requests submitted for VMS medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Duavee® (conjugated estrogens/bazedoxifene tablet): March 2027
- Brisdelle® (paroxetine capsule): April 2029
- Minivelle® (estradiol transdermal system): July 2030
- Angeliq® (drospirenone/estradiol tablet): October 2031
- Bijuva® (estradiol/progesterone capsule): November 2032

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

- **May 2023:** The FDA approved Veozah™ (fezolinetant), an oral medication used for the treatment of moderate-to-severe VMS caused by menopause. Veozah™ is the first neurokinin 3 (NK_3) receptor antagonist approved by the FDA for this indication.

Pipeline:

- **Donesta®:** In March 2023, Mithra announced safety results for Donesta®, a next generation Estetrol (E4)-based product, for the treatment of post-menopausal women 40 to 65 years of age with moderate-to-severe VMS. Efficacy results for Donesta® were announced in 2022 which showed a meaningful reduction in VMS from baseline when compared to placebo with all co-primary efficacy endpoints statistically met. The safety data showed a beneficial effect on cholesterol profile and on bone turnover biomarkers. Mithra plans to file a New Drug Application (NDA) with the FDA in 2023.

Veozah™ (Fezolinetant) Product Summary[4]

Therapeutic Class: NK_3 receptor antagonist

Indication(s): Treatment of moderate-to-severe VMS due to menopause

How Supplied: 45mg tablet

Dosing and Administration:

- One 45mg tablet once daily with or without food
- Baseline blood work should be evaluated for hepatic function and injury before beginning Veozah™.
- Follow-up blood work should be performed at 3 months, 6 months, and 9 months after initiation of therapy and when symptoms suggest liver injury.

Cost Comparison[5]

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Veozah™ (fezolinetant) 45mg tablet	**$17.53**	**$525.90***	**$6,310.80**
estradiol 1mg tablet (generic)	$0.08	$1.68[α]	$20.16
estradiol-norethindrone 0.5-0.1mg tablet (generic)	$0.59	$17.70*	$212.40
gabapentin 300mg capsule (generic)	$0.04	$3.60[β]	$43.20
paroxetine 10mg tablet (generic)	$0.06	$1.80[+]	$21.60
venlafaxine 75mg ER capsule (generic)	$0.11	$3.30[+]	$39.60

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ER = extended-release; Unit = capsule or tablet
*Cost per month is based on the FDA approved once daily dose.
[α]Cost per month is based on the FDA approved dosing of 1mg once daily in a cyclical pattern (3 weeks on, 1 week off)
[β]Cost per month is based on the North American Menopause Society (NAMS) Nonhormone Therapy Position Statement 2023 recommended dosing of 300mg three times daily.
[+]Cost per month is based on the NAMS Nonhormone Therapy Position Statement 2023 recommended dosing for each product administered once daily.

Recommendations

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

Veozah™ (Fezolinetant) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Member must not use CYP1A2 inhibitors (e.g., cimetidine, ciprofloxacin, ethinyl estradiol, fluvoxamine, mexiletine) concomitantly with Veozah™; and

3. Member must not have a history of severe renal impairment, end-stage renal disease, or cirrhosis; and
4. Prescriber must verify baseline renal function and member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
5. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Veozah™, every 3 months for the first 9 months of treatment, and as clinically indicated thereafter; and
6. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
8. A quantity limit of 30 tablets per 30 days will apply.

Additionally, the College of Pharmacy recommends the removal of the prior authorization for Elestrin® (estradiol 0.6% gel) based on net cost (changes shown in red):

~~**Elestrin® (Estradiol 0.06% Gel) Approval Criteria:**~~

~~1. An FDA approved indication for the treatment of moderate-to-severe vasomotor symptoms due to menopause; and~~
~~2. Member must not have any contraindications for use of Elestrin®; and~~
~~3. A patient-specific, clinically significant reason why other topical estradiol formulations (e.g., Divigel®) are not appropriate for the member must be provided; and~~
~~4. Members older than 65 years of age will generally not be approved without supporting information; and~~
~~5. Approvals will be for the duration of 6 months to ensure the need for continued therapy is reassessed periodically and the medication is being used for the shortest duration possible; and~~
~~6. A quantity limit of 52 grams per 30 days will apply.~~

