OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
December 13, 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 – December 13, 2023

DATE: December 6, 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 December meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

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

Update on the Medication Coverage Authorization Unit/Academic Detailing Program Update – Appendix B

Action Item – Vote to Update the Maintenance Drug List – Appendix C

Action Item – Vote to Prior Authorize Symbicort Aerosphere® (Budesonide/Formoterol) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications – Appendix D

Action Item – Vote to Prior Authorize Sohonos™ (Palovarotene) – Appendix E

Action Item – Vote to Prior Authorize Miebo™ (Perfluorohexyloctane Ophthalmic Solution) and Vevye® (Cyclosporine Ophthalmic Solution) – Appendix F

Action Item – Vote to Prior Authorize Veozah™ (Fezolinetant) and Update the Approval Criteria for Vasomotor Symptom (VMS) Medications – Appendix G

Action Item – Vote to Prior Authorize Elrexfio™ (Elranatamab-bcmm) and Talvey™ (Talquetamab-tgvs) and Update the Approval Criteria for the Multiple Myeloma Medications – Appendix H

Action Item – Annual Review of Anticoagulants and Platelet Aggregation Inhibitors – Appendix I

Action Item – Annual Review of Constipation and Diarrhea Medications – Appendix J

Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Hepzato Kit™ (Mephalan) and Zynyz™ (Retifanlimab-dlwr)– Appendix K

Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Rystiggo® (Rozanolixizumab-noli), Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc), and Zilbrysq® (Zilucoplan) – Appendix L

Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Exxua™ (Gepirone) and Zurzuvae™ (Zuranolone) – Appendix M

Annual Review of Lysosomal Storage Disease Medications and 30-Day Notice to Prior Authorize Elfabrio® (Pegunigalsidase Alfa-iwxj), Opfolda™ (Miglustat), and Pombiliti™ (Cipaglucosidase Alfa-atga) – Appendix N

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – December 13, 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. Wilcox

DUR Board Members:

Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Bret Haymore –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person
Dr. Edna Patatanian –	participating in person
Dr. Vineetha Thomas –	participating in person
Dr. Beth Walton –	participating in person
Dr. Cindy West –	participating in person

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https://oklahoma.zoom.us/webinar/register/WN_R_AmCBepQpGQggKXT40uxg
After registering, you will receive a confirmation email containing information about joining the webinar.

Or join by phone:
Dial: +1-602-753-0140 or +1-669-219-2599
Webinar ID: 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. November 8, 2023 DUR Board Meeting Minutes
   B. November 8, 2023 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Academic Detailing Program Update – See Appendix B**
   A. Pharmacy Help Desk Activity for November 2023
   B. Medication Coverage Activity for November 2023
   C. Academic Detailing Program Update

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

5. **Action Item – Vote to Update the Maintenance Drug List – See Appendix C**
   A. Introduction
   B. SoonerCare Maintenance Drug List
   C. College of Pharmacy Recommendations

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

6. **Action Item – Vote to Prior Authorize Symbicort Aerosphere® (Budesonide/Formoterol) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications – See Appendix D**
   A. Market News and Updates
   B. College of Pharmacy Recommendations

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

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

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

8. **Action Item – Vote to Prior Authorize Miebo™ (Perfluorohexyloctane Ophthalmic Solution) and Vevye® (Cyclosporine Ophthalmic Solution) – See Appendix F**
   A. Market News and Updates
   B. Product Summaries
   C. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Veozah™ (Fezolinetant) and Update the Approval Criteria for Vasomotor Symptom (VMS) Medications – See Appendix G**
   A. Market News and Updates
   B. Veozah™ (Fezolinetant) Product Summary
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Elrexfio™ (Elranatamab-bcmm) and Talvey™ (Talquetamab-tgvs) and Update the Approval Criteria for the Multiple Myeloma Medications – See Appendix H**
    A. Market News and Updates
    B. Product Summaries
    C. College of Pharmacy Recommendations

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

11. **Action Item – Annual Review of Anticoagulants and Platelet Aggregation Inhibitors – See Appendix I**
    A. Current Prior Authorization Criteria
    B. Utilization of Anticoagulants and Platelet Aggregation Inhibitors
    C. Prior Authorization of Anticoagulants and Platelet Aggregation Inhibitors

D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Anticoagulants and Platelet Aggregation Inhibitors

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

12. Action Item – Annual Review of Constipation and Diarrhea Medications – See Appendix J

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

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

13. Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Hepzato Kit™ (Mephalan) and Zynyz™ (Retifanlimab-dlwr) – See Appendix K

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

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

14. Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Rystiggo® (Rozanolixizumab-noli), Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc), and Zilbrysq® (Zilucoplan) – See Appendix L

A. Current Prior Authorization Criteria
B. Utilization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents
C. Prior Authorization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Complement Inhibitors and Miscellaneous Immunomodulatory Agents

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

15. **Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Exxua™ (Gepirone) and Zurzuvae™ (Zuranolone) – See Appendix M**
    A. Current Prior Authorization Criteria
    B. Utilization of Antidepressants
    C. Prior Authorization of Antidepressants
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of Antidepressants

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

16. **Annual Review of Lysosomal Storage Disease Medications and 30-Day Notice to Prior Authorize Elfabrio® (Pegunigalsidase Alfa-iwxj), Opfolda™ (Miglustat), and Pombiliti™ (Cipaglucosidase Alfa-atga) – See Appendix N**
    A. Current Prior Authorization Criteria
    B. Utilization of Lysosomal Storage Disease Medications
    C. Prior Authorization of Lysosomal Storage Disease Medications
    D. Market News and Updates
    E. Product Summaries
    F. College of Pharmacy Recommendations
    G. Utilization Details of Lysosomal Storage Disease Medications

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

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

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

18. **Future Business* (Upcoming Product and Class Reviews)**
    No live DUR Board meeting scheduled for January 2024. January 2024 will be a packet-only meeting.
    A. Antihyperlipidemics
    B. Bladder Control Medications
    C. Glaucoma Medications
    D. Non-Malignant Solid Tumor Medications
    *Future product and class reviews subject to change.

19. **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 8, 2023

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
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
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): Derek Johnson, Neenu Joshua	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:	
Wendy Segal, MedSphere	Donna Polichemi, Takeda
Lori Howarth, Bayer	Irene Chung, Aetna
Shellie Keast, Mercer	Dana Pipkin, Sarepta
Brent Parker, Merck	Gary Parenteau, Dexcom
Rhonda Clark, Indivior	Chad Sanders, Ipsen
Scott Stepien, Ipsen	Kristen Winters, Oklahoma Complete Health
Chrystal Mayes, Sanofi	Melissa Abbott, Eisai
Justin Springfield, Gilead	Nima Nabavi, Amgen
Todd Ness, AbbVie	Fred McClellan, Ascendis
Bryan Steffan, Boehringer	Ed Clasby, Medtronic
David Prather, Novo Nordisk	

PRESENT FOR PUBLIC COMMENT:	
N/A	

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**

ACTION: NONE REQUIRED

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

3A: October 11, 2023 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore

Dr. Patatanian moved to approve; seconded by Mr. Foster

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/USE OF STATINS IN MEMBERS WITH DIABETES MELLITUS (DM)**

4A: PHARMACY HELPDESK ACTIVITY FOR OCTOBER 2023

4B: MEDICATION COVERAGE ACTIVITY FOR OCTOBER 2023

4C: USE OF STATINS IN MEMBERS WITH DM

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

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **APPROVAL OF 2024 DUR BOARD MEETING DATES**

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

Mr. Foster moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE ELEVIDYS (DELANDISTROGENE MOXEPARVOVEC-ROKL) AND UPDATE THE APPROVAL CRITERIA FOR THE MUSCULAR DYSTROPHY MEDICATIONS**

6A: MARKET NEWS AND UPDATES

6B: ELEVIDYS (DELANDISTROGENE MOXEPARVOVEC-ROKL) PRODUCT SUMMARY

6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss
Dr. Walton moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE JESDUVROQ™ (DAPRODUSTAT) AND UPDATE THE APPROVAL CRITERIA FOR THE ANEMIA MEDICATIONS**

7A: MARKET NEWS AND UPDATES

7B: JESDUVROQ™ (DAPRODUSTAT) PRODUCT SUMMARY

7C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **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**

8A: MARKET NEWS AND UPDATES

8B: PRODUCT SUMMARIES

8C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE VEOPOZ™ (POZELIMAB-BBFG)**

9A: MARKET NEWS AND UPDATES

9B: VEOPOZ™ (POZELIMAB-BBFG) PRODUCT SUMMARY

9C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **VOTE TO PRIOR AUTHORIZE OJJAARA (MOMELOTINIB)**

10A: MARKET NEWS AND UPDATES

10B: OJJAARA (MOMELOTINIB) PRODUCT SUMMARY

10C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 11: **ANNUAL REVIEW OF ATOPIC DERMATITIS (AD) MEDICATIONS**

11A: CURRENT PRIOR AUTHORIZATION CRITERIA

11B: UTILIZATION OF AD MEDICATIONS
11C: PRIOR AUTHORIZATION OF AD MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF AD MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Dr. Walton
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF INJECTABLE AND VAGINAL PROGESTERONE PRODUCTS
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF INJECTABLE AND VAGINAL PROGESTERONE PRODUCTS
12C: PRIOR AUTHORIZATION OF INJECTABLE AND VAGINAL PROGESTERONE PRODUCTS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF INJECTABLE AND VAGINAL PROGESTERONE PRODUCTS
Materials included in agenda packet; presented by Dr. Moss
Dr. Walton moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF MULTIPLE MYELOMA MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ELREXFIO™ (ELRANATAMAB-BCMM) AND TALVEY™ (TALQUESTAMAB-TGVS)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF MULTIPLE MYELOMA MEDICATIONS
13C: PRIOR AUTHORIZATION OF MULTIPLE MYELOMA MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: PRODUCT SUMMARIES
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: UTILIZATION DETAILS OF MULTIPLE MYELOMA MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

<u>AGENDA ITEM NO. 14:</u> ANNUAL REVIEW OF ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE SYMBICORT AEROSPHERE® (BUDESONIDE/FORMOTEROL FUMARATE)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
14C: PRIOR AUTHORIZATION OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS
14F: UTILIZATION DETAILS OF ASTHMA AND COPD MAINTENANCE MEDICATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

<u>AGENDA ITEM NO. 15:</u> 30-DAY NOTICE TO PRIOR AUTHORIZE SOHONOS™ (PALOVAROTENE)
15A: INTRODUCTION

15B: SOHONOS™ (PALOVAROTENE) PRODUCT SUMMARY
15C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 16: ANNUAL REVIEW OF VASOMOTOR SYMPTOM (VMS) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE VEOZAH™ (FEZOLINETANT)
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF VMS MEDICATIONS
16C: PRIOR AUTHORIZATION OF VMS MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: VEOZAH™ (FEZOLINETANT) PRODUCT SUMMARY
16F: COLLEGE OF PHARMACY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF VMS MEDICATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 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)
17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF DED MEDICATIONS
17C: PRIOR AUTHORIZATION OF DED MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: PRODUCT SUMMARIES
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF DED MEDICATIONS
Materials included in agenda packet; presented by Dr. Morgan
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN DECEMBER

AGENDA ITEM NO. 18: ANNUAL REVIEW OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)
18C: PRIOR AUTHORIZATION OF SKYSONA® (ELIVALDOGENE AUTOTEMCEL)
18D: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Morgan
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
20A: ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
20B: ANTIDEPRESSANTS
20C: LYSOSOMAL STORAGE DISEASE MEDICATIONS
20D: SKIN CANCER MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams

ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: ADJOURNMENT

The meeting was adjourned at 5:29 pm.

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

Memorandum

Date: November 9, 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 November 8, 2023

Recommendation 1: Use of Statins in Members with Diabetes Mellitus

NO ACTION REQUIRED.

Recommendation 2: 2024 DUR Board Meeting Dates

MOTION CARRIED by unanimous approval.

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

Recommendation 3: Vote to Prior Authorize Elevidys (Delandistrogene Moxeparvovec-rokl) and Update the Approval Criteria for the Muscular Dystrophy Medications

MOTION CARRIED by unanimous approval.

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.

Recommendation 4: Vote to Prior Authorize Jesduvroq™ (Daprodustat) and Update the Approval Criteria for Anemia Medications

MOTION CARRIED by unanimous approval.

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.

Recommendation 5: 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

MOTION CARRIED by unanimous approval.

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™)±**
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®)**

Targeted Immunomodulator Agents*			
Tier-1 (DMARDs appropriate to disease state)	**Tier-2***	**Tier-3**	**Special Prior Authorization (PA)**
		~~**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®)#**~~	
		~~**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.
ß 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).
¶Unique criteria applies for a diagnosis of giant cell arteritis (GCA), chimeric antigen receptor (CAR) T-cell-induced cytokine release syndrome (CRS)**, and systemic sclerosis-associated interstitial lung disease (SSc-ILD)**.
¤Unique criteria applies for acute graft versus host disease (aGVHD) prophylaxis in hematopoietic stem cell transplant (HSCT) recipients.
#Unique criteria applies for a diagnosis of atopic dermatitis (AD).
€Unique criteria applies for a diagnosis of alopecia areata.
§Unique criteria applies for a diagnosis of polymyalgia rheumatica (PMR).
**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.~~

Recommendation 6: Vote to Prior Authorize Veopoz™ (Pozelimab-bbfg)

MOTION CARRIED by unanimous approval.

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.

Recommendation 7: Vote to Prior Authorize Ojjaara (Momelotinib)

MOTION CARRIED by unanimous approval.

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.

Recommendation 8: Annual Review of Atopic Dermatitis (AD) Medications

MOTION CARRIED by unanimous approval.

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.

Recommendation 9: Annual Review of Injectable and Vaginal Progesterone Products

MOTION CARRIED by unanimous approval.

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 American College of Obstetricians and Gynecologists (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.

Recommendation 10: Annual Review of Multiple Myeloma Medications and 30-Day Notice to Prior Authorize Elrexfio™ (Elranatamab-bcmm) and Talvey™ (Talquetamab-tgvs)

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

Recommendation 11: Annual Review of Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications and 30-Day Notice to Prior Authorize Symbicort Aerosphere® (Budesonide/Formoterol Fumarate)

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

Recommendation 12: 30-Day Notice to Prior Authorize Sohonos™ (Palovarotene)

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

Recommendation 13: Annual Review of Vasomotor Symptom (VMS) Medications and 30-Day Notice to Prior Authorize Veozah™ (Fezolinetant)

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

Recommendation 14: Annual Review of Dry Eye Disease (DED) Medications and 30-Day Notice to Prior Authorize Miebo™ (perfluorohexyloctane) and Vevye® (Cyclosporine Ophthalmic Solution)

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

Recommendation 15: Annual Review of Skysona® (Elivaldogene Autotemcel)

NO ACTION REQUIRED.

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

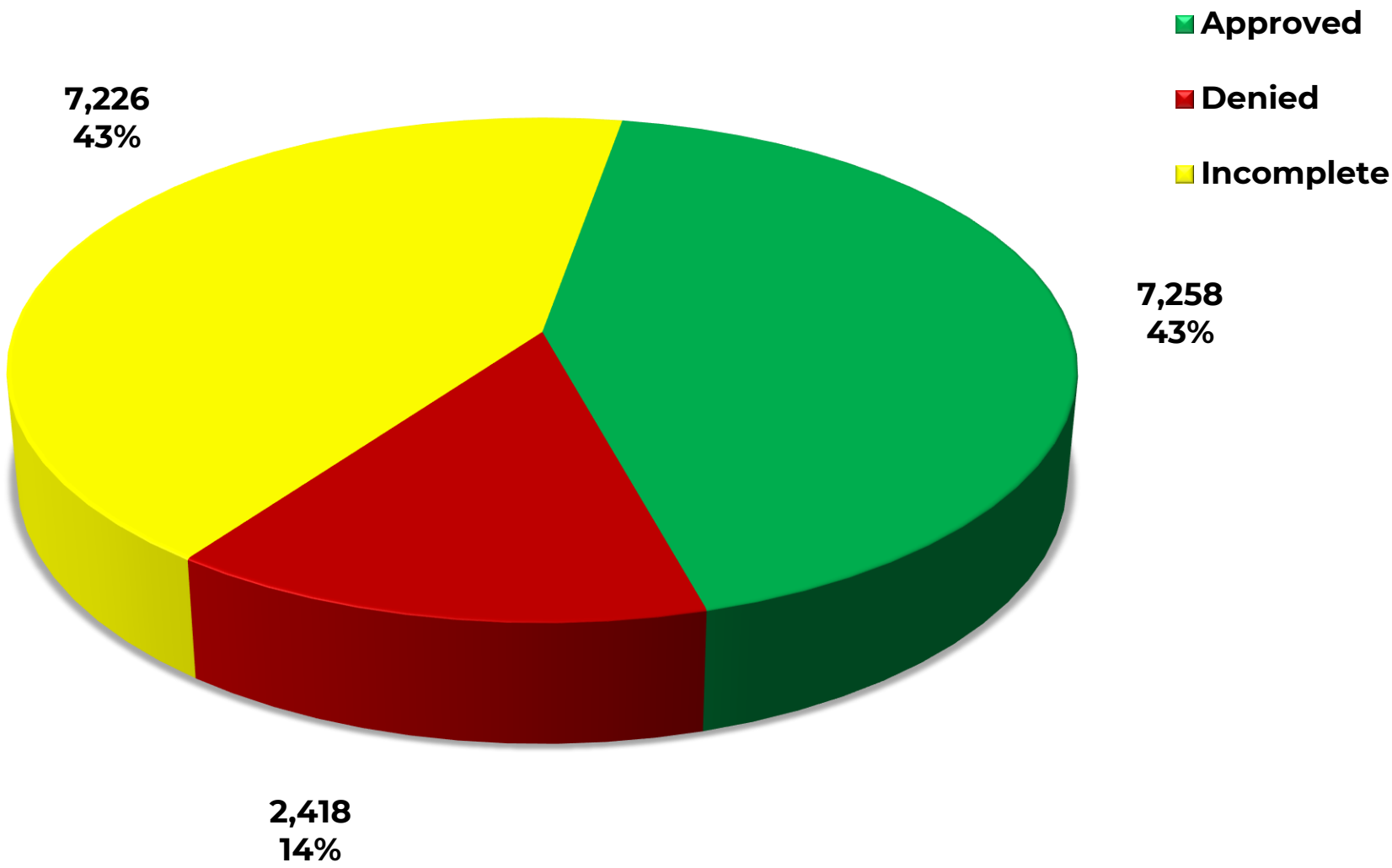
NO ACTION REQUIRED.