Utilization Details of VMS Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ORAL ESTROGEN PRODUCTS						
ESTRADIOL TAB 1MG	4,916	1,579	$59,104.45	$12.02	3.11	4.19%
ESTRADIOL TAB 2MG	4,643	1,165	$75,598.44	$16.28	3.99	5.36%
ESTRADIOL TAB 0.5MG	1,923	677	$23,345.81	$12.14	2.84	1.66%
PREMARIN TAB 0.625MG	627	164	$203,322.89	$324.28	3.82	14.42%
PREMARIN TAB 1.25MG	488	135	$171,078.77	$350.57	3.61	12.13%
PREMARIN TAB 0.3MG	364	97	$105,484.17	$289.79	3.75	7.48%
PREMARIN TAB 0.9MG	74	18	$22,396.60	$302.66	4.11	1.59%
PREMARIN TAB 0.45MG	66	25	$21,480.76	$325.47	2.64	1.52%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MENEST TAB 0.3MG	9	5	$1.330.34	$147.82	1.8	0.09%
MENEST TAB 1.25MG	3	1	$689.07	$229.69	3	0.05%
MENEST TAB 0.625MG	2	1	$179.30	$89.65	2	0.01%
SUBTOTAL	**13,115**	**3,867**	**$684,010.60**	**$52.15**	**3.39**	**48.50%**
TOPICAL ESTROGEN PRODUCTS						
ESTRADIOL DIS 0.1MG BIWEEKLY	752	176	$47,135.58	$62.68	4.27	3.34%
ESTRADIOL DIS 0.05MG BIWEEKLY	567	158	$34,124.53	$60.18	3.59	2.42%
ESTRADIOL DIS 0.1MG WEEKLY	502	134	$30,100.21	$59.96	3.75	2.13%
ESTRADIOL DIS 0.05MG WEEKLY	470	112	$23,851.49	$50.75	4.2	1.69%
DOTTI DIS 0.1MG	337	82	$20,785.52	$61.68	4.11	1.47%
ESTRADIOL DIS 0.025MG WEEKLY	259	74	$14,708.59	$56.79	3.5	1.04%
ESTRADIOL DIS 0.075MG BIWEEKLY	210	54	$12,614.82	$60.07	3.89	0.89%
ESTRADIOL DIS 0.025MG BIWEEKLY	183	53	$11,668.92	$63.76	3.45	0.83%
ESTRADIOL DIS 0.0375MG BIWEEKLY	165	54	$10,519.26	$63.75	3.06	0.75%
DOTTI DIS 0.05MG	144	44	$8,726.57	$60.60	3.27	0.62%
DOTTI DIS 0.0375MG BIWEEKLY	131	33	$8,498.71	$64.88	3.97	0.60%
DOTTI DIS 0.075MG	117	26	$6,961.17	$59.50	4.5	0.49%
ESTRADIOL DIS 0.0375MG WEEKLY	105	25	$6,097.92	$58.08	4.2	0.43%
DOTTI DIS 0.025MG	74	28	$4,590.50	$62.03	2.64	0.33%
ESTRADIOL DIS 0.075MG WEEKLY	70	20	$3,779.26	$53.99	3.5	0.27%
ESTRADIOL GEL 1MG/GM	59	24	$7,737.09	$131.14	2.46	0.55%
DIVIGEL GEL 1MG/GM	50	11	$8,283.46	$165.67	4.55	0.59%
DIVIGEL GEL 0.5MG	38	9	$5,598.13	$147.32	4.22	0.40%
ESTRADIOL DIS 0.06MG WEEKLY	29	7	$1,332.42	$45.95	4.14	0.09%
DIVIGEL GEL 0.25MG	28	6	$4,461.74	$159.35	4.67	0.32%
ESTRADIOL GEL 0.5MG	27	10	$3,591.13	$133.00	2.7	0.25%
VIVELLE-DOT DIS 0.1MG	26	5	$1,387.90	$53.38	5.2	0.10%
DIVIGEL GEL 1.25MG	24	6	$3,428.91	$142.87	4	0.24%
ESTRADIOL GEL 1.25MG	21	8	$1,884.24	$89.73	2.63	0.13%
ESTRADIOL GEL 0.75MG	18	5	$2,103.25	$116.85	3.6	0.15%
LYLLANA DIS 0.05MG	16	5	$974.86	$60.93	3.2	0.07%
LYLLANA DIS 0.0375MG	14	4	$887.95	$63.43	3.5	0.06%
DIVIGEL GEL 0.75MG	11	5	$1,623.87	$147.63	2.2	0.12%
LYLLANA DIS 0.1MG	11	6	$698.04	$63.46	1.83	0.05%
ESTRADIOL GEL 0.25MG	10	6	$1,346.40	$134.64	1.67	0.10%
CLIMARA DIS 0.06MG	9	1	$1,440.09	$160.01	9	0.10%
LYLLANA DIS 0.075MG	8	4	$500.53	$62.57	2	0.04%
EVAMIST SPR 1.53MG	7	4	$971.19	$138.74	1.75	0.07%
LYLLANA DIS 0.025MG	6	2	$397.74	$66.29	3	0.03%
MENOSTAR DIS 14MCG	5	1	$852.40	$170.48	5	0.06%
CLIMARA DIS 0.1MG	3	1	$478.41	$159.47	3	0.03%
CLIMARA DIS 0.025MG	3	1	$171.66	$57.22	3	0.01%
SUBTOTAL	**4,509**	**1,204**	**$294,314.46**	**$65.27**	**3.75**	**20.87%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
INJECTABLE ESTROGEN PRODUCTS						
ESTRADIOL VAL INJ 20MG/ML	330	132	$36,568.48	$110.81	2.5	2.59%