Recommendation 17: Future Business

NO ACTION REQUIRED.

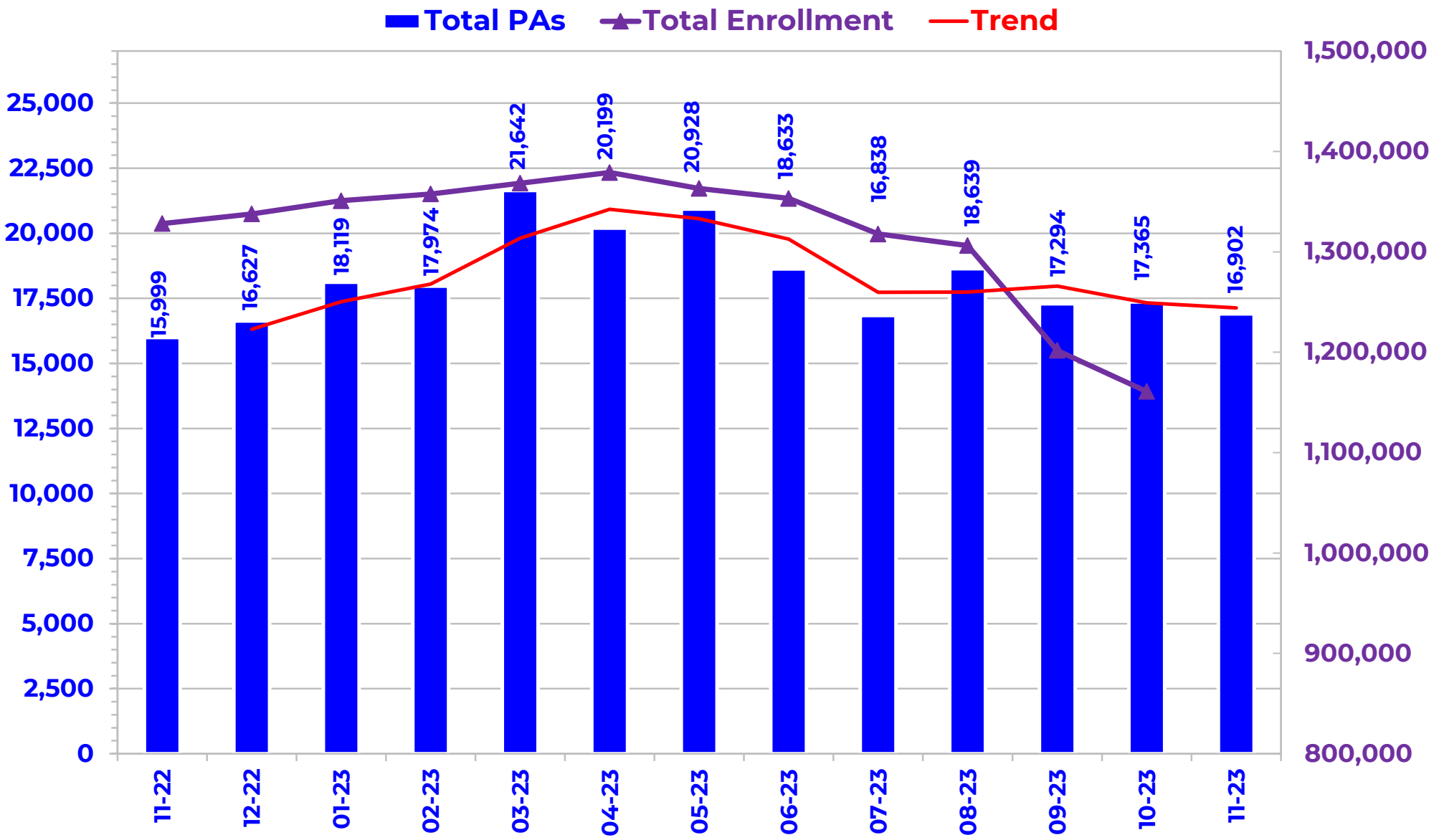
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: NOVEMBER 2023



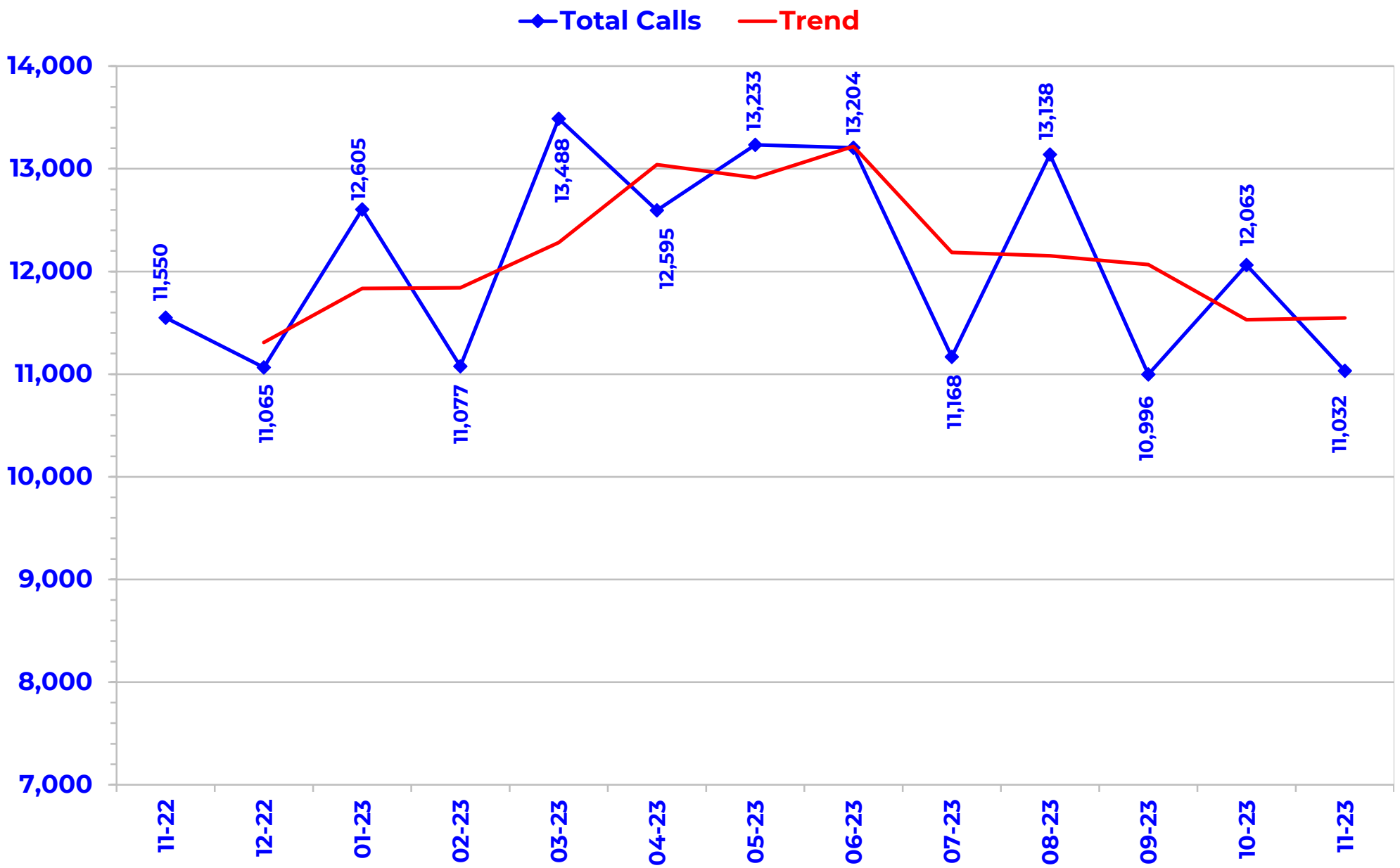
PA totals include approved/denied/incomplete/overrides

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: NOVEMBER 2022 – NOVEMBER 2023



Prior Authorization Activity

11/1/2023 Through 11/30/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	203	74	14	115	356
Analgesic - NonNarcotic	11	1	1	9	177
Analgesic, Narcotic	461	219	40	202	112
Antiasthma	97	27	22	48	248
Antibiotic	64	21	17	26	229
Anticonvulsant	281	130	7	144	303
Antidepressant	407	118	66	223	280
Antidiabetic	2,134	607	547	980	358
Antigout	14	7	1	6	315
Antihemophilic Factor	17	10	0	7	274
Antihistamine	88	27	20	41	339
Antimigraine	765	144	252	369	272
Antineoplastic	282	190	21	71	181
Antiobesity	19	0	17	2	0
Antiparasitic	20	7	2	11	18
Antiulcers	63	14	8	41	127
Anxiolytic	45	3	4	38	334
Atypical Antipsychotics	694	259	73	362	351
Benign Prostatic Hypertrophy	13	2	6	5	347
Biologics	374	204	42	128	305
Bladder Control	111	13	33	65	339
Blood Thinners	38	1	4	33	361
Botox	59	40	6	13	352
Buprenorphine Medications	114	43	15	56	132
Calcium Channel Blockers	23	7	2	14	360
Cardiovascular	156	68	6	82	345
Chronic Obstructive Pulmonary Disease	327	58	76	193	348
Constipation/Diarrhea Medications	347	76	101	170	189
Contraceptive	47	15	4	28	360
Corticosteroid	19	8	3	8	172
Dermatological	658	238	181	239	226
Diabetic Supplies	576	210	55	311	175
Diuretic	14	8	1	5	315
Endocrine & Metabolic Drugs	113	34	26	53	283
Erythropoietin Stimulating Agents	28	18	4	6	103
Estrogen Derivative	18	4	2	12	359
Fibric Acid Derivatives	10	2	1	7	360
Fish Oils	37	6	9	22	360
Gastrointestinal Agents	168	49	30	89	230
Genitourinary Agents	14	4	0	10	234

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Glaucoma	17	5	2	10	238
Growth Hormones	147	113	7	27	119
Hematopoietic Agents	23	10	3	10	282
Hepatitis C	33	19	1	13	13
HFA Rescue Inhalers	29	4	1	24	139
Insomnia	118	7	19	92	151
Insulin	280	91	29	160	348
Miscellaneous Antibiotics	32	6	3	23	50
Multiple Sclerosis	96	51	9	36	233
Muscle Relaxant	57	10	11	36	220
Nasal Allergy	36	4	7	25	223
Neurological Agents	307	113	56	138	185
Neuromuscular Agents	14	5	1	8	264
NSAIDs	43	4	8	31	361
Ocular Allergy	12	4	3	5	156
Ophthalmic	25	5	4	16	172
Ophthalmic Anti-infectives	28	2	6	20	16
Ophthalmic Corticosteroid	25	5	3	17	225
Osteoporosis	26	5	4	17	318
Other*	420	142	61	217	254
Otic Antibiotic	28	2	2	24	25
Pediculicide	19	8	1	10	17
Respiratory Agents	53	36	1	16	326
Statins	70	13	22	35	212
Stimulant	3,235	1,749	148	1,338	308
Synagis	90	41	35	14	24
Testosterone	213	51	62	100	334
Thyroid	30	10	1	19	353
Topical Antifungal	50	5	14	31	189
Topical Corticosteroids	49	3	16	30	249
Vitamin	127	23	72	32	213
Pharmacotherapy	62	58	1	3	249
Emergency PAs	0	0	0	0	
Total	**14,723**	**5,570**	**2,332**	**6,821**	

* 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	37	18	5	14	289
Compound	8	7	0	1	66
Dosage Change	380	363	1	16	18
High Dose	4	3	1	0	248
Ingredient Duplication	9	7	0	2	15
Lost/Broken Rx	85	79	2	4	21
MAT Override	279	236	5	38	83
NDC vs Age	318	244	23	51	277
NDC vs Sex	13	11	0	2	101
Nursing Home Issue	49	47	0	2	14
Opioid MME Limit	117	37	5	75	136
Opioid Quantity	32	23	1	8	169
Other	64	52	7	5	19
Prescriber Temp Unlock	1	1	0	0	25
Quantity vs Days Supply	635	462	30	143	237
STBS/STBSM	8	5	2	1	26
Step Therapy Exception	26	17	2	7	346
Stolen	9	9	0	0	45
Temporary Unlock	2	2	0	0	6
Third Brand Request	103	65	2	36	25
Overrides Total	**2,179**	**1,688**	**86**	**405**	
Total Regular PAs + Overrides	**16,902**	**7,258**	**2,418**	**7,226**	

Denial Reasons	
Unable to verify required trials.	6,033
Does not meet established criteria.	2,447
Lack required information to process request.	1,163
Other PA Activity	
Duplicate Requests	1,798
Letters	42,821
No Process	4
Changes to existing PAs	1,369
Helpdesk Initiated Prior Authorizations	1,052
PAs Missing Information	723

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

Academic Detailing Program Update

Oklahoma Health Care Authority
December 2023

Background[1,2]

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

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

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

- Clinical treatment guidelines
- Provider resources
- Patient and parent resources
- Diagnostic and treatment tools
- Topic-specific continuing medical education (CME) course listings
- Drug alerts and statements from the U.S. Food and Drug Administration (FDA)
- National quality measures [e.g., Healthcare Effectiveness Data and Information Set (HEDIS)]

- OHCA Product Based Prior Authorization (PBPA) coverage criteria

To date, AD services have been provided to nearly 1,100 health care providers and/or their administrative staff. As previously reported, changes in prescribing patterns and associated improvements in health care utilization have led to cost savings to OHCA in the amount of $3,041,690 through December 2022. This amount is inclusive of all federal and supplemental rebates for the analysis periods following AD on the treatment of the following for pediatric SoonerCare members:

- Attention-deficit/hyperactivity disorder (ADHD)
- Use of second generation/atypical antipsychotic medications (SGAs)
- Upper respiratory infections (URIs)
- Persistent asthma
- Diabetes

Current Topic: Usage of Prenatal Vitamins (PNVs)[3,4,5,6,7,8]

The College of Pharmacy and OHCA have engaged in multiple efforts to increase PNV utilization among pregnant SoonerCare members. PNVs have a $0 copay and do not count toward the monthly prescription limit. Prescribers also have the option to select from dozens of PNVs that are covered without prior authorization (PA). In June 2020, prescribers and pharmacies received an educational outreach letter addressing a concerning decrease in PNV utilization in pregnant SoonerCare members. The educational outreach highlighted SoonerCare's preferred PNVs and included specific NDCs to encourage increased prescribing of PNVs. The College of Pharmacy also incorporates prenatal education into its workflow to increase PNV utilization. When a PA for any non-PNV medication is received for a member in the Soon-To-Be-Sooners (STBS) program, the member's claims history is reviewed for PNV paid claims. If the member does not have a paid claim for a PNV, a reminder is included in the PA response to the prescriber and the pharmacy. A similar reminder is included when PA responses are generated for pregnancy-related medications such as those for pregnancy-related nausea and vomiting.

PNV usage rates have been historically difficult to improve for SoonerCare members, and adherence remains low. During calendar year (CY) 2021, only 26% of members with an outcome of delivery had at least 1 claim for a PNV. This usage pattern persisted despite ongoing strong evidence in favor of prescribing PNVs to all women who are pregnant or planning to become pregnant. PNVs contain micronutrients necessary for fetal development and optimal maternal nutrition. PNVs play an especially important role during the first trimester in reducing the risk of neural tube defects (NTDs) associated with deficits in folic acid. Additionally, multiple studies have emphasized the importance of iron supplementation in reducing the occurrence of iron

deficiency anemia which can lead to preterm births and low birth weights. Other micronutrients found in PNVs have been shown to reduce the risks of maternal hypertension, including pre-eclampsia.