DEPO-ESTRADIOL INJ 5MG/ML	101	69	$15,794.21	$156.38	1.46	1.12%
ESTRADIOL VIAL INJ 40MG/ML	55	29	$10,905.01	$198.27	1.9	0.77%
DELESTROGEN INJ 10MG/ML	25	11	$3,531.67	$141.27	2.27	0.25%
ESTRADIOL VIAL INJ 10MG/ML	18	14	$2,697.52	$149.53	1.29	0.19%
DELESTROGEN INJ 40MG/ML	2	2	$635.94	$317.97	1	0.05%
SUBTOTAL	**531**	**297**	**$70,126.83**	**$132.07**	**2.07**	**4.97%**
ORAL ESTROGEN/PROGESTIN PRODUCTS						
PREMPRO TAB 0.3-1.5MG	291	80	$93,637.36	$321.78	3.64	6.64%
PREMPRO TAB 0.625-2.5MG	193	47	$72,204.85	$374.12	4.11	5.12%
ESTRA/NORETH TAB 1-0.5MG	111	43	$4,738.18	$42.69	2.58	0.34%
PREMPRO TAB 0.45-1.5MG	91	30	$34,077.97	$374.48	3.03	2.42%
ESTRA/NORETH TAB 0.5-0.1MG	82	29	$3,536.72	$43.13	2.83	0.25%
NORETH/ETHIN TAB 0.5MG-2.5MCG	67	24	$3,251.50	$48.53	2.79	0.23%
PREMPRO TAB 0.625-5MG	66	18	$30,117.28	$456.32	3.67	2.14%
NORETH/ETHIN TAB 1MG-5MCG	35	10	$1,572.81	$44.94	3.5	0.11%
MIMVEY TAB 1-0.5MG	35	17	$2,077.72	$59.36	2.06	0.15%
FYAVOLV TAB 0.5MG-2.5MCG	18	9	$1,097.80	$60.99	2	0.08%
ANGELIQ TAB 0.25-0.5MG	11	4	$3,658.78	$332.62	2.75	0.26%
PREFEST TAB 1-0.09MG	5	2	$1,395.78	$279.16	2.5	0.10%
ANGELIQ TAB 0.5-1MG	5	3	$2,461.30	$492.26	1.67	0.17%
BIJUVA CAP 1-100MG	3	1	$715.71	$238.57	3	0.05%
AMABELZ TAB 0.5-0.1MG	2	2	$113.57	$56.79	1	0.01%
JINTELI TAB 1MG-5MCG	2	2	$199.78	$99.89	1	0.01%
PREPHASE TAB 0.0625-5MG	2	1	$443.82	$221.91	2	0.03%
FYAVOLV TAB 1MG-5MCG	1	1	$35.56	$35.56	1	0.00%
AMABELZ TAB 1-0.5MG	1	1	$40.40	$40.40	1	0.00%
SUBTOTAL	**1,021**	**324**	**$255,376.89**	**$250.12**	**3.15**	**18.11%**
TOPICAL ESTROGEN/PROGESTIN PRODUCTS						
CLIMARA PRO DIS 0.045-0.015MG/DAY	145	37	$32,802.96	$226.23	3.92	2.33%
COMBIPATCH DIS 0.05-0.014MG/DAY	108	34	$24,910.22	$230.65	3.18	1.77%
COMBIPATCH DIS 0.05-0.025MG/DAY	103	21	$23,740.31	$230.49	4.9	1.68%
SUBTOTAL	**356**	**92**	**$81,453.49**	**$228.80**	**3.87**	**5.78%**
VAGINAL ESTROGEN PRODUCTS						
FEMRING MIS 0.1MG/24H	20	12	$13,985.27	$699.26	1.67	0.99%
FEMRING MIS 0.05MG/24H	17	8	$11,058.52	$650.50	2.13	0.78%
SUBTOTAL	**37**	**20**	**$25,043.79**	**$676.89**	**1.85**	**1.78%**
TOTAL	**19,569**	**4,858***	**$1,410,326.06**	**$72.07**	**4.03**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP=capsule; DIS = patch; ESTRA/NORETH = estradiol/norethindrone; INJ = injection; MIS = insert; NORETH/ETHIN = norethindrone/ethinyl estradiol; SPR = spray; TAB = tablet; VAL = valerate
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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[3] Mithra. Mithra Announces Promising Topline Safety Results from Donesta® Phase 3 Study in North America. Available online at: https://www.mithra.com/en/mithra-announces-promising-topline-safety-results-from-donesta-phase-3-study-in-north-america/. Issued 03/03/2023. Last accessed 10/16/2023.
[4] Veozah™ Prescribing Information. Astellas Pharma, Inc. Available online at: https://www.astellas.com/us/system/files/veozah_uspi.pdf, Last revised 05/2023. Last accessed 10/11/2023.
[5] Shufelt C, Brown V, Carpenter J, et al. The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society. *Menopause* 2023 30(6):573-590. doi: 10.1097/GME.0000000000002200.

Appendix O

Fiscal Year 2023 Annual Review of Dry Eye Disease (DED) Medications and 30-day Notice to Prior Authorize Miebo™ (Perfluorohexyloctane Ophthalmic Solution) and Vevye® (Cyclosporine Ophthalmic Solution)

Oklahoma Health Care Authority
November 2023

Current Prior Authorization Criteria

Cequa® (Cyclosporine 0.09% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to increase tear production in members with keratoconjunctivitis sicca (dry eye); and
2. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
4. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Eysuvis® (Loteprednol Etabonate 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. A documented trial of intermittent or regular artificial tear use within the past 3 months; and
3. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion), which is available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids including Lotemax® (loteprednol 0.5% suspension) must be provided; and
5. Member must not have any contraindications to Eysuvis®; and
6. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Restasis MultiDose® (Cyclosporine 0.05% Ophthalmic Emulsion) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Restasis® in the individual dosage formulation (single-use vials), which is available without a prior authorization, must be provided; and

2. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided.

Tyrvaya® (Varenicline Nasal Spray) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 18 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per product) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use all available ophthalmic preparations for the treatment of DED must be provided; and
6. A quantity limit of 8.4mL (2 bottles) per 30 days will apply.

Xiidra® (Lifitegrast) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 17 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per trial) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A quantity limit of 2 vials per day will apply.

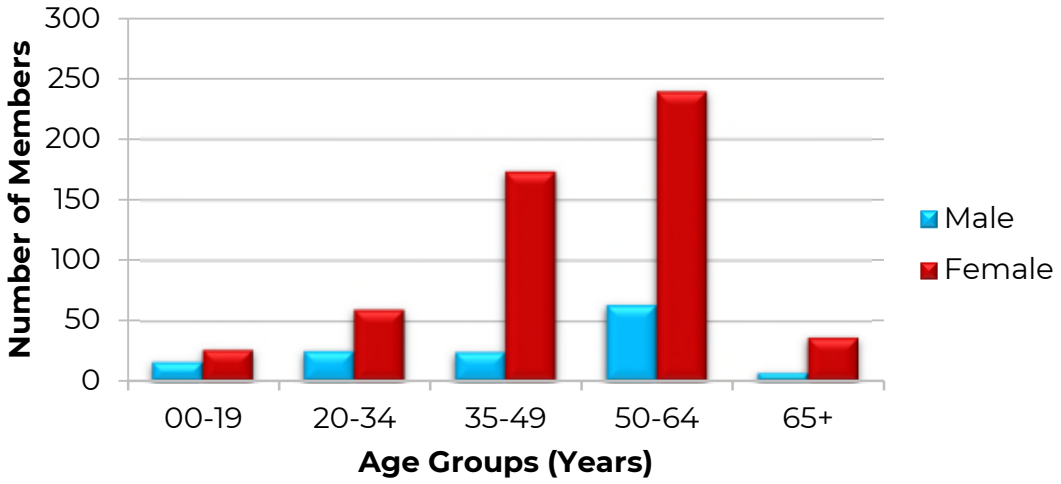
Utilization of DED Medications: Fiscal Year 2023

Comparison of Fiscal Years

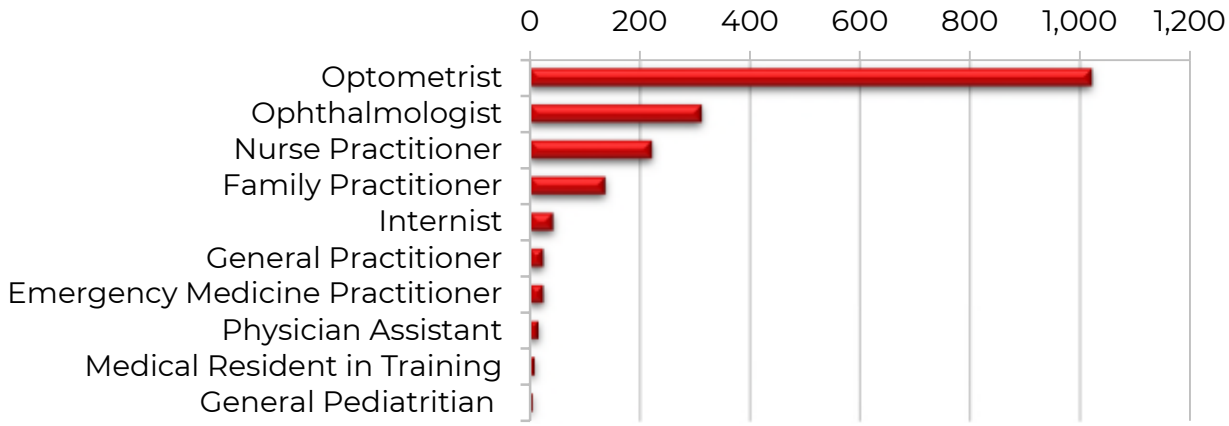
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	533	1,431	$769,570.01	$537.78	$17.89	82,213	43,011
2023	668	1,825	$712,055.21	$390.17	$13.08	103,743	54,431
% Change	**25.30%**	**27.50%**	**-7.50%**	**-27.40%**	**-26.90%**	**26.20%**	**26.60%**
Change	**135**	**394**	**-$57,514.80**	**-$147.61**	**-$4.81**	**21,530**	**11,420**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing DED Medications