With this in mind, the AD program addressed PNV usage as the most recent provider topic. Providers were identified somewhat differently as compared to previous AD topics. For previous topics, providers meeting 3 or more of the following criteria were offered a detailing visit:

1. Having ≥50% increase in the number of disease-state medical claims across 2 consecutive years
2. Having ≥50% increase in the number of disease-state pharmacy claims across 2 consecutive years
3. Having hospital claims for any member with a diagnosis of the disease state
4. Having >100 members in their practice with claims for any disease state medication (excluding specialty providers)
5. Having ≥50% more disease state medical claims than their same specialty peers (e.g., general practitioner, physician assistant)
6. Having ≥50% more claims for any disease state medication than their same specialty peers (e.g., general practitioner, physician assistant)

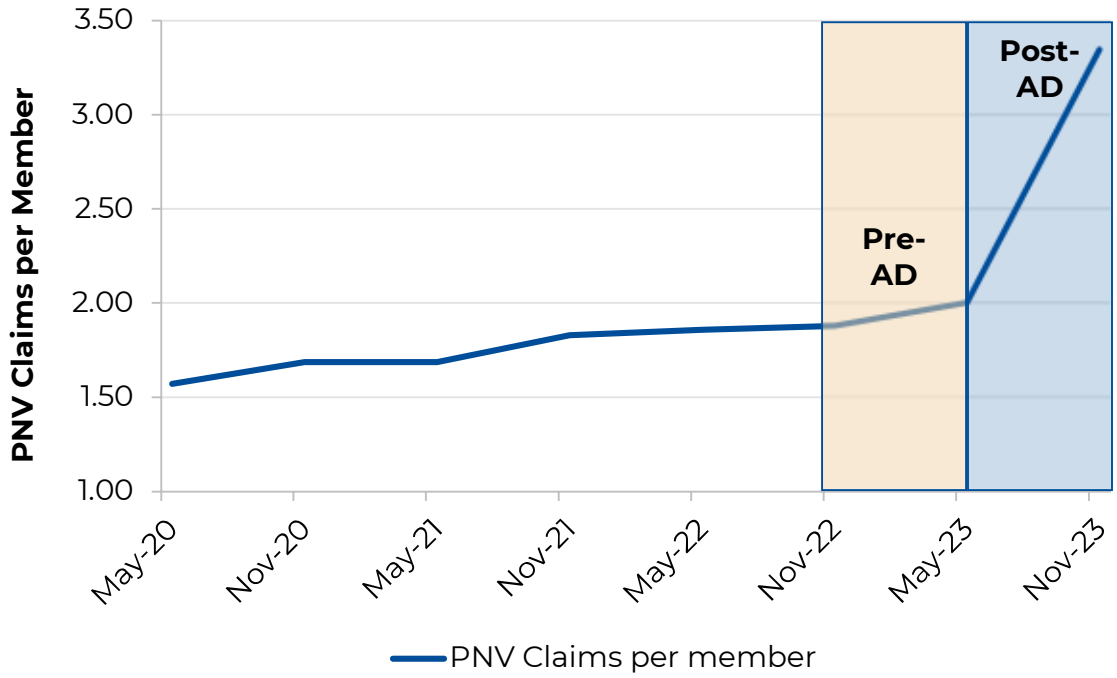
Compared to chronic diseases such as asthma and acute, but also predictable, illnesses such as URIs, pregnancy care provider identification proved to be much more difficult. There were no guarantees that detailed providers would treat pregnant members in the months following their AD education. Providers frequently establish a pregnancy diagnosis then are only partially involved or entirely uninvolved in pregnancy-related care for a specific member during the pregnancy. AD is historically offered to non-specialists, however pregnancy-related care is frequently delivered by specialists. In Oklahoma, 53.2% of all counties are defined as maternity care deserts, meaning they are without birthing facilities or maternity care providers. Ultimately, 43 providers meeting 3 or more of the following criteria during the 6-month pre-AD period were offered and received a PNV-AD visit:

1. Having ≥1 paid claim per pregnant member for PNVs
2. Having ≥1 member with a pregnancy diagnosis and ≤18 years of age
3. Having a practice setting within a county having ≥35.5 teen births per 1,000 females
4. Having ≥1 member with a pregnancy diagnosis and residing in a county having ≥35.5 teen births per 1,000 females
5. Having a practice setting within a county designated as a maternity care desert
6. Having ≥1 member with a pregnancy diagnosis and residing in a county designated as a maternity care desert

Results: Usage of PNVs[9,10]

Prescribing patterns were compared for providers with members having paid claims for PNVs during both the pre- and post-AD periods. PNV claims were 30, 60, or 90 days in duration. At the end of the 6-month pre-AD period, 169 members received 12,570 total days of PNV treatment resulting in an average of 2 PNV claims and 74 days of PNV treatment per member. At the end of the 6-month post-AD period, 153 members received 15,945 total days of PNV treatment resulting in an average of 3.35 PNV claims and 104 days of PNV treatment per member. This represents a 67.5% improvement in the number of PNV claims, and a 40.5% improvement in of days of PNV treatment. Longer term PNV patterns were also assessed for detailed providers. Changes in PNV claims per member are represented in Figure 1.

Figure 1: Claims per Member



According to multiple clinical trials and meta-analyses, NTDs can be prevented with PNV usage with an estimated number needed to treat of 847. Lifetime costs associated with a single child having spina bifida, 1 of the most common NTDs, is estimated at $726,934. During the post-AD period, 153 members had paid claims for PNVs, resulting in an estimated cost savings of $131,311 over 6 months or $262,623 per year.

During the pre-AD period, the highest number of PNV claims per member for any individual provider was 4 PNV claims per member. During the post-AD period, 2 providers managed to achieve an average of 7 PNV claims per member, and 3 providers achieved 5 PNV claims per member. Most

significantly, more than 77% of all detailed providers achieved at least 3 PNV claims per member. The number of PNV providers achieving 1 to 9 claims per member is represented in Figure 2.

Figure 2: Number of Providers by Number of Average Claims per Member		
Average # PNV Paid Claims per Member	**# of Providers (Pre-AD)**	**# of Providers (Post-AD)**
1	21	0
2	10	13
3	8	22
4	4	3
5	0	3
6	0	0
7	0	2
8	0	0
9	0	0

It is important to note that PNV utilization may be somewhat falsely low due to the large number of over-the-counter (OTC) products available. Data for the use of OTC products in SoonerCare members is not obtainable and is not included in this analysis. However, the impact of OTC PNVs is expected to be minimal due to the high out-of-pocket cost of these agents compared to the $0 copay cost of prescription agents. Some members may have also received prenatal care through pregnancy resource centers and/or their local health departments. Depending on PNV availability and member access, PNVs may have been obtained through these additional channels. However, the impact is still expected to be low as these channels regularly encourage their clients to access SoonerCare benefits whenever possible.

Provider Satisfaction

Provider satisfaction continues to remain very high as measured by post-visit satisfaction surveys. Providers meeting comparison criteria and those in co-practice were given satisfaction surveys in order to determine their acceptance of the program and to predict the likelihood of participation in future AD topics. Participants in the detailing sessions were given an online survey with an anonymous link and survey results are shown in Figure 3. To date, only 12 providers have been excluded from the PMC-AD program due to an unwillingness to participate. Other reasons for exclusion of targeted providers included the following:

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

Figure 3: AD Provider Satisfaction	
The information provided was:	**% choosing agree or strongly agree**
Easily understood	96%
Clearly presented	98%
Evidence-based	97%
Based on the information, I intend to:	**% choosing agree or strongly agree**
Make practice changes as a result	84%
Recommend this program to colleagues	88%
Participate in future topics	90%

AD = academic detailing

Academic Meeting Presentation(s)

Since July 2016, the PMC-AD program leaders have been invited to present program outcomes and breakout sessions at the International Conference on Academic Detailing, the Academy of Managed Care Pharmacy (AMCP), and the American Drug Utilization Review Society (ADURS). Additionally, a poster presentation featuring ADHD-AD results was awarded a silver ribbon at the Nexus 2017 meeting of AMCP. The primary PMC-AD pharmacist is also currently 1 of 9 national training facilitators for NaRCAD.

Summary

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

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

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Appendix C

SoonerCare Maintenance Drug List

Oklahoma Health Care Authority
December 2023

Introduction[1]

Most adult SoonerCare members have a 6 prescription limit each month; therefore, prescribing for and dispensing 90-day supplies of chronic maintenance medications will help members who are on multiple medications obtain the maintenance medications necessary. Dispensing 90-day supplies of chronic maintenance medications has been shown to increase medication adherence and persistence, compared to dispensing 30-day supplies. Additionally, 90-day supplies will reduce the SoonerCare member's financial burden as they will pay the same copay for a 90-day or 30-day supply.

In November 2019, the Oklahoma Health Care Authority (OHCA) Board voted to update the current policy and rules regarding dispensing limitations. Previously, medications could only be dispensed and reimbursed by SoonerCare up to a 34-day supply or if the quantity did not exceed 100 units. The updated OHCA policy and rules state the following regarding dispensing limitations and a maintenance drug list (317:30-5-77.1):

> "Prescription quantities shall be limited to a 34-day supply, except in the following situations:
> 1. The Drug Utilization Review (DUR) Board has recommended a different day supply or quantity limit based on published medical data, including the manufacturer's package insert; or
> 2. The product is included on the Maintenance List of medications which are exempted from this limit and may be dispensed up to a 90-day supply; or
> 3. The manufacturer of the drug recommends a dispensing quantity less than a 34-day supply….".
>
> "The DUR Board shall develop a Maintenance List of medications which are used in general practice on a continuing basis. These drugs shall be made available through the Vendor Drug Program in quantities up to a 90-day supply when approved by the prescriber. The DUR Board shall review the Maintenance List at least annually."

The DUR Board recommended and voted on categories of medications for inclusion on the maintenance drug list in December 2019, and the SoonerCare Maintenance Drug List was implemented in January 2020. The

purpose of this report is to provide the DUR Board with the current maintenance drug list for review, which is to be maintained by the DUR Board. Medications included in the maintenance drug list allow a 90-day supply of medications in the claims processing system without the need for an override. Action by the DUR Board is not required unless changes are recommended to the current maintenance drug list.

SoonerCare Maintenance Drug List

The current SoonerCare Maintenance Drug List is available on the OHCA website (https://oklahoma.gov/ohca/rx) and includes the following categories of medications:

- Alzheimer's Medications
- Anticonvulsants
- Antidepressants/Anxiolytics
- Antihypertensive Medications
- Antipsychotic Medications
- Anti-Ulcer Medications
- Bladder Control Medications
- Benign Prostatic Hyperplasia (BPH) Medications
- Cardiovascular Medications
- Chronic Obstructive Pulmonary Disease (COPD) Medications
- Diabetes Medications
- Glaucoma Medications
- Hyperlipidemia Medications
- Parkinson's Medications
- Thyroid Medications

Please note that not all medications in each category can be processed for a 90-day supply.

Recommendations

The College of Pharmacy recommends the addition of non-controlled attention-deficit/hyperactivity disorder (ADHD) medications to the maintenance drug list.

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Appendix D

Vote to Prior Authorize Symbicort Aerosphere® (Budesonide/Formoterol) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications

Oklahoma Health Care Authority
December 2023

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

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 approved by the FDA 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.

News:

- **April 2023:** Lonhala® Magnair® (glycopyrrolate inhalation solutions) has been discontinued by the manufacturer.
- **August 2023:** A generic equivalent formulation of Spiriva® HandiHaler® (tiotropium bromide) has been launched in the United States for the treatment of COPD.

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 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. 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 6 months after which time compliance will be evaluated for continued approval.

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

1. An FDA approved diagnosis of CIU; and

2. Member must be 12 years of age or older; and
3. Other forms of urticaria must be ruled out; and
4. Other potential causes of urticaria must be ruled out; and
5. Member must have an Urticaria Activity Score (UAS) ≥16; and
6. For authorization of Xolair® vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
7. For authorization of Xolair® prefilled autoinjector or prefilled syringe, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
8. Prescriber must be an allergist, immunologist, or dermatologist (or an advanced care practitioner with a supervising physician that is an allergist, immunologist, or dermatologist); and
9. A trial of a second generation antihistamine dosed at 4 times the maximum FDA dose within the last 3 months for at least 4 weeks (or less if symptoms are intolerable); and
10. Initial dosing will only be approved for 150mg every 4 weeks. If the member has inadequate results at this dose, then the dose may be increased to 300mg every 4 weeks; and
11. Initial approvals will be for the duration of 3 months at which time compliance will be evaluated for continued approval.

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

1. An FDA approved indication for add-on maintenance treatment of nasal polyps in adult members with inadequate response to nasal corticosteroids; and
2. Member must be 18 years of age or older; and
3. Member must have a trial of intranasal corticosteroids for at minimum the past 4 weeks; and
4. Prescriber must verify member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
5. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/ congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management; and
6. Member has evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy; and

7. Member must have a pretreatment serum IgE level between 30 and 1,500 IU/mL; and
8. Member's weight must be between 31kg and 150kg; and
9. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
10. For authorization of Xolair® vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
11. For authorization of Xolair® prefilled autoinjector or prefilled syringe, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
12. Xolair® must be prescribed by an otolaryngologist, allergist, immunologist, or pulmonologist or the member must have been evaluated by an otolaryngologist, allergist, immunologist, or pulmonologist within the last 12 months (or an advanced care practitioner with a supervising physician who is an otolaryngologist, allergist, immunologist, or pulmonologist); and
13. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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

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

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[1] Novartis Pharmaceuticals. Novartis Receives FDA Approval of Xolair® (Omalizumab) Self-injection with Prefilled Syringe Across All Indications for Appropriate Patients. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/novartis-receives-fda-approval-of-xolair-omalizumab-self-injection-with-prefilled-syringe-across-all-indications-for-appropriate-patients-301266937.html. Issued 04/12/2021. Last accessed 11/21/2023.
[2] Amgen. Tezspire® Approved for Self-administration in the U.S. with a New Pre-filled Pen. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/tezspire-approved-for-self-administration-in-the-us-with-a-new-pre-filled-pen-301736900.html. Issued 02/02/2023. Last accessed 11/21/2023.
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[7] U.S. Food and Drug Administration (FDA). FDA Drug Shortages: Discontinuations. Available online at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm#tabs-2. Last revised 10/2023. Last accessed 11/21/2023.
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Appendix E

Vote to Prior Authorize Sohonos™ (Palovarotene)

Oklahoma Health Care Authority
December 2023

Market News and Updates[1]

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

- **August 2023:** The 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 fibrodysplasia ossificans progressiva (FOP). Sohonos™ is the first and only FDA approved medication for FOP.

Sohonos™ (Palovarotene) Product Summary[2]

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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[1] Ipsen. U.S. FDA Approves Ipsen's Sohonos™ (Palovarotene) Capsules, the First and Only Treatment for People with Fibrodysplasia Ossificans Progressiva. Available online at: https://www.ipsen.com/press-releases/us-fda-approves-ipsens-sohonostm-palovarotene-capsules-the-first-and-only-treatment-for-people-with-fibrodysplasia-ossificans-progressiva/. Issued 08/16/2023. Last accessed 11/28/2023.
[2] Sohonos™ (Palovarotene) Prescribing Information. Ipsen Biopharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215559s000lbl.pdf. Last revised 08/2023. Last accessed 11/28/2023.

Appendix F

Vote to Prior Authorize Miebo™ (Perfluorohexyloctane Ophthalmic Solution) and Vevye® (Cyclosporine Ophthalmic Solution)

Oklahoma Health Care Authority
December 2023

Market News and Updates[1,2]

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 dry eye disease (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.

Miebo™ (Perfluorohexyloctane Ophthalmic Solution) Product Summary[3]

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) Product Summary[4]

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, and Xiidra® (lifitegrast ophthalmic solution) 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, and Xiidra® (lifitegrast ophthalmic solution) must be provided; and

6. A quantity limit of 5mL per 25 days will apply.

[1] Antrim A. FDA Approves Perfluorohexyloctane Ophthalmic Solution for Dry Eye Disease. *Pharmacy Times*. Available online at: https://www.pharmacytimes.com/view/fda-approves-perfluorohexyloctane-ophthalmic-solution-for-dry-eye-disease. Issued 05/19/2023. Last accessed 11/29/2023.
[2] Novaliq. Novaliq Announces FDA Approval of Vevye® (Cyclosporine Ophthalmic Solution) 0.1% for the Treatment of the Signs and Symptoms of Dry Eye Disease. Available Online at: https://www.novaliq.com/press-releases/2023/06/08/novaliq-announces-fda-approval-of-vevye-cyclosporine-ophthalmic-solution-0-1-for-the-treatment-of-the-signs-and-symptoms-of-dry-eye-disease/. Issued 06/08/2023. Last accessed 11/29/2023.
[3] Miebo™ (Perfluorohexyloctane Ophthalmic Solution) Prescribing Information. Bausch & Lomb. Available online at: https://www.bausch.com/globalassets/pdf/packageinserts/pharma/miebo-package-insert.pdf. Last revised 05/2023. Last accessed 11/29/2023.
[4] Vevye® (Cyclosporine 0.1% Ophthalmic Solution) Prescribing Information. Novaliq. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217469s000lbl.pdf. Last revised 05/2023. Last accessed 11/29/2023.