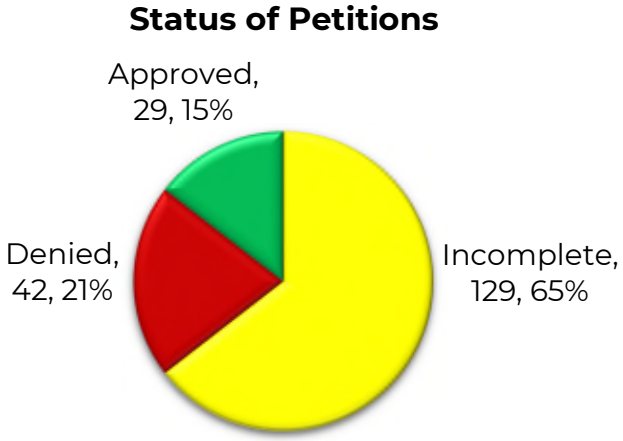


Top Prescriber Specialties of DED Medications by Number of Claims



Prior Authorization of DED Medications

There were 200 prior authorization requests submitted for DED medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



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

Anticipated Patent Expiration(s):

- Eysuvis® (loteprednol etabonate 0.25% ophthalmic suspension): May 2033
- Xiidra® (lifitegrast 5% ophthalmic solution): December 2033
- Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion): May 2034
- Tyrvaya® (varenicline nasal spray): October 2035
- Cequa® (cyclosporine 0.09% ophthalmic solution): February 2037
- Miebo™ (perfluorohexyloctane ophthalmic solution): June 2037
- Vevye® (cyclosporine 0.1% ophthalmic solution): October 2039

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

- **May 2023:** Miebo™ (perfluorohexyloctane ophthalmic solution) was approved by the FDA for treatment of the signs and symptoms of DED. Miebo™ is a first in class semi-fluorinated alkane that directly targets tear evaporation.
- **May 2023:** Vevye® (cyclosporine 0.1% ophthalmic solution) was approved by the FDA for treatment of signs and symptoms of DED. Vevye® is a cyclosporine product that is solubilized in a water-free excipient that does not contain anti-microbial preservatives, oils, or surfactants.

Pipeline:

- **Reproxalap:** Reproxalap is a novel reactive aldehyde species (RASP) inhibitor being studied for the treatment of DED. Both the Phase 2a

and 2b trials found a statistically significant improvement in DED symptoms from baseline. The Phase 2a trial also found a significant difference in disease improvement after 4 weeks of treatment. Phase 3 trial data is not available at this time. The FDA has accepted a New Drug Application (NDA) for reproxalap for the treatment of the signs and symptoms of DED. A Prescription Drug User Fee Act (PDUFA) date for this medication has been set as November 23, 2023.

Miebo™ (Perfluorohexyloctane Ophthalmic Solution)[6]

Therapeutic Class: Semi-fluorinated alkane

Indication(s): Treatment of the signs and symptoms of DED in patients 18 years of age and older

How supplied: 3mL multi-dose bottle containing 100% perfluorohexyloctane with dropper tips and screw caps

Dosing and administration: 1 drop in each affected eye 4 times a day

Vevye® (Cyclosporine 0.1% Ophthalmic Solution)[7]

Therapeutic Class: Calcineurin inhibitor immunosuppressant

Indication(s): Treatment of the signs and symptoms of DED in patients 18 years of age and older

How Supplied: 5mL bottle containing 0.1% cyclosporine solution that delivers 0.01mL per drop

Dosing and Administration: 1 drop in each affected eye twice daily, at least 12 hours apart

Cost Comparison

Product	Cost Per Unit	Cost Per Month	Cost Per Year
Miebo™ (perfluorohexyloctane op sol) bottle	**$257.00**	**$3,084[£]**	**$37,008.00**
Restasis® (cyclosporine 0.05% op emu) single-use vial	$10.32	$619.20*	$7,430.40
cyclosporine 0.05% op emu single-use vial (generic)	$2.79	$167.40*	$2,008.80
Xiidra® (lifitegrast 5% op sol) single-use vial	$10.96	$657.60*	$7,891.20

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
[£]Cost per month based on the FDA approved dosing of 1 drop in each affected eye 4 times daily.
*Cost per month based on the FDA approved dosing of 1 drop in each eye every 12 hours.
emu = emulsion; op = ophthalmic; sol = solution
Unit = each mL for Miebo™ and each single-use vial for the other products listed
Please note: Cost information for Vevye® is not available at this time to allow for a cost comparison.

Recommendations

The College of Pharmacy recommends the prior authorization of Miebo™ and Vevye® with the following criteria (shown in red):

Miebo™ (Perfluorohexyloctane) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
6. A quantity limit of 12mL per 30 days will apply.

Vevye® (Cyclosporine 0.1% Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without prior authorization, must be provided; and
6. A quantity limit of 5mL per 25 days will apply.