Appendix G

Vote to Prior Authorize Veozah™ (Fezolinetant) and Update the Approval Criteria for the Vasomotor Symptom (VMS) Medications

Oklahoma Health Care Authority
December 2023

Market News and Updates[1]

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.

Veozah™ (Fezolinetant) Product Summary[2]

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[3]

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.~~

[1] U.S. Food and Drug Administration (FDA). FDA Approves Novel Drug to Treat Moderate to Severe Hot Flashes Caused by Menopause. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-novel-drug-treat-moderate-severe-hot-flashes-caused-menopause. Issued 05/12/2023. Last accessed 11/09/2023.
[2] 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 11/09/2023.
[3] 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 H

Vote to Prior Authorize Elrexfio™ (Elranatamab-bcmm) and Talvey™ (Talquetamab-tgvs) and Update the Approval Criteria for the Multiple Myeloma Medications

Oklahoma Health Care Authority
December 2023

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

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[5]

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[6]

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.~~

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[1] U.S. Food and Drug Administration (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 11/28/2023.
[2] 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 11/28/2023.
[3] GSK. GSK Provides an Update on Blenrep (Belantamab Mafodotin-blmf) U.S. Marketing Authorization. Available online at: https://www.gsk.com/en-gb/media/press-releases/gsk-provides-update-on-blenrep-us-marketing-authorisation/. Issued 11/22/2022. Last accessed 11/28/2023.
[4] Oncopeptides AB. Oncopeptides Provides Update on Pepaxto® U.S. 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 11/28/2023.
[5] 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 11/28/2023.
[6] 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 11/28/2023.

Appendix I

Fiscal Year 2023 Annual Review of Anticoagulants and Platelet Aggregation Inhibitors

Oklahoma Health Care Authority
December 2023

Current Prior Authorization Criteria

Aggrenox® (Aspirin/Dipyridamole Extended-Release) Approval Criteria:

1. An FDA approved indication for the prophylaxis of recurrent thromboembolic stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use immediate-release dipyridamole and over-the-counter (OTC) aspirin in place of Aggrenox® must be provided; and
4. A quantity limit of 60 capsules for a 30-day supply will apply.

Brilinta® (Ticagrelor) Approval Criteria:

1. The first 365 days of therapy with Brilinta® 90mg twice daily does not require prior authorization.
2. After the first 365 days, a patient-specific, clinically significant reason for continuing the 90mg twice daily dosage will need to be provided or the member should be switched to the 60mg twice daily dosage.
3. Approvals will be for the duration of 1 year.

Pradaxa® (Dabigatran) Approval Criteria:

1. Pradaxa® (dabigatran) capsules require the following:
    a. An FDA approved indication of 1 of the following:
        i. Non-valvular atrial fibrillation; or
        ii. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) after treatment with a parenteral anticoagulant for 5 to 10 days; or
        iii. To reduce the risk of recurrent DVT or PE in members who have been previously treated; or
        iv. For the prophylaxis of DVT and PE in members who have undergone hip replacement surgery; or
        v. Treatment of venous thromboembolic events (VTE) in pediatric members 8 to 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days; or
        vi. To reduce the risk of recurrent VTE in pediatric members 8 to 18 years of age who have been previously treated.
2. Pradaxa® (dabigatran) oral pellets require the following:

a. An FDA approved indication of 1 of the following:
    i. Treatment of VTE in members who have been treated with a parenteral anticoagulant for at least 5 days; or
    ii. To reduce the risk of recurrent VTE in members who have been previously treated; and
b. Member must be 3 months of age or older; and
c. Members older than 10 years of age require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used.

Savaysa® (Edoxaban) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. To reduce the risk of stroke and systemic embolism (SE) in patients with non-valvular atrial fibrillation (NVAF); or
    b. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) following 5 to 10 days of initial therapy with a parenteral anticoagulant; and
2. Requests for therapy for the treatment of DVT and PE must verify that the member has undergone 5 to 10 days of initial therapy with a parenteral anticoagulant; and
3. Members with NVAF must not have a creatinine clearance (CrCl) >95mL/min due to increased risk of ischemic stroke compared to warfarin at the highest dose studied (60mg); and
4. A patient-specific, clinically significant reason why the member cannot use Eliquis® (apixaban), Pradaxa® (dabigatran), and Xarelto® (rivaroxaban) must be provided; and
5. A quantity limit of 30 tablets per 30 days will apply.

Zontivity® (Vorapaxar) Approval Criteria:

1. An FDA approved indication for the reduction of thrombotic cardiovascular events in members with 1 of the following:
    a. History of myocardial infarction (MI); or
    b. Peripheral arterial disease (PAD); and
2. Zontivity® must be used in combination with aspirin and/or clopidogrel (not monotherapy); and
3. Zontivity® will not be approved for members with history of transient ischemic attack (TIA), stroke, or intracranial hemorrhage (ICH) or with active pathological bleeding; and
4. A quantity limit of 30 tablets per 30 days will apply.

Utilization of Anticoagulants and Platelet Aggregation Inhibitors: Fiscal Year 2023

Comparison of Fiscal Years: Anticoagulants

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	4,626	19,731	$9,499,944.26	$481.47	$11.81	1,262,298	804,589
2023	6,424	27,156	$14,503,514.77	$534.08	$13.11	1,818,562	1,106,449
% Change	**38.9%**	**37.6%**	**52.7%**	**10.9%**	**11.0%**	**44.1%**	**37.5%**
Change	**1,798**	**7,425**	**$5,003,570.51**	**$52.61**	**$1.30**	**556,264**	**301,860**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: The prior authorization requirement for Eliquis® and Xarelto® was removed 05/2023.
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 anticoagulants totaled $14,298,924.15.[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: Platelet Aggregation Inhibitors

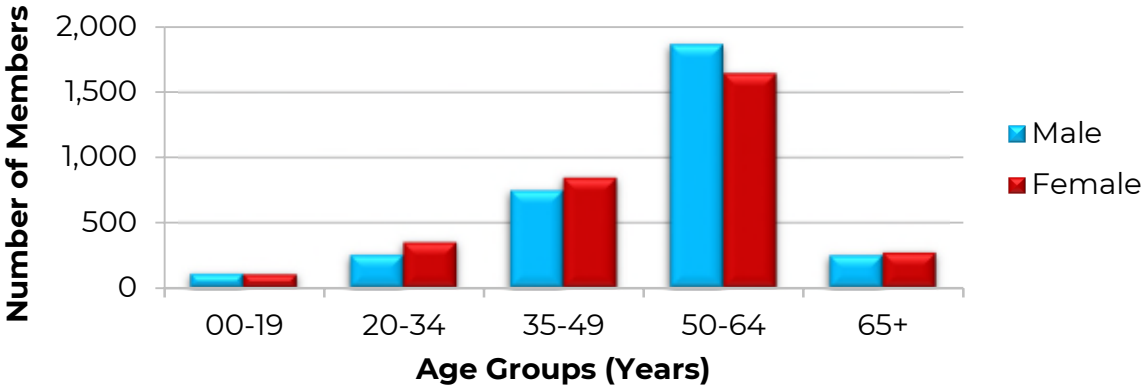
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	5,158	18,034	$1,305,134.83	$72.37	$1.40	1,013,869	934,763
2023	6,403	23,493	$1,906,875.41	$81.17	$1.56	1,341,192	1,225,331
% Change	**24.1%**	**30.3%**	**46.1%**	**12.2%**	**11.4%**	**32.3%**	**31.1%**
Change	**1,245**	**5,459**	**$601,740.58**	**$8.80**	**$0.16**	**327,323**	**290,568**

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

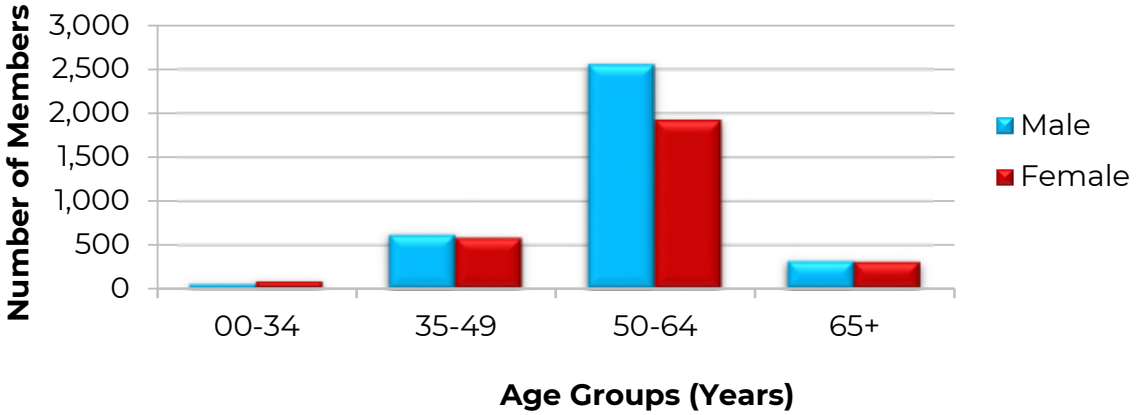
- Aggregate drug rebates collected during fiscal year 2023 for the platelet aggregation inhibitors totaled $1,369,918.59.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[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.

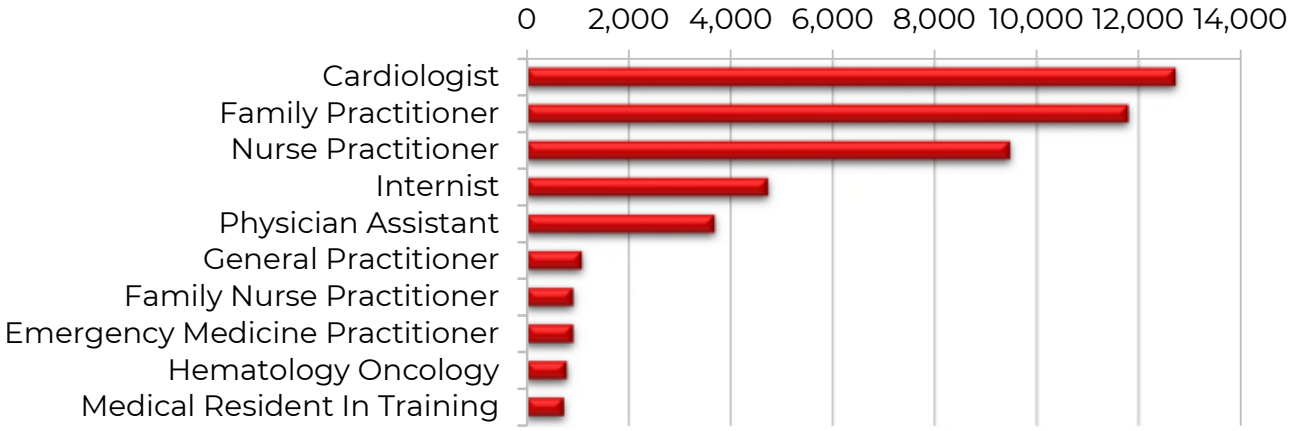
Demographics of Members Utilizing Anticoagulants



Demographics of Members Utilizing Platelet Aggregation Inhibitors



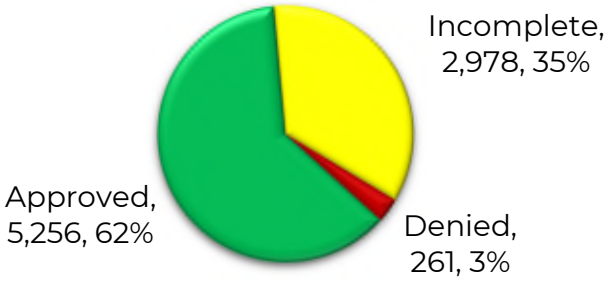
Top Prescriber Specialties of Anticoagulants and Platelet Aggregation Inhibitors by Number of Claims



Prior Authorization of Anticoagulants and Platelet Aggregation Inhibitors

There were 8,495 prior authorization requests submitted for anticoagulants and platelet aggregation inhibitors during fiscal year 2023. The prior authorization requirement was removed from Eliquis® (apixaban) and Xarelto® (rivaroxaban) in May 2023, which should result in a decrease in prior authorization requests in fiscal year 2024. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Xarelto® (rivaroxaban oral suspension): August 2024
- Pradaxa® (dabigatran pellets): March 2026
- Zontivity® (vorapaxar tablets): December 2027
- Savaysa® (edoxaban tablets): March 2028
- Eliquis® (apixaban tablets): February 2031
- Pradaxa® (dabigatran capsules): July 2031
- Brilinta® (ticagrelor tablets): January 2036
- Xarelto® (rivaroxaban tablets): July 2039

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

- **July 2023:** The FDA approved Balfaxar® (prothrombin complete concentrate, human-lans) for the urgent reversal of vitamin K antagonists (e.g., warfarin) in adults who require urgent surgery or invasive procedures. Balfaxar® is a non-activated 4 factor prothrombin complex concentrate (4F-PCC) containing vitamin K-dependent factors. It was compared head-to-head to Kcentra® (prothrombin complex concentrate, human) and found to be non-inferior.

News:

- **June 2023:** The Andexxa® [coagulation factor Xa (recombinant), inactivated-zhzo] Phase 4 post-marketing trial was stopped early due to achieving the pre-specified stopping criteria of superior hemostatic efficacy versus usual care. Andexxa® rapidly reverses the

anticoagulation effects of direct acting factor Xa (FXa) inhibitors, Eliquis® and Xarelto®, and was granted accelerated approval by the FDA in 2018. AstraZeneca will now proceed with regulatory filings to obtain full label approval.

Pipeline:

- **Abelacimab:** Abelacimab is a highly selective monoclonal antibody that keeps FXI in an inactive state leading to dual inhibition of both FXI and FXIa. Data was presented at the American Heart Association (AHA) meeting showing that abelacimab had a 67% reduction in the primary endpoint of major or clinically relevant non-major bleeding compared with rivaroxaban in patients with atrial fibrillation. Abelacimab is also being studied in cancer-associated thrombosis.
- **Milvexian:** Milvexian is an investigational oral FXIa inhibitor that is being studied in the Librexia program which includes 3 different trials looking at 3 different indications: stroke, acute coronary syndrome, and atrial fibrillation. All 3 indications were granted Fast Track designation from the FDA.
- **Tecarfarin:** Tecarfarin is a vitamin K antagonist that is being studied for the prevention of systemic thromboembolism of cardiac origin in patients with end-stage renal disease and atrial fibrillation. Tecarfarin was developed using a process that targets a different pathway than other anticoagulants, potentially allowing for a better safety profile and fewer drug-drug interactions. Tecarfarin was granted Orphan Drug designation and has now been granted Fast Track designation from the FDA.

Recommendations

The College of Pharmacy recommends the following changes to the anticoagulant medications based on net costs (changes shown in red):

Pradaxa® (Dabigatran) Approval Criteria:

1. Pradaxa (dabigatran) capsules require the following:
    a. An FDA approved indication of 1 of the following:
        i. Non-valvular atrial fibrillation; or
        ii. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) after treatment with a parenteral anticoagulant for 5 to 10 days; or
        iii. To reduce the risk of recurrent DVT or PE in members who have been previously treated; or
        iv. For the prophylaxis of DVT and PE in members who have undergone hip replacement surgery; or

v. Treatment of venous thromboembolic events (VTE) in pediatric members 8 to 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days; or
vi. To reduce the risk of recurrent VTE in pediatric members 8 to 18 years of age who have been previously treated; and

b. A patient-specific, clinically significant reason why the member cannot use Eliquis® (apixaban) and Xarelto® (rivaroxaban) must be provided.

2. Pradaxa (dabigatran) oral pellets require the following:
   a. An FDA approved indication of 1 of the following:
      i. Treatment of VTE in members who have been treated with a parenteral anticoagulant for at least 5 days; or
      ii. To reduce the risk of recurrent VTE in members who have been previously treated; and
   b. Member must be 3 months of age or older; and
   c. Members older than 7 ~~10~~ years of age require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
   d. A patient-specific, clinically significant reason why the member cannot use Xarelto® (rivaroxaban) oral suspension must be provided.

Utilization Details of Anticoagulants: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
APIXABAN PRODUCTS						
ELIQUIS TAB 5MG	13,592	3,621	$9,302,694.61	$684.42	3.75	64.14%
ELIQUIS TAB 2.5MG	1,495	391	$928,654.86	$621.17	3.82	6.40%
ELIQUIS ST P TAB 5MG	55	53	$36,032.73	$655.14	1.04	0.25%
SUBTOTAL	**15,142**	**4,065**	**$10,267,382.20**	**$678.07**	**3.72**	**70.79%**
WARFARIN PRODUCTS						
WARFARIN TAB 5MG	1,976	540	$22,656.94	$11.47	3.66	0.16%
WARFARIN TAB 4MG	742	179	$8,380.44	$11.29	4.15	0.06%
WARFARIN TAB 1MG	703	193	$8,324.27	$11.84	3.64	0.06%
WARFARIN TAB 3MG	571	152	$6,668.75	$11.68	3.76	0.05%
WARFARIN TAB 6MG	486	132	$5,943.23	$12.23	3.68	0.04%
WARFARIN TAB 2MG	422	125	$5,256.39	$12.46	3.38	0.04%
WARFARIN TAB 7.5MG	421	148	$4,894.58	$11.63	2.84	0.03%
WARFARIN TAB 2.5MG	402	125	$4,888.53	$12.16	3.22	0.03%
WARFARIN TAB 10MG	377	108	$4,025.55	$10.68	3.49	0.03%
JANTOVEN TAB 5MG	51	19	$694.34	$13.61	2.68	0.00%
JANTOVEN TAB 1MG	15	6	$226.37	$15.09	2.5	0.00%
JANTOVEN TAB 6MG	14	4	$156.81	$11.20	3.5	0.00%
JANTOVEN TAB 2MG	11	4	$153.99	$14.00	2.75	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
JANTOVEN TAB 3MG	8	4	$113.00	$14.13	2	0.00%
JANTOVEN TAB 7.5MG	5	2	$66.05	$13.21	2.5	0.00%
JANTOVEN TAB 2.5MG	2	2	$28.36	$14.18	1	0.00%
JANTOVEN TAB 4MG	1	1	$8.27	$8.27	1	0.00%
SUBTOTAL	**6,207**	**1,744**	**$72,485.87**	**$11.68**	**3.56**	**0.50%**
RIVAROXABAN PRODUCTS						
XARELTO TAB 20MG	3,462	928	$2,645,678.46	$764.21	3.73	18.24%
XARELTO TAB 10MG	854	357	$518,279.13	$606.88	2.39	3.57%
XARELTO TAB 2.5MG	691	178	$432,815.80	$626.36	3.88	2.98%
XARELTO TAB 15MG	392	141	$275,434.87	$702.64	2.78	1.90%
XARELTO SUS 1MG/ML	212	62	$160,703.39	$758.03	3.42	1.11%
XARELTO ST P TAB 15/20MG	23	23	$19,603.22	$852.31	1	0.14%
SUBTOTAL	**5,634**	**1,689**	**$4,052,514.87**	**$719.30**	**3.34**	**27.94%**
DABIGATRAN PRODUCTS						
PRADAXA CAP 150MG	103	24	$67,244.48	$652.86	4.29	0.46%
DABIGATRAN CAP 150MG	42	13	$19,991.85	$476.00	3.23	0.14%
PRADAXA CAP 75MG	8	2	$3,865.60	$483.20	4	0.03%
PRADAXA CAP 110MG	1	1	$507.41	$507.41	1	0.00%
PRADAXA PACK 30MG	1	1	$9,446.33	$9,446.33	1	0.07%
SUBTOTAL	**155**	**41**	**$101,055.67**	**$651.97**	**3.78**	**0.70%**
EDOXABAN PRODUCTS						
SAVAYSA TAB 30MG	12	1	$4,794.12	$399.51	12	0.03%
SAVAYSA TAB 60MG	6	2	$5,282.04	$880.34	3	0.04%
SUBTOTAL	**18**	**3**	**$10,076.16**	**$559.79**	**6**	**0.07%**
TOTAL	**27,156**	**6,424***	**$14,503,514.77**	**$534.08**	**4.23**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; ST P = starter pack; SUS = suspension; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Utilization Details of Platelet Aggregation Inhibitors: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLOPIDOGREL PRODUCTS						
CLOPIDOGREL TAB 75MG	17,580	5,485	$227,925.34	$12.97	3.21	11.95%
CLOPIDOGREL TAB 300MG	1	1	$20.44	$20.44	1	0.00%
SUBTOTAL	**17,581**	**5,486**	**$227,945.78**	**$12.97**	**3.2**	**11.95%**
TICAGRELOR PRODUCTS						
BRILINTA TAB 90MG	3,635	761	$1,487,846.84	$409.31	4.78	78.03%
BRILINTA TAB 60MG	382	69	$155,872.94	$408.04	5.54	8.17%
SUBTOTAL	**4,017**	**830**	**$1,643,719.78**	**$409.19**	**4.84**	**86.20%**
PRASUGREL PRODUCTS						
PRASUGREL TAB 10MG	1,780	298	$32,012.83	$17.98	5.97	1.68%
PRASUGREL TAB 5MG	97	19	$1,991.67	$20.53	5.11	0.10%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**1,877**	**317**	**$34,004.50**	**$18.12**	**5.92**	**1.78%**
ASPIRIN/DIPYRIDAMOLE PRODUCTS						
ASA/DIPYRIDA CAP 25-200MG	18	2	$1,205.35	$66.96	9	0.06%
SUBTOTAL	**18**	**2**	**$1,205.35**	**$66.96**	**9**	**0.06%**
TOTAL	**23,493**	**6,403***	**$1,906,875.41**	**$81.17**	**3.67**	**100%**

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 11/2023. Last accessed 11/15/2023.

[2] Octapharma. Octapharma's Prothrombin Complex Concentrate, Balfaxar®, Receives FDA Approval for Warfarin Reversal in Urgent Surgery & Invasive Procedures. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/octapharmas-prothrombin-complex-concentrate-balfaxar-receives-fda-approval-for-warfarin-reversal-in-urgent-surgery--invasive-procedures-301886222.html. Issued 07/26/2023. Last accessed 11/15/2023.

[3] AstraZeneca. Andexxa® Phase IV Trial Stopped Early After Achieving Pre-Specified Criteria on Hemostatic Efficacy Versus Usual Care. Available online at: https://www.astrazeneca-us.com/media/press-releases/2023/andexxa-phase-iv-trial-stopped-early-after-achieving-pre-specified-criteria-on-hemostatic-efficacy-versus-usual-care.html. Issued 06/05/2023. Last accessed 11/15/2023.

[4] Janssen Pharmaceutical. Milvexian Granted U.S. FDA Fast Track Designation for All Three Indications Under Evaluation in Phase 3 Librexia Program: Ischemic Stroke, Acute Coronary Syndrome and Atrial Fibrillation. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/milvexian-granted-us-fda-fast-track-designation-for-all-three-indications-under-evaluation-in-phase-3-librexia-program-ischemic-stroke-acute-coronary-syndrome-and-atrial-fibrillation-301834509.html. Issued 05/25/2023. Last accessed 11/15/2023.

[5] Cadrenal Therapeutics. Cadrenal Therapeutics (Nasdaq: CVKD) Granted FDA Fast Track Designation for Tecarfarin for Prevention of Systemic Thromboembolism of Cardiac Origin in Patients with End-Stage Renal Disease and Atrial Fibrillation. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/cadrenal-therapeutics-nasdaq-cvkd-granted-fda-fast-track-designation-for-tecarfarin-for-prevention-of-systemic-thromboembolism-of-cardiac-origin-in-patients-with-end-stage-renal-disease-and-atrial-fibrillation-301727778.html. Issued 01/23/2023. Last accessed 11/15/2023.

[6] Cadrenal Therapeutics. Tecarfarin: A Late-Stage Novel Therapy with Orphan Drug Indication for the Treatment of ESRD + AFib. Available online at: https://www.cadrenal.com/tecarfarin/. Last accessed 11/15/2023.

[7] Anthos Therapeutics. Anthos Therapeutics' Novel Dual-Acting Factor XI/XIa Inhibitor, Abelacimab 150mg, Demonstrated a 67% Reduction in the Primary Endpoint of Major or Clinically Relevant Non-Major Bleeding Compared with Rivaroxaban in Patients with Atrial Fibrillation. *Businesswire*. Available online at: https://www.businesswire.com/news/home/20231112917868/en/. Issued 11/12/2023. Last accessed 11/15/2023.

Appendix J

Fiscal Year 2023 Annual Review of Constipation and Diarrhea Medications

Oklahoma Health Care Authority
December 2023

Current Prior Authorization Criteria: Constipation Medications

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

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
6. A quantity limit of 60 capsules per 30 days will apply.

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

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, except methadone, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be

within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
6. Amitiza® must be discontinued if treatment with the opioid pain medication is also discontinued; and
7. A quantity limit of 60 capsules per 30 days will apply.

Ibsrela® (Tenapanor) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 60 tablets per 30 days will apply.

Linzess® (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and

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

Motegrity® (Prucalopride) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
5. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 tablets per 30 days will apply.

Movantik® (Naloxegol) Approval Criteria:

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

3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Movantik® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 30 tablets per 30 days will apply.

Pizensy™ (Lactitol) Approval Criteria:

1. An FDA approved indication for treatment of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Member must not have a known contraindication to Pizensy™ (i.e., suspected gastrointestinal obstruction, galactosemia); and
3. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
7. Use of the unit-dose packets will require a patient-specific, clinically significant reason why the member cannot use the multi-dose bottle; and
8. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and

9. A quantity limit of 560 grams per 28 days will apply.

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

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
3. Member must have current use of opioid medications; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. Member must not have known or suspected gastrointestinal obstruction; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use the tablet formulation of Relistor® must be provided; and
9. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62kg; and/or
    b. Caregiver unable to draw up dose from vial; and
10. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
11. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
12. A quantity limit of 30 units per month will apply.

Relistor® (Methylnaltrexone) Injection Approval Criteria [Opioid-Induced Constipation (OIC) in Terminal Disease Diagnosis]:

1. An FDA approved diagnosis of OIC in members with severe terminal disease who are receiving only palliative care (life expectancy <6 months); and
2. Member must have current use of opioid medications; and

3. Documented treatment attempts with a minimum of 3 alternative products, excluding bulk forming laxatives; and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
4. Mechanical gastrointestinal obstruction has been ruled out; and
5. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62 kg; and/or
    b. Caregiver unable to draw up dose from vial; and
6. A quantity limit of 30 units per month will apply; and
7. Approvals will be for the duration of 16 weeks of therapy. Use of Relistor® beyond 4 months has not been studied in patients with severe terminal disease.

Relistor® (Methylnaltrexone) Tablets Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that have failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 90 tablets per 30 days will apply.

Symproic® (Naldemedine) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members older than 50 years of age; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why member cannot use Amitiza® (lubiprostone) or Movantik® (naloxegol) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Symproic® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 30 tablets per 30 days will apply.

Trulance® (Plecanatide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members older than 50 years of age; and
4. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners; and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and

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

Zelnorm® (Tegaserod) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in female members 18 to 64 years of age; and
2. Member must be female for authorization of Zelnorm® (the safety and efficacy of Zelnorm® in men with IBS-C have not been established); and
3. Member must not have any of the contraindications for use of Zelnorm® [i.e., history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina; history of ischemic colitis or other forms of intestinal ischemia; severe renal impairment (estimated glomerular filtration rate {eGFR} <15mL/min/1.73m^2) or end-stage renal disease (ESRD); moderate or severe hepatic impairment (Child-Pugh B or C); history of bowel obstruction, symptomatic gallbladder disease, suspected sphincter or Oddi dysfunction, or abdominal adhesions; hypersensitivity to tegaserod)]; and
4. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
5. Documented and updated colon screening for members older than 50 years of age; and
6. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
8. Approval will initially be for 6 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment. Zelnorm® should be discontinued in patients who have not had adequate control of symptoms after 4 to 6 weeks of treatment; and
9. A quantity limit of 60 tablets per 30 days will apply.

Current Prior Authorization Criteria: Diarrhea Medications

Aemcolo® (Rifamycin) Approval Criteria:

1. An FDA approved diagnosis of traveler's diarrhea; and
2. Member must be 18 years of age or older; and
3. Traveler's diarrhea must be due to non-invasive strains of *Escherichia coli*; and
4. A patient-specific, clinically significant reason why the member cannot use Xifaxan® (rifaximin) oral tablets must be provided; and
5. A quantity limit of 12 tablets per 3 days will apply.

Motofen® (Difenoxin/Atropine) Approval Criteria:

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

Mytesi® (Crofelemer) Approval Criteria:

1. An FDA approved diagnosis of non-infectious diarrhea in adult members with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) currently on anti-retroviral therapy; and
2. Duration of diarrhea has been ≥4 weeks; and
3. Dietary modifications have failed; and
4. Prescribers must verify that infectious diarrhea has been ruled out via confirmation of all of the following:
    a. CD4 count has been measured and possible opportunistic infections have been ruled out; and
    b. Member does not have fever; and
    c. Stool studies for pathogens are negative including:
        i. Bacterial cultures; and
        ii. Ova, parasite, cryptosporidium, and/or giardia; and
        iii. *Clostridium difficile* (*Clostridium difficile* testing should include a glutamate dehydrogenase screen and if positive, should be followed by a confirmatory test or nucleic acid amplification test in members with documented diarrhea; a toxin enzyme immunoassay should not be used as a stand-alone test); and

5. If stool study results are negative and the member has severe symptoms, particularly in the case of advanced immunodeficiency, an endoscopy with biopsy is recommended, at the prescriber's discretion, to rule out inflammatory bowel disease, cancer, cytomegalovirus (CMV) infection, microsporidium, or mycobacterium avium complex (MAC); and
6. A quantity limit of 60 tablets per 30 days will apply. Initial approvals will be for 4 weeks of therapy. Subsequent approvals may be granted for 6 months if the prescriber documents the member is responding well to treatment.

Viberzi® (Eluxadoline) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
2. Member must be 18 years of age or older; and
3. Member must not have any of the contraindications for use of Viberzi® (i.e., removed gallbladder; biliary duct obstruction or sphincter of Oddi disease or dysfunction; alcoholism, alcohol abuse, or alcohol addiction; history of pancreatitis or structural diseases of the pancreas; severe hepatic impairment; history of chronic or severe constipation; mechanical gastrointestinal obstruction); and
4. Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
6. A quantity limit of 60 tablets per 30 days will apply.

Xermelo® (Telotristat Ethyl) Approval Criteria:

1. An FDA approved diagnosis of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy; and
2. Member must be 18 years of age or older; and
3. Member must have been taking a stable dose of SSA therapy for the last 3 months and be inadequately controlled (4 or more bowel movements per day); and
4. Prescriber must verify member will continue taking SSA therapy in combination with Xermelo®; and

5. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
6. A quantity limit of 90 tablets per 30 days will apply.

Xifaxan® (Rifaximin) 200mg Approval Criteria:

1. An FDA approved diagnosis of traveler's diarrhea; and
2. Member must be 12 years of age or older; and
3. Traveler's diarrhea must be due to noninvasive strains of *Escherichia coli*; and
4. A quantity limit of 9 tablets per 3 days will apply.

Xifaxan® (Rifaximin) 550mg Approval Criteria:

1. An FDA approved indication for the reduction in risk of overt hepatic encephalopathy (HE) recurrence; or
2. An FDA approved diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and
   a. For the diagnosis of IBS-D: Documentation of trials of 2 of the following 3 medications that failed to relieve diarrhea: loperamide, dicyclomine, or diphenoxylate/atropine (each trial should be for at least 10 to 14 consecutive days at the recommended dosing). Trials must be within the past 90 days. Documentation should be provided including dates, dosing, and reason for trial failure; and
   b. For the diagnosis of IBS-D: Member must be 18 years of age or older; and
3. A quantity limit of 60 tablets per 30 days will apply. Patients with the diagnosis of IBS-D needing 42 tablets for a 14-day treatment regimen (550mg 3 times daily for 14 days) will be approved for a quantity limit override upon meeting Xifaxan® approval criteria. Patients with IBS-D who experience a recurrence of symptoms can be retreated up to 2 times with the same 14-day treatment regimen (550mg 3 times daily for 14 days).