Utilization Details of DED Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CYCLOSPORINE PRODUCTS						
CYCLOSPORINE EMU 0.05% OP	1,123	467	$314,832.28	$280.35	2.4	44.21%
RESTASIS EMU 0.05% OP	624	222	$348,031.73	$557.74	2.81	48.88%
SUBTOTAL	**1,747**	**689**	**$662,864.01**	**$379.43**	**2.54**	**93.09%**
LIFITEGRAST PRODUCTS						
XIIDRA DRO 5%	69	20	$44,755.38	$ 648.63	3.45	6.29%
SUBTOTAL	**69**	**20**	**$44,755.38**	**$648.63**	**3.45**	**6.29%**
LOTEPREDNOL PRODUCTS						
EYSUVIS DRO 0.25%	1	1	$485.49	$485.49	1	0.07%
SUBTOTAL	**1**	**1**	**$485.49**	**$485.49**	**1**	**0.07%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VARENICLINE PRODUCTS						
TYRVAYA SOL 0.03MG	8	2	$3,950.33	$493.79	4	0.55%
SUBTOTAL	**1**	**1**	**$3,950.33**	**$493.79**	**4**	**0.55%**
TOTAL	**1,825**	**668***	**$712,055.21**	**$390.17**	**2.7**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DRO = drop; EMU = emulsion; OP = ophthalmic; SOL = solution
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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Appendix P

Fiscal Year 2023 Annual Review of Skysona® (Elivaldogene Autotemcel)

Oklahoma Health Care Authority
November 2023

Current Prior Authorization Criteria

Skysona® (Elivaldogene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of early, active cerebral adrenoleukodystrophy (CALD) in male members 4 to 17 years of age; and
2. Diagnosis must be confirmed by all of the following:
    a. Molecular genetic testing confirming a mutation in the *ABCD1* gene (results of genetic testing must be submitted); and
        i. Members must not have a full deletion of the *ABCD1* gene; and
    b. Lab results indicating elevated very long-chain fatty acids (VLCFAs); and
    c. Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating the following:
        i. Loes score between 0.5 and 9 on the 34-point scale; and
        ii. Gadolinium enhancement (GdE+) on MRI of demyelinating lesions; and
    d. Neurological Function Score (NFS) of ≤1; and
3. Skysona® must be prescribed by a neurologist, endocrinologist, or hematologist/oncologist with expertise in the treatment of CALD and the administration of Skysona®; and
4. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
5. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
6. Member must not be taking statins, Lorenzo's oil, or dietary regimens used to lower VLCFA levels; and
7. Member must not have an immediate family member with known or suspected familial cancer syndrome (FCS); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to the 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 Skysona®); and

10. Members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona®; and
11. Prescriber must verify members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and
12. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Skysona®; and
13. 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 Skysona®, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
14. Skysona® must be administered at a Skysona® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Skysona® dose from receipt to storage to administration; and
15. Approvals will be for 1 dose per member per lifetime.

Utilization of Skysona® (Elivaldogene Autotemcel): Fiscal Year 2023

There was no SoonerCare utilization of Skysona® (elivaldogene autotemcel) during fiscal year 2023 (07/01/2022 to 06/30/2023).

Prior Authorization of Skysona® (Elivaldogene Autotemcel)

There were no prior authorization requests submitted for Skysona® (elivaldogene autotemcel) during fiscal year 2023.

Recommendations

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

Appendix Q

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

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

FDA NEWS RELEASE

For Immediate Release: October 31, 2023

FDA Approves Interchangeable Biosimilar for Multiple Inflammatory Diseases

The FDA approved Wezlana™ (ustekinumab-auub) as a biosimilar to and interchangeable with Stelara® (ustekinumab) for multiple inflammatory diseases. Wezlana™, like Stelara®, is approved to treat the following indications:

- Adult patients with:
  - Moderate-to-severe plaque psoriasis who are candidates for phototherapy or systemic therapy; and
  - Active psoriatic arthritis; and
  - Moderately-to-severely active Crohn's disease; and
  - Moderately-to-severely active ulcerative colitis; or
- Pediatric patients 6 years of age and older with:
  - Moderate-to-severe plaque psoriasis who are candidates for phototherapy or systemic therapy; and
  - Active psoriatic arthritis.

Health care professionals should review the *Prescribing Information* in the labeling for detailed information about the approved uses.

Biological products include medications for treating many serious illnesses and chronic health conditions. A biosimilar is a biological product that is highly similar to, and has no clinically meaningful differences from, a biological product already approved by the FDA (also called the reference product). An interchangeable biosimilar is a biosimilar that has been shown to meet other requirements under the law and may be substituted for the reference product without consulting the prescriber. The substitution may occur at the pharmacy, subject to state pharmacy laws which vary by state, a practice commonly called "pharmacy-level substitution" — similar to how generic drugs are substituted for brand name drugs. All biological products are approved only after they meet the FDA's rigorous approval standards. This means health care providers and patients can expect the same safety and effectiveness from both a biosimilar and an interchangeable biosimilar, just as they would for a reference product. Biosimilar and interchangeable biosimilar products may cost less than the brand-name medicine.