Utilization of Constipation and Diarrhea Medications: Fiscal Year 2023

Comparison of Fiscal Years: Constipation Medications

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	314	1,376	$587,106.56	$426.68	$14.08	48,138	41,699
2023	451	1,988	$901,055.34	$453.25	$14.96	65,924	60,228
% Change	**43.60%**	**44.50%**	**53.50%**	**6.20%**	**6.30%**	**36.90%**	**44.40%**
Change	**137**	**612**	**$313,948.78**	**$26.57**	**$0.88**	**17,786**	**18,529**

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

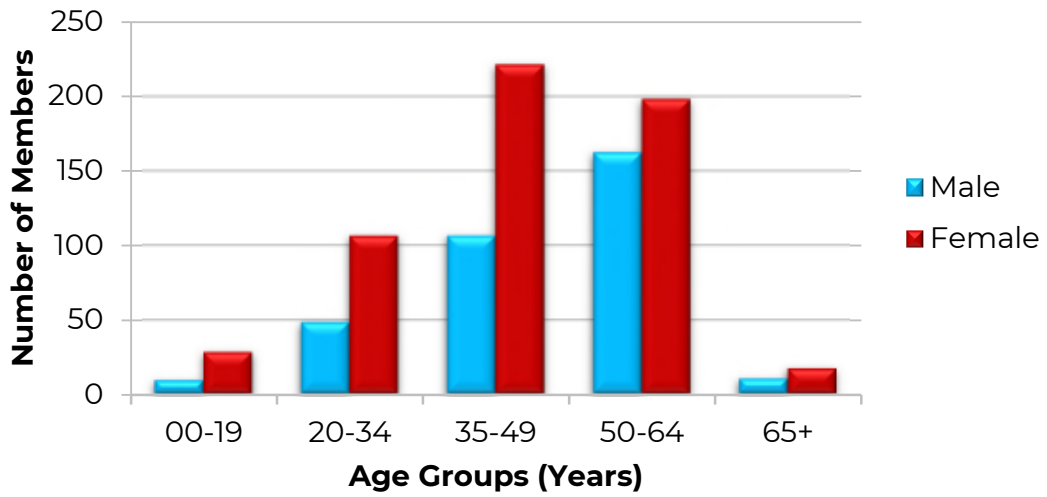
Comparison of Fiscal Years: Diarrhea Medications

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	369	1,409	$3,621,132.93	$2,570.00	$90.37	81,786	40,070
2023	459	1,972	$5,567,899.41	$2,823.48	$97.19	114,056	57,288
% Change	**24.40%**	**40.00%**	**53.80%**	**9.90%**	**7.50%**	**39.50%**	**43.00%**
Change	**90**	**563**	**$1,946,766.48**	**$253.48**	**$6.82**	**32,270**	**17,218**

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
The above table includes Xifaxan® (rifaximin), which was first approved by the FDA in 2004 and has a significant federal rebate. Please note, the majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

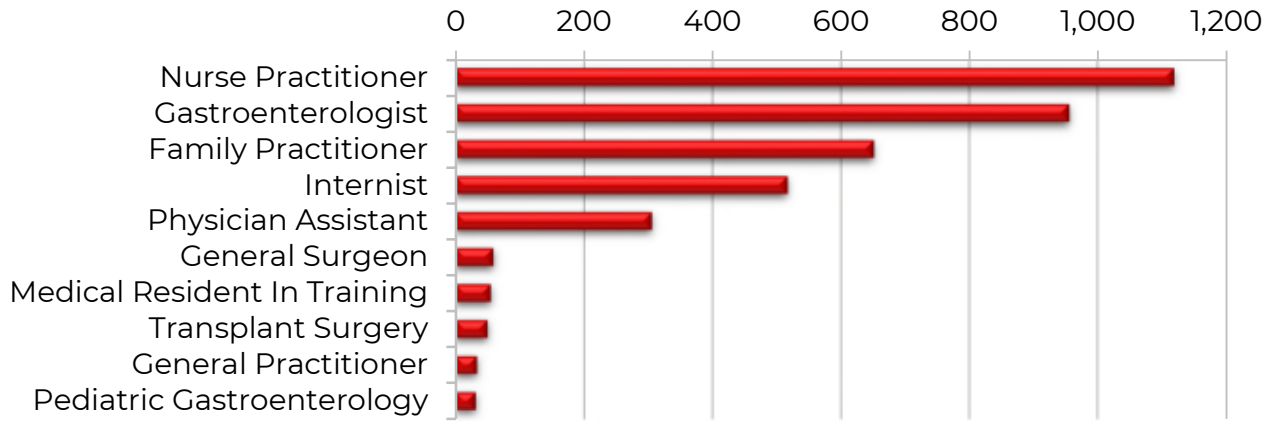
- Aggregate drug rebates collected during fiscal year 2023 for the constipation and diarrhea medications totaled $5,255,089.39.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Constipation and Diarrhea Medications



[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.

Top Prescriber Specialties of Constipation and Diarrhea Medications by Number of Claims



Prior Authorization of Constipation and Diarrhea Medications

There were 4,424 prior authorization requests submitted for constipation and diarrhea 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[1,2,3,4,5,6,7,8,9,10]

Anticipated Patent Expiration(s):

- Aemcolo® (rifamycin): May 2025
- Amitiza® (lubiprostone): October 2027
- Xifaxan® (rifaximin): October 2029
- Ibsrela® (tenapanor): May 2030
- Relistor® (methylnaltrexone injection): December 2030
- Xermelo® (telotristat ethyl): February 2031
- Relistor® (methylnaltrexone tablet): March 2031
- Mytesi® (crofelemer): October 2031
- Movantik® (naloxegol): April 2032
- Viberzi® (eluxadoline): March 2033
- Symproic® (naldemedine): May 2033
- Linzess® (linaclotide): August 2033

- Pizensy™ (lactitol): May 2037

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

- **June 2023:** Linzess® (linaclotide) was FDA approved for the treatment of functional constipation (FC) in patients 6 to 17 years of age. The approval was the result of a clinical trial that evaluated patients with FC and irritable bowel syndrome with constipation (IBS-C) and is still ongoing for the IBS-C diagnosis. The primary efficacy endpoint of the trial looked at the improvement from baseline in number of spontaneous bowel movements (SBMs) and found a statistically significant improvement in the number of SBMs in patients treated with linaclotide.

News:

- **June 2022:** Zelnorm® (tegaserod) was withdrawn from market by its manufacturer, Alfasigma USA, Inc., following a press release that stated the decision was a business decision and not due to any safety or efficacy concerns. The medication was pulled from the market once before in 2007 due to a safety issue concerning findings of an increased risk of heart attack and stroke but was made available again in 2019 for the treatment of IBS-C in adult women younger than 65 years of age.

Guideline Update(s):

- **May 2021:** The U.S. Preventative Services Task Force (USPSTF) released a Recommendation Statement agreeing with the previous recommendations put out by the American Cancer Society (ACS) regarding colorectal cancer screening. The USPSTF recommends routine screening for colorectal cancer in patients with an average risk starting as young as 45 years of age, which is 5 years sooner than the previous recommendation of 50 years of age. The recommendation is based on findings that suggest there is a slight increase in risk for younger patients to develop colorectal cancer and the observation of an increase in younger patients being diagnosed with colorectal cancers over the past few years.
- **June 2023:** The American Gastroenterological Association and the American College of Gastroenterology released an updated guideline for the treatment of chronic idiopathic constipation (CIC) in adults. This guideline update continues to strongly recommend the use of polyethylene glycol (PEG) for treatment of CIC. Stimulant laxatives, such as bisacodyl, are recommended for short term relief of constipation. Use of prescription medications, such as lubiprostone and linaclotide, should be reserved after failed trials of over-the-counter (OTC) medications.

Pipeline:

- **Pradigastat:** Pradigastat is an oral diacyglycerol acyltransferase 1 (DGAT1) inhibitor that was originally being studied in patients with hypertriglyceridemia but was shown in clinical trials to increase bowel movements and result in softer stools. Due to this discovery, pradigastat is currently being evaluated in a Phase 2 trial for the management of CIC. Trial results are not yet available and a Phase 3 trial has not been initiated.
- **Crofelemer:** Crofelemer is an oral cyclic adenosine monophosphate (cAMP)-stimulated cystic fibrosis transmembrane conductance regulator (CFTR) inhibitor that inhibits the chloride ion channels and calcium activated chloride ion channels to regulate fluid secretion and high-volume water loss. Crofelemer was previously FDA approved in 2012 under brand name Mytesi® to treat diarrhea in patients with human immunodeficiency virus and acquired immunodeficiency syndrome (HIV/AIDS) who are on antiretroviral therapy (ART). Crofelemer is being studied in irritable bowel syndrome with diarrhea (IBS-D), and patients are currently being recruited for a Phase 3 trial evaluating the efficacy of crofelemer in IBS-D.

Recommendations

The College of Pharmacy recommends updating the Linzess® (linaclotide) approval criteria based on the new FDA approved pediatric indication and to align with the updates to the USPSTF guidelines with the following changes (shown in red):

Linzess® (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Chronic idiopathic constipation (CIC) in members 18 years of age or older; or
   b. Irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; or
   c. Functional constipation in members 6 to 17 years of age; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
   a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
   b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and

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

Additionally, the College of Pharmacy recommends updating the colon screening criteria for all other constipation medications to reflect the updates to the USPSTF guidelines and recommends updating the CIC and IBS-C approval criteria for Amitiza® (lubiprostone) and the approval criteria for Symproic® (naldemedine) based on net costs (changes shown in red):

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

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and

6. A patient-specific, clinically significant reason why the member cannot use Linzess® (linaclotide) or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
8. A quantity limit of 60 capsules per 30 days will apply.

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

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, except methadone, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
7. Amitiza® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 60 capsules per 30 days will apply.

Ibsrela® (Tenapanor) Approval Criteria:

1. An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and

2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 tablets per 30 days will apply.

Motegrity® (Prucalopride) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be

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

Movantik® (Naloxegol) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
   a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
   b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. Movantik® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 30 tablets per 30 days will apply.

Pizensy™ (Lactitol) Approval Criteria:

1. An FDA approved indication for treatment of chronic idiopathic constipation (CIC) in members 18 years of age or older; and
2. Member must not have a known contraindication to Pizensy™ (i.e., suspected gastrointestinal obstruction, galactosemia); and
3. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
4. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Member must not have known or suspected gastrointestinal obstruction; and
6. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and
8. Use of the unit-dose packets will require a patient-specific, clinically significant reason why the member cannot use the multi-dose bottle; and
9. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
10. A quantity limit of 560 grams per 28 days will apply.

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

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

4. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. Member must not have known or suspected gastrointestinal obstruction; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use the tablet formulation of Relistor® must be provided; and
9. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62kg; and/or
    b. Caregiver unable to draw up dose from vial; and
10. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
11. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
12. A quantity limit of 30 units per month will apply.

Relistor® (Methylnaltrexone) Tablets Approval Criteria:

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

4. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different types of products that have failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 90 tablets per 30 days will apply.

Symproic® (Naldemedine) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be

within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and

~~6. A patient-specific, clinically significant reason why member cannot use Amitiza® (lubiprostone) or Movantik® (naloxegol) must be provided; and~~

7. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
8. Symproic® must be discontinued if treatment with the opioid pain medication is also discontinued; and
9. A quantity limit of 30 tablets per 30 days will apply.

Trulance® (Plecanatide) Approval Criteria:

1. An FDA approved diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
   a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
   b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners; and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. A quantity limit of 30 tablets per 30 days will apply.

Finally, the College of Pharmacy recommends the removal of coverage and of the prior authorization criteria for Zelnorm® (tegaserod) based on its removal from the market (changes shown in red):

~~**Zelnorm® (Tegaserod) Approval Criteria:**~~

1. ~~An FDA approved diagnosis of irritable bowel syndrome with constipation (IBS-C) in female members 18 to 64 years of age; and~~
2. ~~Member must be female for authorization of Zelnorm® (the safety and efficacy of Zelnorm® in men with IBS-C have not been established); and~~
3. ~~Member must not have any of the contraindications for use of Zelnorm® [i.e., history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), or angina; history of ischemic colitis or other forms of intestinal ischemia; severe renal impairment (estimated glomerular filtration rate [eGFR] <15mL/min/1.73m^2) or end-stage renal disease (ESRD); moderate or severe hepatic impairment (Child-Pugh B or C); history of bowel obstruction, symptomatic gallbladder disease, suspected sphincter or Oddi dysfunction, or abdominal adhesions; hypersensitivity to tegaserod)]; and~~
4. ~~Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and~~
5. ~~Documented and updated colon screening for members older than 50 years of age; and~~
6. ~~Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and~~
   a. ~~1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and~~
   b. ~~Members with an oncology-related diagnosis are exempt from the trial requirements; and~~
7. ~~A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Linzess® (linaclotide), or Trulance® (plecanatide) must be provided; and~~
8. ~~Approval will initially be for 6 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment. Zelnorm® should be discontinued in patients who have not had adequate control of symptoms after 4 to 6 weeks of treatment; and~~
9. ~~A quantity limit of 60 tablets per 30 days will apply.~~

Utilization Details of Constipation Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LINACLOTIDE PRODUCTS						
LINZESS CAP 290MCG	578	177	$272,190.64	$470.92	4.94	30.21%
LINZESS CAP 145MCG	542	133	$258,278.31	$476.53	4.08	28.66%
LINZESS CAP 72MCG	263	64	$124,812.93	$474.57	4.11	13.85%
SUBTOTAL	**1,383**	**314**	**$655,281.88**	**$473.81**	**4.4**	**72.72%**
LUBIPROSTONE PRODUCTS						
LUBIPROSTONE CAP 24MCG	135	38	$31,465.88	$233.08	3.55	3.49%
LUBIPROSTONE CAP 8MCG	59	25	$13,815.11	$234.15	2.36	1.53%
AMITIZA CAP 24MCG	30	10	$10,144.75	$338.16	3	1.13%
AMITIZA CAP 8MCG	2	2	$375.82	$187.91	1	0.04%
SUBTOTAL	**226**	**75**	**$55,801.56**	**$246.91**	**3.01**	**6.19%**
PLECANATIDE PRODUCTS						
TRULANCE TAB 3MG	234	73	$120,369.75	$514.40	3.21	13.36%
SUBTOTAL	**234**	**73**	**$120,369.75**	**$514.40**	**3.21**	**13.36%**
NALOXEGOL PRODUCTS						
MOVANTIK TAB 25MG	66	19	$25,140.92	$380.92	3.47	2.79%
MOVANTIK TAB 12.5MG	15	7	$5,459.41	$363.96	2.14	0.61%
SUBTOTAL	**81**	**26**	**$30,600.33**	**$377.78**	**3.12**	**3.40%**
PRUCALOPRIDE PRODUCTS						
MOTEGRITY TAB 2MG	39	10	$18,633.34	$477.78	3.9	2.07%
MOTEGRITY TAB 1MG	4	1	$1,015.12	$253.78	4	0.11%
SUBTOTAL	**43**	**11**	**$19,648.46**	**$456.94**	**3.91**	**2.18%**
NALDEMEDINE PRODUCTS						
SYMPROIC TAB 0.2MG	11	4	$4,520.12	$410.92	2.75	0.50%
SUBTOTAL	**11**	**4**	**$4,520.12**	**$410.92**	**2.75**	**0.50%**
METHYLNALTREXONE PRODUCTS						
RELISTOR TAB 150MG	5	2	$6,587.74	$1,317.55	2.5	0.73%
SUBTOTAL	**5**	**2**	**$6,587.74**	**$1,317.55**	**2.5**	**0.73%**
TENAPANOR PRODUCTS						
IBSRELA TAB 50MG	5	1	$8,245.50	$1,649.10	5	0.92%
SUBTOTAL	**5**	**1**	**$8,245.50**	**$1,649.10**	**5**	**0.92%**
TOTAL	**1,988**	**451***	**$901,055.34**	**$453.25**	**3.39**	**100%**

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

Utilization Details of Diarrhea Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RIFAXIMIN PRODUCTS						
XIFAXAN TAB 550MG	1,935	448	$5,528,221.17	$2,856.96	4.32	99.29%
XIFAXAN TAB 200MG	9	6	$2,346.94	$260.77	1.5	0.04%
SUBTOTAL	**1,944**	**454**	**$5,530,568.11**	**$2,844.94**	**4.28**	**99.33%**
ELUXADOLINE PRODUCTS						
VIBERZI TAB 100MG	24	5	$31,608.32	$1,317.01	4.8	0.57%
VIBERZI TAB 75MG	4	1	$5,722.98	$1,430.75	4	0.10%
SUBTOTAL	**28**	**6**	**$37,331.30**	**$1,333.26**	**4.67**	**0.67%**
TOTAL	**1,972**	**459***	**$5,567,899.41**	**$2,823.48**	**4.29**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Xifaxan® (rifaximin) was first FDA approved in 2004 and has a significant federal rebate. Please note, the majority of utilization of rifaximin was for the 550mg strength for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.

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Appendix K

Fiscal Year 2023 Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Hepzato Kit™ (Melphalan) and Zynyz™ (Retifanlimab-dlwr)

Oklahoma Health Care Authority
December 2023

Current Prior Authorization Criteria

Utilization data for Tecentriq® (atezolizumab) and approval criteria for indications other than skin cancer can be found in the April 2023 Drug Utilization Review (DUR) Board packet. This medication and criteria are reviewed annually with the lung cancer medications.

Bavencio® (Avelumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of metastatic MCC; and
2. Member must be 12 years of age or older.

Bavencio® (Avelumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC; and
2. Used as first-line treatment; and
3. Used in combination with axitinib.

Bavencio® (Avelumab) Approval Criteria [Urothelial Carcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial carcinoma; and
2. Disease has progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy; or
3. Used as maintenance therapy for members not progressing on a first-line platinum-containing regimen.