The FDA's approval of Wezlana™ is based on a comprehensive review of scientific evidence demonstrating it is highly similar to Stelara® and that there are no clinically meaningful differences between the 2 products in terms of safety, purity, and potency (i.e., safety and effectiveness). This evidence included comparisons of the products on an analytical level using an extensive battery of chemical and biological tests and biological assays that confirmed similarity in the structural and functional features of Wezlana™ and Stelara® (including those known to impact safety and efficacy), and comparative human pharmacokinetic data, clinical immunogenicity data, and other clinical safety and effectiveness data. The evidence also demonstrated that Wezlana™ met the other legal requirements to be interchangeable with Stelara® at the pharmacy level.

Like Stelara®, the most serious known side effect of Wezlana™ is infection. The most common adverse reactions with ustekinumab products are nasopharyngitis, upper respiratory tract infection, headache, fatigue, nausea, vomiting, injection site erythema,

vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, sinusitis, abdominal pain, influenza, fever, and diarrhea.

The labeling for Wezlana™, like Stelara®, contains a warning to alert health care professionals and patients about an increased risk of serious infections leading to hospitalization. There is also a warning that some malignancies, hypersensitivity reactions, and cases of posterior reversible encephalopathy syndrome (PRES) have been reported in patients who received Wezlana™ in clinical studies. Wezlana™ must be dispensed with a patient *Medication Guide* that describes important information about its uses and risks.

The FDA granted the approval of Wezlana™ to Amgen, Inc.

FDA NEWS RELEASE

For Immediate Release: October 26, 2023

FDA Raises Concerns About Probiotic Products Sold for Use in Hospitalized Preterm Infants

As part of the FDA's commitment to protecting public health, they are advising the public, including health care providers, of the possible risks that products containing live bacteria or yeast, which are commonly called probiotics, pose to preterm infants in hospital settings. The FDA recently sent a letter to health care providers warning them about this topic and has issued 2 warning letters to companies for illegally selling their products for use in treating or preventing certain diseases in preterm infants.

Probiotic products contain live organisms such as bacteria or yeast and are commonly marketed as foods, including as dietary supplements. The FDA is concerned as these products can be dangerous for preterm infants and are being illegally sold to treat or prevent diseases in preterm infants in hospital settings, such as to reduce the risk of necrotizing enterocolitis. Preterm infants who are administered a probiotic product are at risk of invasive, potentially fatal disease, or infection, caused by the bacteria or yeast contained in the probiotics.

The FDA is aware that certain probiotic products used in hospital settings to prevent necrotizing enterocolitis have contributed to invasive disease, including 1 infant death in 2023, and have been associated with more than 2 dozen other reported adverse events in the United States since 2018. The FDA is also concerned about and is investigating reports that these products may have contributed to additional adverse events, including death, and is working to obtain the proper evidence and medical records, where possible. Any death or adverse event in an infant following the use of a probiotic product is very concerning, and the FDA is actively working with health care providers to better understand the link between the probiotic products used and the adverse events in preterm infants reported by these institutions.

Importantly, the FDA has not approved any probiotic product for use as a drug or biological product in infants of any age. Unapproved, unlicensed probiotics that are used to treat or prevent a disease or condition in preterm infants have not undergone the FDA's thorough premarket evaluation for safety and effectiveness. Further, they have not been evaluated for compliance with the FDA's rigorous manufacturing and testing standards for drugs and biological products, including testing for other organisms. For these products to be lawfully marketed as drugs and biological products, the FDA requires approval of a Biologics License Application (BLA) to ensure they have been appropriately evaluated. In the absence of an approved product, health care providers who administer products containing live bacteria or yeast to treat, mitigate, cure, or prevent a disease or condition are required to submit an Investigational New Drug (IND)

application to the FDA to ensure the investigational use of an unapproved product is conducted with the appropriate safeguards.

The FDA is committed to ensuring that any violations and safety issues presented by these products are addressed by their manufacturers. The FDA issued a warning letter to Abbott Laboratories on October 24, 2023, for its product, Similac Probiotic Tri-Blend, which contains *B. infantis* (Bb-02), *S. thermophilus* (TH-4), and *B. lactis* (BB-12). Of note, this product is not an infant formula and is not related to the previous issues the FDA has noted with powdered infant formula manufactured by Abbott Nutrition. Abbott has agreed to discontinue sales of its Similac Probiotic Tri-Blend product and is working with the FDA to take additional corrective actions.

The warning letter notes the company sells the probiotic product for use in hospital settings for preterm infants. Based on the intended uses on the company's websites and Abbott's marketing materials, the product is an unapproved new drug and an unlicensed biological product being sold in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act. Additionally, the product is an adulterated dietary supplement under the FD&C Act because, when intended for consumption by preterm infants, the Bb-02 and TH-4 ingredients have not met the applicable safety requirements.

The FDA also recently issued a warning letter to Infinant Health, Inc (formerly Evolve BioSystems Inc.) regarding its probiotic product, Evivo with MCT Oil, an unapproved and unlicensed product sold for use in treating or preventing disease in preterm infants, in violation of the FD&C Act and the Public Health Service Act. The product was intended to be added to food for preterm infants and as such was also found to be an adulterated food under the FD&C Act. This product has since been voluntarily recalled and is no longer available in the United States.