Braftovi® (Encorafenib) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of advanced or metastatic CRC; and
2. *BRAF* V600E mutation positive; and
3. Used in combination with cetuximab or panitumumab; and
4. Disease must have progressed following adjuvant therapy within 12 months; or
5. Used following progression of any line of metastatic therapy.

Braftovi® (Encorafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
3. Used in combination with binimetinib.

Cotellic® (Cobimetinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Cobimetinib is not indicated for wild-type *BRAF* melanoma; and
3. Member meets 1 of the following:
    a. Used as first-line therapy in combination with vemurafenib; or
    b. Used as second-line therapy or subsequent therapy with vemurafenib.

Erivedge® (Vismodegib) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced BCC that has either:
    a. Recurred following surgery or radiation therapy; or
    b. Surgery or radiation is contraindicated; or
2. Diagnosis of metastatic BCC.

Imlygic® (Talimogene Laherparepvec) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable cutaneous, subcutaneous, or nodal lesions that are recurrent after initial surgery; and
    a. Not indicated in members with visceral metastases; and
2. Member is not immunocompromised or pregnant.

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

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

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

1. Diagnosis of recurrent or metastatic cervical cancer; and
2. Tumor must express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1)]; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
    a. Disease progression on or after chemotherapy; or

b. As first-line therapy in combination with chemotherapy, with or without bevacizumab.

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

1. Diagnosis of unresectable or metastatic CRC; and
2. Metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

Keytruda® (Pembrolizumab) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of recurrent or metastatic disease; and
2. Not curable by radiation or surgery.

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

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo (nivolumab)]; and
2. Disease progression following prior systemic therapy; and
3. Member is not a candidate for curative surgery or radiation; and
4. Used in 1 of the following settings:
    a. In combination with lenvatinib for advanced endometrial cancer that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); or
    b. As a single agent for advanced endometrial cancer that is MSI-H or dMMR.

Keytruda® (Pembrolizumab) Approval Criteria [Esophageal or Gastroesophageal Junction (GEJ) Carcinoma Diagnosis]:

1. Diagnosis of locally advanced, recurrent, or metastatic esophageal or GEJ carcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. In combination with platinum- and fluoropyrimidine-based chemotherapy; or
4. For second-line or greater therapy:
    a. Following disease progression after 1 or more prior lines of systemic therapy; and
    b. Tumor must be squamous cell histology; and
    c. Used as a single agent; and
    d. Tumor expresses programmed death ligand 1 (PD-L1) [combined positive score (CPS ≥10).

Keytruda® (Pembrolizumab) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced, unresectable, or metastatic gastric or GEJ adenocarcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. Human epidermal receptor 2 (HER2)-positive disease; and
    c. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy.

Keytruda® (Pembrolizumab) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Used in first-line or recurrent setting; and
2. Squamous cell histology; and
3. If used in the recurrent setting, member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

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

1. Diagnosis of relapsed or progressive HCC; and
2. Member must have been previously treated with sorafenib; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

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

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

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

1. Member meets 1 of the following:

    a. Adjuvant treatment of adult and pediatric members 12 years of age or older with stage 2B, 2C, or 3 melanoma following complete resection; or
    b. Diagnosis of unresectable or metastatic melanoma; and
2. Used as a single agent; and
3. Member meets 1 of the following:
    a. Used as first-line therapy; or
    b. Used as second-line therapy or subsequent therapy for disease progression if not previously used; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
5. For adjuvant treatment of melanoma, approvals will be for a maximum duration of 1 year.

Keytruda® (Pembrolizumab) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of recurrent, locally advanced, or metastatic MCC; and
2. No history of prior systemic chemotherapy; and
3. Used as a single agent; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Metastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of metastatic NSCLC; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression as follows:
    a. As a single agent, first-line: ≥1%; or
    b. First-line in combination: No expression required; or
    c. As a single agent, second-line: ≥1%; and
4. Member meets 1 of the following:
    a. Previously untreated, metastatic squamous NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel; or
    b. Previously untreated, metastatic non-squamous NSCLC in combination with pemetrexed and carboplatin; or
    c. New diagnosis as first-line therapy (member has not received chemotherapy to treat disease) if:
        i. Tumor does not express sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations; or
    d. Used as a single agent for disease progression on or after platinum-containing chemotherapy (i.e., cisplatin, carboplatin):

i. Members with EGFR-mutation-positive tumors should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations* (*examples of drugs for EGFR-mutation-positive tumors: osimertinib, erlotinib, afatinib, or gefitinib);* and
ii. Members with ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab. *This does not apply if tumors do not have these mutations (examples of drugs for ALK-mutation-positive tumors: crizotinib, ceritinib, or alectinib).*

Keytruda® (Pembrolizumab) Approval Criteria [Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumor (Tissue/Site-Agnostic) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)]; and
2. MSI-H or dMMR solid tumors that have progressed following prior treatment with no satisfactory alternative treatment options.

Keytruda® (Pembrolizumab) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of stage 3 NSCLC; and
   a. Ineligible for surgery or definitive chemoradiation; and
   b. Tumor proportion scores for programmed death ligand 1 (PD-L1) expression ≥1%; and
   c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of high-risk, NMIBC; and
2. Member must have failed therapy with Bacillus Calmette-Guerin (BCG)-therapy; and
3. Member must be ineligible for or has elected not to undergo cystectomy.

Keytruda® (Pembrolizumab) Approval Criteria [Primary Mediastinal Large B-cell Lymphoma (PMBCL) Diagnosis]:

1. Diagnosis of PMBCL; and
2. Member must have refractory disease or relapsed after 2 or more prior lines of therapy; and
3. Authorizations will not be granted for members who require urgent cytoreduction; and

4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of new or recurrent stage 4 clear-cell RCC; and
    a. Member has not received previous systemic therapy for advanced disease; and
    b. Must be used in combination with axitinib or lenvatinib; and
    c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; or
2. Diagnosis of RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

Keytruda® (Pembrolizumab) Approval Criteria [Small Cell Lung Cancer (SCLC) Diagnosis]:

1. Diagnosis of metastatic SCLC; and
2. Progressed on or following a platinum-based regimen and at least 1 other regimen; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)].

Keytruda® (Pembrolizumab) Approval Criteria [Tumor Mutational Burden-High (TMB-H) Solid Tumors Diagnosis]:

1. Diagnosis of unresectable or metastatic TMB-H [≥10 mutations/megabase (mut/Mb)] solid tumors; and
2. Used following disease progression after prior treatment; and
3. No satisfactory alternative treatment options.

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

1. Member must have 1 of the following:
    a. Locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
    b. Within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
    c. Frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy; and
        i. Cisplatin ineligibility is defined as:
            1. Baseline creatinine clearance of <60mL/min; or
            2. ECOG performance status of 2; or
            3. Class III heart failure; or

4. Grade 2 or greater peripheral neuropathy; or
5. Grade 2 or greater hearing loss; and

2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Kimmtrak® (Tebentafusp-tebn) Approval Criteria [Uveal Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic uveal melanoma; and
2. Positive expression of HLA-A*02:01 genotype.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced or metastatic BCC; and
2. Member has previously been treated with a hedgehog pathway inhibitor (HHI); or
3. Treatment with a HHI is not appropriate for the member.

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Cutaneous Squamous Cell Carcinoma (cSCC) Diagnosis]:

1. Diagnosis of metastatic or locally advanced cSCC; and
2. Member is ineligible for curative surgery or radiation; and
3. Member has not received prior immunotherapy agent(s) [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab), Yervoy® (ipilimumab)].

Libtayo® (Cemiplimab-rwlc) Approval Criteria [Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of advanced, unresectable, or metastatic NSCLC; and
2. Used in the first-line setting; and
3. No epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 mutations; and
4. Used in 1 of the following settings:
    a. Used as a single agent; and
        i. High programmed death ligand 1 (PD-L1) expression [tumor proportion score (TPS) ≥50%]; or
    b. Used in combination with platinum-based chemotherapy; and
        i. No requirement for PD-L1 expression.

Mekinist® (Trametinib) Approval Criteria [Anaplastic Thyroid Cancer (ATC) Diagnosis]:

1. Diagnosis of ATC; and
2. Locally advanced or metastatic disease; and
3. *BRAF* V600E mutation; and
4. No satisfactory locoregional treatment options.

Mekinist® (Trametinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
    a. Used as first-line therapy in combination with dabrafenib; or
    b. Used as second-line or subsequent therapy with dabrafenib; or
    c. Used as second-line therapy or subsequent therapy as a single agent if:
        i. Member was intolerant to prior *BRAF* inhibitor therapy (i.e., dabrafenib, vemurafenib); and
        ii. No evidence of disease progression on prior *BRAF* inhibitor therapy (i.e., dabrafenib, vemurafenib).

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

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
    a. Trametinib is not indicated for wild-type *BRAF* NSCLC; and
3. Used in combination with dabrafenib.

Mekinist® (Trametinib) Approval Criteria [Serous Ovarian Cancer Diagnosis]:

1. Diagnosis of persistent disease or recurrent low-grade serous carcinoma; and
2. Meets 1 of the following:
    a. Immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
    b. Progression on primary, maintenance, or recurrence therapy; or
    c. Stable or persistent disease (if not on maintenance therapy); or
    d. Complete remission and relapse after completing chemotherapy.

Mekinist® (Trametinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
4. Used in combination with dabrafenib.

Mektovi® (Binimetinib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
3. Used in combination with encorafenib.

Odomzo® (Sonidegib) Approval Criteria [Basal Cell Carcinoma (BCC) Diagnosis]:

1. Diagnosis of locally advanced BCC that has either:
    a. Recurred following surgery or radiation therapy; or
    b. Surgery or radiation is contraindicated; or
2. Diagnosis of metastatic BCC.

Opdivo® (Nivolumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:

1. Member has had complete resection of melanoma; and
2. Diagnosis of stage 3 melanoma following complete resection; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Used as a single agent; and
5. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; and
    b. Maximum duration of 1 year.

Opdivo® (Nivolumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR).

Opdivo® (Nivolumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) or Esophageal or Gastroesophageal Junction (GEJ) Cancer Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
    a. Used in the first-line setting; and
    b. Used in combination with 1 of the following:
        i. Fluoropyrimidine- and platinum-based chemotherapy; or
        ii. Ipilimumab; or
2. Diagnosis of esophageal or GEJ cancer; and
    a. Member has received preoperative chemoradiation; and
    b. Member underwent R0 (complete) resection and has residual disease; and
    c. As a single agent; or
3. Palliative therapy for members who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease; and
    a. Human epidermal receptor 2 (HER2)-negative disease; and
        i. Used in first-line setting; and
            1. Used in combination with oxaliplatin and fluorouracil or capecitabine; and
            2. Adenocarcinoma pathology; or
        ii. Used in the second-line or greater setting; and

1. As a single agent; and
2. Squamous cell pathology.

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

1. Diagnosis of advanced or metastatic disease; and
2. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Opdivo® (Nivolumab) Approval Criteria [Head and Neck Cancer Diagnosis]:

1. Diagnosis of recurrent or metastatic head and neck cancer; and
2. Squamous cell histology; and
3. Member has received prior platinum-containing regimen (i.e., cisplatin, carboplatin); and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
5. Dose as follows: 240mg every 2 weeks or 480mg every 4 weeks.

Opdivo® (Nivolumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Member must have unresectable disease and is not a transplant candidate; or
2. Metastatic disease or extensive liver tumor burden; and
3. Must meet 1 of the following:
    a. If used as first-line therapy, must be used as single agent; and
        i. Ineligible for tyrosine kinase inhibitors or anti-angiogenic agents; or
    b. If used as second-line or greater therapy, may be used as single agent or in combination with ipilimumab; and
        i. Must not have failed other checkpoint inhibitors.

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

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma; and
    a. Exception: Lymphocyte-predominant Hodgkin lymphoma; and
2. Used as a single agent; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Opdivo® (Nivolumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with ipilimumab.

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

1. Diagnosis of NSCLC; and

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

Opdivo® (Nivolumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
2. Used in 1 of the following settings:
    a. For nivolumab monotherapy:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease; and
        ii. Failed prior therapy with 1 of the following medications:
            1. Sunitinib; or
            2. Sorafenib; or
            3. Pazopanib; or
            4. Axitinib; or
    b. For nivolumab use in combination with ipilimumab:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; or
    c. For nivolumab use in combination with cabozantinib:
        i. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with advanced RCC; and

        ii. Nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years; and
3. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. In combination with ipilimumab: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks thereafter; or
    c. In combination with cabozantinib: cabozantinib 40mg once daily with nivolumab 240mg every 2 weeks or 480mg every 4 weeks; nivolumab, when used in combination with cabozantinib for RCC, will be approved for a maximum duration of 2 years.

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

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

Opdivo® (Nivolumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Used as a single agent or in combination with ipilimumab:
    a. As first-line therapy for untreated melanoma; or
    b. As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and
        i. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
3. Dose as follows:
    a. Single agent: 240mg every 2 weeks or 480mg every 4 weeks; or
    b. In combination with ipilimumab: nivolumab 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 240mg every 2 weeks or 480mg every 4 weeks.

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

1. Diagnosis of urothelial carcinoma; and
    a. Member has undergone radical resection; and
    b. Disease is at high risk of recurrence; or
2. Diagnosis of metastatic or unresectable locally advanced disease; and
    a. Used as second-line or greater therapy; and

b. Previous failure of a platinum-containing regimen; and
c. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)].

Opdualag™ (Nivolumab/Relatlimab-rmbw) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Member must be 12 years of age or older; and
3. As first-line therapy; and
4. Member has not previously failed programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab), Opdivo® (nivolumab)].

Tafinlar® (Dabrafenib) Approval Criteria [Anaplastic Thyroid Cancer (ATC) Diagnosis]:

1. Diagnosis of ATC; and
2. Locally advanced or metastatic disease; and
3. *BRAF* V600E mutation; and
4. No satisfactory locoregional treatment options.

Tafinlar® (Dabrafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
   a. Dabrafenib is not indicated for wild-type *BRAF* melanoma; and
3. Used as a single agent or in combination with trametinib; and
4. Must meet 1 of the following:
   a. Used as first-line therapy; or
   b. Used as second-line or subsequent therapy.

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

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
   a. Not indicated for wild-type BRAF NSCLC; and
3. Used as a single agent or in combination with trametinib.

Tafinlar® (Dabrafenib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
4. Used in combination with trametinib.

Tecentriq® (Atezolizumab) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600 mutation-positive; and
3. Used in combination with cobimetinib and vemurafenib.

Yervoy® (Ipilimumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:

1. Member has had complete resection of melanoma with lymphadenectomy; and
2. Member has stage 3 disease with regional nodes of >1mm and no in-transit metastasis; and
3. Used as a single agent; and
4. Maximum dose of 10mg/kg will apply.

Yervoy® (Ipilimumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of unresectable or metastatic CRC; and
2. Tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and
3. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Esophageal Squamous Cell Carcinoma (ESCC) Diagnosis]:

1. Diagnosis of unresectable advanced or metastatic ESCC; and
    a. Used in the first-line setting; and
    b. Used in combination with nivolumab.

Yervoy® (Ipilimumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Member must have unresectable disease and is not a transplant candidate; or
2. Metastatic disease or extensive liver tumor burden; and
3. Used as second-line or greater therapy; and
4. Used in combination with nivolumab; and
5. Must not have failed other checkpoint inhibitors.

Yervoy® (Ipilimumab) Approval Criteria [Mesothelioma Diagnosis]:

1. Diagnosis of malignant pleural mesothelioma that cannot be surgically removed; and
2. Used as first-line therapy; and
3. Used in combination with nivolumab.

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

1. Diagnosis of recurrent, advanced, or metastatic NSCLC; and
    a. Used for first-line therapy and must meet the following:
        i. No epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; and
        ii. Used in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy; and

iii. Expresses programmed death ligand 1 (PD-L1) ≥1%.

Yervoy® (Ipilimumab) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of relapsed or surgically unresectable stage 4 disease in the initial treatment of members with intermediate or poor risk, previously untreated, advanced RCC; and
2. Used in combination with nivolumab; and
3. Member has not failed previous programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Dose as follows: nivolumab 3mg/kg followed by ipilimumab 1mg/kg on the same day, every 3 weeks for a maximum of 4 doses, then nivolumab 240mg every 2 weeks or 480mg every 4 weeks.

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

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

Yervoy® (Ipilimumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Used in combination with nivolumab as:
   a. First-line therapy; or
   b. Second-line or subsequent therapy for disease progression if nivolumab was not previously used; or
3. Used as a single agent for 1 of the following:
   a. First-line therapy as a single course of 4 treatments; or
   b. Second-line or subsequent lines of therapy as a single course of 4 treatments; or
   c. Retreatment, consisting of a 4-dose limit, for a member who had:
      i. No significant systemic toxicity during prior ipilimumab therapy; and
      ii. Whose disease progressed after being stable >6 months following completion of a prior course of ipilimumab; and
      iii. For whom no intervening therapy has been administered; and
4. Maximum dose of 3mg/kg will apply.