The FDA understands there are conflicting data in the literature on the safety and effectiveness of probiotics for the prevention of necrotizing enterocolitis, and that the study of the use of probiotics has been complicated by several factors, including the use of different probiotics in different trials. Because of the potential for harm posed by these products in highly vulnerable individuals, such as preterm infants, the FDA urges the industry, clinical, and research funding communities to focus on high quality clinical trials with products meeting quality criteria to provide definitive evidence to inform the use of these products by health care providers and, where appropriate, to support applications for drugs and biological products for use in infants of any age.

The FDA continues to carefully review and investigate adverse event reports for probiotics. To inform the FDA's surveillance efforts, and to better understand these issues to help protect public health, the FDA encourages health care providers and caregivers to report adverse events following use of probiotics to the manufacturer, the FDA's MedWatch program, and CFSAN's Adverse Event Reporting System. Caregivers may also speak with their health care provider regarding concerns or questions with these products.

FDA NEWS RELEASE

For Immediate Release: October 24, 2023

FDA Approves New Therapy for Rare Form of Blood Cancers Called Myelodysplastic Syndromes (MDS)

The FDA approved Tibsovo® (ivosidenib) for the treatment of adult patients with relapsed or refractory (R/R) MDS with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. This is the first targeted therapy approved for this

indication. The FDA also approved the Abbott RealTime IDH1 Assay as a companion diagnostic for the selection of R/R MDS patients with an IDH1 mutation.

Tibsovo® was previously approved for certain adults with newly-diagnosed acute myeloid leukemia (AML), relapsed or refractory AML, and locally advanced or metastatic cholangiocarcinoma. The Abbott RealTime IDH1 Assay was also previously approved as a companion diagnostic to identify AML patients with an IDH1 mutation for treatment with Tibsovo® or Rezlidhia® (olutasidenib).

Tibsovo® was granted Priority Review designation, Breakthrough Therapy designation, and Orphan Drug designation for the indication noted above.

The FDA granted the approval of Tibsovo® to Servier Pharmaceuticals LLC. The FDA granted the approval of the RealTime IDH1 Assay to Abbott Laboratories.

Current Drug Shortages Index (as of October 24, 2023):

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***
Alprostadil Suppository	***Currently in Shortage***
Amifostine Injection, Powder, Lyophilized, For Solution	***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***
Azacitidine Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Bazedoxifene Acetate, Estrogens, Conjugated Tablet, Film Coated	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection, Solution	***Currently in Shortage***
Capecitabine Tablet	***Currently in Shortage***
Carboplatin Injection, Solution	***Currently in Shortage***
Cefixime Capsule	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection, Powder, For Solution	***Currently in Shortage***
Chloramphenicol Sodium Succinate Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection, Solution	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***

Clindamycin Phosphate Injection, Solution	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Collagenase Clostridium Histolyticum Ointment	***Currently in Shortage***
Conivaptan Hydrochloride Injection, Solution	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cyclopentolate Hydrochloride, Phenylephrine Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection, 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 Injection, Solution	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection, Solution	***Currently in Shortage***
Diazepam Gel	***Currently in Shortage***
Difluprednate Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Digoxin Injection, Solution	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol Injection	***Currently in Shortage***
Disopyramide Phosphate Capsule	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection, Solution	***Currently in Shortage***
Dulaglutide Injection, Solution	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Edetate Calcium Disodium Injection	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Epinephrine Injection	***Currently in Shortage***
Erythromycin Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Fluconazole Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Sodium Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablet	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Heparin Sodium Injection, Solution	***Currently in Shortage***

Hydrocortisone Sodium Succinate Injection, Powder, For Solution	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection, Solution	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
I.V. Fat Emulsion	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Isoniazid Tablet	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Tablet, Film Coated	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection, Solution	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection, Solution	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu-177 Vipivotide Tetraxetan Injection, Solution	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mannitol Injection, Solution	***Currently in Shortage***
Mepivacaine Hydrochloride Injection, Solution	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methotrexate Sodium Injection, Solution	***Currently in Shortage***
Methotrexate Sodium Tablet	***Currently in Shortage***
Methyldopa Tablet, Film Coated	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection, Suspension	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection, Solution	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric) Injection	***Currently in Shortage***
Neomycin Sulfate Tablet	***Currently in Shortage***
Nitroglycerin Injectable	***Currently in Shortage***
Nizatidine Capsule	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injection, Suspension	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection, Solution, Concentrate	***Currently in Shortage***

Potassium Chloride Injection	***Currently in Shortage***
Potassium Chloride Injection, Solution	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Remifentanil Hydrochloride Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Rocuronium Bromide Injection, Solution	***Currently in Shortage***
Rocuronium Bromide Solution	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection, Solution	***Currently in Shortage***
Semaglutide Injection, Solution	***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 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection	***Currently in Shortage***
Sodium Chloride Irrigant	***Currently in Shortage***
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection, Solution	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Somatropin Injection, Solution	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sucralfate Tablet	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablet	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection, Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injection, Suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsule	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection, Powder, Lyophilized, For Solution	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***
Water Injection	***Currently in Shortage***
Water Irrigant	***Currently in Shortage***