Zelboraf® (Vemurafenib) Approval Criteria [Erdheim-Chester Disease (ECD) Diagnosis]:

1. Diagnosis of ECD; and

2. *BRAF* V600E or V600K mutation; and
3. Used as a single agent.

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

1. Diagnosis of hairy-cell leukemia; and
2. Used as a single agent; and
3. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine).

Zelboraf® (Vemurafenib) Approval Criteria [Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. *BRAF* V600E or V600K mutation; and
   a. Vemurafenib is not indicated for wild-type *BRAF* melanoma; and
3. Must meet 1 of the following:
   a. Used as first-line therapy; or
   b. Used as second-line or subsequent therapy; and
4. Used as a single agent or in combination with cobimetinib.

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

1. Diagnosis of refractory or metastatic NSCLC; and
2. *BRAF* V600E or V600K mutation; and
   a. Vemurafenib is not indicated for wild-type *BRAF* NSCLC; and
3. Used as a single agent.

Utilization of Skin Cancer Medications: Fiscal Year 2023

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

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	27	183	$1,668,536.09	$9,117.68	$317.63	11,925	5,253
2023	39	330	$3,244,376.20	$9,831.44	$338.45	24,874	9,586
% Change	**44.40%**	**80.30%**	**94.40%**	**7.80%**	**6.60%**	**108.60%**	**82.50%**
Change	**12**	**147**	**$1,575,840.11**	**$713.76**	**$20.82**	**12,949**	**4,333**

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

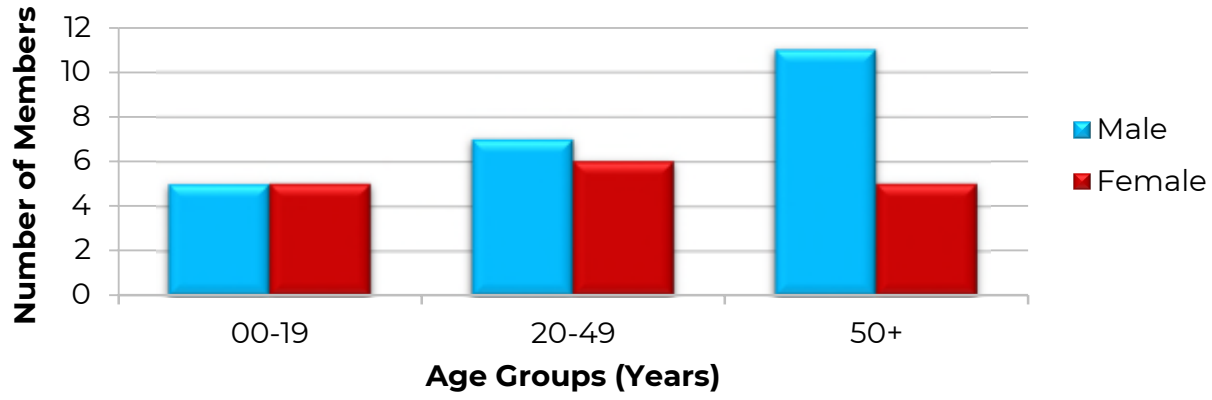
Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	276	1,315	$15,027,704.13	$11,427.91	4.76
2023	431	2,511	$28,312,651.99	$11,275.45	5.83
% Change	**56.16%**	**90.95%**	**88.40%**	**-1.33%**	**22.48%**
Change	**155**	**1,196**	**$13,284,947.86**	**-$152.46**	**1.07**

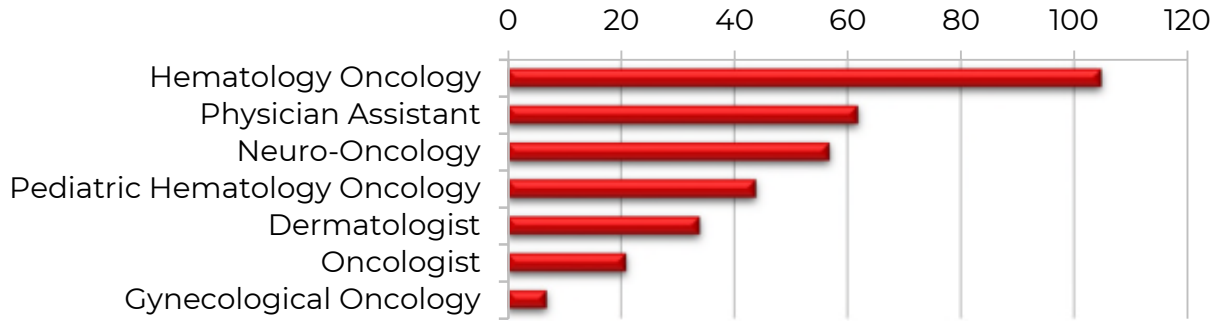
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

- Aggregate drug rebates collected during fiscal year 2023 for skin cancer medications totaled $5,826,893.97.[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 Skin Cancer Medications: Pharmacy Claims



Top Prescriber Specialties of Skin Cancer Medications by Number of Claims: Pharmacy 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 Skin Cancer Medications

There were 1,163 prior authorization requests submitted for skin cancer 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[1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17]

Anticipated Patent Expiration(s):

- Erivedge® (vismodegib): December 2028
- Zelboraf® (vemurafenib): June 2032
- Braftovi® (encorafenib): August 2033
- Mektovi® (binimetinib): October 2033
- Mekinist® (trametinib dimethyl sulfoxide): March 2034
- Odomzo® (sonidegib phosphate): March 2036
- Cotellic® (cobimetinib fumarate): December 2036
- Tafinlar® (dabrafenib mesylate): June 2038

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

- **October 2022:** The FDA approved Cotellic® (cobimetinib) for a new indication for the treatment of adult patients with histiocytic neoplasms.
- **January 2023:** The FDA approved Keytruda® (pembrolizumab) for a new indication for the adjuvant treatment of stage 1B (T2a ≥4cm), stage 2, or stage 3A non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy.
- **February 2023:** The FDA approved Opdivo® (nivolumab) for an age expansion for 2 melanoma indications: (1) treatment of adult and pediatric patients 12 years of age and older with unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab and (2) treatment of adult and pediatric patients 12 years of age and older with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting.

- **March 2023:** The FDA approved Mekinist® (trametinib) in combination with Tafinlar® (dabrafenib) for a new indication for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a *BRAF* V600E mutation who require systemic therapy.
- **March 2023:** The FDA granted accelerated approval to Zynyz™ (retifanlimab-dlwr) for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).
- **April 2023:** The FDA granted accelerated approval for Keytruda® for a new indication in combination with Padcev® (enfortumab vedotin-ejfv) for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.
- **August 2023:** The FDA approved Hepzato Kit™ (melphalan) as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting <50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.
- **August 2023:** The FDA granted accelerated approval to Mekinist® (trametinib) in combination with Tafinlar® (dabrafenib) for an expanded age range in patients 1 year of age and older with unresectable or metastatic solid tumors with *BRAF* V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This combination was previously granted accelerated FDA approval for this indication in patients 6 years of age and older in June 2022.
- **October 2023:** The FDA approved Braftovi® (encorafenib) in combination with Mektovi® (binimetinib) for a new indication for the treatment of adult patients with metastatic NSCLC with a *BRAF* V600E mutation, as detected by an FDA-approved test.
- **October 2023:** The FDA approved Opdivo® for an expanded indication for the adjuvant treatment of adult and pediatric patients 12 years of age and older with completely resected stage 2B, 2C, 3, or 4 melanoma.
- **October 2023:** The FDA approved Keytruda® for a new indication for the treatment of patients with resectable (tumors ≥4cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
- **October 2023:** The FDA approved Keytruda® for a new indication, in combination with gemcitabine and cisplatin, for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer.
- **November 2023:** The FDA approved a revised indication for Keytruda®, in combination with trastuzumab, fluoropyrimidine, and platinum-

containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma. The new indication now restricts use to patients whose tumors express programmed death ligand 1 (PD-L1) [combined positive score (CPS) ≥1] as determined by an FDA-approved test.

- **November 2023:** The FDA approved Keytruda® for a new indication, in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma.

Guideline Update(s):

- The National Comprehensive Cancer Network (NCCN) now recommends Opdivo® (nivolumab) in combination with Adcetris® (brentuximab vedotin) as second line or subsequent therapy for relapsed/refractory classical Hodgkin lymphoma after failure of autologous stem cell transplant (SCT), allogeneic SCT, or in those who are transplant-ineligible.

Hepzato Kit™ (Melphalan) Product Summary[18]

Therapeutic Class: Alkylating drug

Indication(s): Liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation

How Supplied: Hepzato Kit™ includes the following components:

- (5) single-dose vials (SDVs) containing 50mg lyophilized melphalan for reconstitution
- (5) SDVs containing 10mL sterile diluent for reconstitution
- (2) plastic containers containing 250mL 0.9% sodium chloride injection
- Hepatic delivery system (HDS) device

Dosing and Administration:

- Administered by infusion into the hepatic artery via the HDS device every 6-8 weeks for up to 6 total infusions
- Recommended dose is 3mg/kg based on ideal body weight (IBW) up to a maximum of 220mg during a single treatment

Cost: Cost information for Hepzato Kit™ is not available at this time.

Zynyz™ (Retifanlimab-dlwr) Product Summary[19]

Therapeutic Class: Programmed death receptor-1 (PD-1)–blocking antibody

Indication(s): Treatment of adult patients with metastatic or recurrent locally advanced MCC

How Supplied: 500mg/20mL solution in a SDV

Dose: 500mg by IV infusion over 30 minutes every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months

Cost: The Wholesale Acquisition Cost (WAC) of Zynyz™ is $712 per milliliter, resulting in a cost of $14,240 per dose or $185,120 per year based on the recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Hepzato Kit™ (melphalan) and Zynyz™ (retifanlimab-dlwr) with the following criteria (shown in red):

Hepzato Kit™ (Melphalan) Approval Criteria [Uveal Melanoma Diagnosis]:

1. Diagnosis of metastatic uveal melanoma; and
2. Presence of hepatic metastases affecting <50% of the liver; and
3. No other extrahepatic metastases; or
4. Presence of extrahepatic metastases limited to the bone, lymph nodes, subcutaneous tissue, and/or lung that is amenable to resection or radiation.

Zynyz™ (Retifanlimab-dlwr) Approval Criteria [Merkel Cell Carcinoma (MCC) Diagnosis]:

1. Diagnosis of metastatic or recurrent locally advanced MCC; and
2. Member must be 18 years of age or older; and
3. A maximum treatment duration of 24 months will apply.

The College of Pharmacy also recommends updating the approval criteria for Braftovi® (encorafenib), Cotellic® (cobimetinib), Keytruda® (pembrolizumab), Mekinist® (trametinib), Opdivo® (nivolumab), and Tafinlar® (dabrafenib) based on recent FDA approvals (new criteria and changes shown in red):

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

1. Diagnosis of metastatic NSCLC; and
2. *BRAF* V600E mutation; and
3. Used in combination with binimetinib.

Cotellic® (Cobimetinib) Approval Criteria [Histiocytic Neoplasm Diagnosis]:

1. Diagnosis of a histiocytic neoplasm; and
2. Member must be 18 years of age or older; and
3. Used as a single agent.

Keytruda® (Pembrolizumab) Approval Criteria [Biliary Tract Cancer (BTC) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic BTC; and
2. Used in combination with gemcitabine and cisplatin.

Keytruda® (Pembrolizumab) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced, unresectable, or metastatic gastric or GEJ adenocarcinoma; and
2. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Opdivo® (nivolumab)]; and
3. For first-line therapy:
    a. Human epidermal receptor 2 (HER2)-positive disease; and
        i. Used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy; and
        ii. Tumor is positive for expression of programmed death ligand 1 (PD-L1) with a combined positive score (CPS) ≥1; or
    b. HER2-negative disease; and
        i. Used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Keytruda® (Pembrolizumab) Approval Criteria [Nonmetastatic Non-Small Cell Lung Cancer (NSCLC) Diagnosis]:

1. Diagnosis of stage 3 NSCLC; and
    a. Ineligible for surgery or definitive chemoradiation; and
    b. Tumor proportion scores for PD-L1 expression ≥1%; and
    c. Member has not previously failed other PD-1 inhibitors [e.g., Opdivo (nivolumab)]; or
2. Diagnosis of stage 1B (T2a ≥4cm), stage 2, or stage 3A NSCLC; and
    a. Used as adjuvant treatment following resection and platinum-based chemotherapy; or
3. Diagnosis of resectable (tumors ≥4cm or node positive) NSCLC; and
    a. Used as neoadjuvant treatment in combination with platinum-containing chemotherapy; and
    b. Continued as a single agent as adjuvant treatment after surgery.

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

1. Member must have 1 of the following:

a. Locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy; or
b. Within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; or
c. Frontline for members with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy; and
    i. Cisplatin ineligibility is defined as:
        1. Baseline creatinine clearance of <60mL/min; or
        2. ECOG performance status of 2; or
        3. Class III heart failure; or
        4. Grade 2 or greater peripheral neuropathy; or
        5. Grade 2 or greater hearing loss; and

2. Used as monotherapy or in combination with enfortumab vedotin-ejfv; and
3. Member has not previously failed other programmed death 1 (PD-1) inhibitors [i.e., Opdivo® (nivolumab)].

Mekinist® (Trametinib) Approval Criteria [Low-Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of LGG; and
2. Must be a pediatric member 1 year of age or older; and
3. *BRAF* V600E mutation; and
4. Used in combination with dabrafenib.

Mekinist® (Trametinib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and
2. *BRAF* V600E mutation; and
3. Member must be 1 year of age or older; and
4. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
5. Used in combination with dabrafenib.

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

1. Diagnosis of metastatic NSCLC; and
2. *BRAF* V600E mutation; and
3. Used in combination with encorafenib.

Opdivo® (Nivolumab) Approval Criteria [Adjuvant Treatment of Melanoma Diagnosis]:

1. Member has had complete resection of melanoma; and
2. Diagnosis of stage 2B, 2C, 3, or 4 melanoma following complete resection; and

3. Member is 12 years of age or older; and
4. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
5. Used as a single agent; and
6. Dose as follows:
    a. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; ~~and~~ or
    b. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; and
    c. Maximum duration of 1 year.

Opdivo® (Nivolumab) Approval Criteria [Unresectable or Metastatic Melanoma Diagnosis]:

1. Diagnosis of unresectable or metastatic melanoma; and
2. Member is 12 years of age or older; and
3. Used as a single agent or in combination with ipilimumab:
    a. As first-line therapy for untreated melanoma; or
    b. As second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy; and
        i. Member has not previously failed other programmed death 1 (PD-1) inhibitors [e.g., Keytruda® (pembrolizumab)]; and
4. Dose as follows:
    a. Single agent:
        i. Adult and pediatric patients ≥40kg: 240mg every 2 weeks or 480mg every 4 weeks; or
        ii. Pediatric patients <40kg: 3mg/kg every 2 weeks or 6mg/kg every 4 weeks; or
    b. In combination with ipilimumab:
        i. Adult and pediatric patients ≥40kg: Nivolumab 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 240mg every 2 weeks or 480mg every 4 weeks; or
        ii. Pediatric patients <40kg: 1mg/kg, followed by ipilimumab on the same day, every 3 weeks for 4 doses, then 3mg/kg every 2 weeks or 6mg/kg every 4 weeks.

Tafinlar® (Dabrafenib) Approval Criteria [Low-Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of LGG; and
2. Must be a pediatric member 1 year of age or older; and
3. *BRAF* V600E mutation; and
4. Used in combination with trametinib.

Tafinlar® (Dabrafenib) Approval Criteria [Solid Tumor Diagnosis]:

1. Diagnosis of metastatic solid tumor; and

2. *BRAF* V600E mutation; and
3. Member must be 1 year of age or older; and
4. Member has progressed on prior therapies with no satisfactory alternative treatment options; and
5. Used in combination with trametinib.

Lastly, the College of Pharmacy recommends updating the Opdivo® (nivolumab) approval criteria for a diagnosis of classical Hodgkin lymphoma based on NCCN recommendations (changes shown in red):

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

1. Diagnosis of relapsed or refractory classical Hodgkin lymphoma; and
   a. Exception: lymphocyte-predominant HL
2. Nivolumab must be used in 1 of the following settings:
   a. As a single-agent; or
   b. In combination with brentuximab vedotin as second line or subsequent therapy after failure of autologous stem cell transplant (SCT), allogeneic SCT, or those who are transplant-ineligible; and
3. Member has not previously failed other PD-1 inhibitors [e.g., Keytruda® (pembrolizumab)].

Utilization Details of Skin Cancer Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DABRAFENIB PRODUCTS						
TAFINLAR CAP 75MG	54	10	$532,931.21	$9,869.10	5.4	16.43%
TAFINLAR CAP 50MG	42	7	$340,633.78	$8,110.33	6	10.50%
SUBTOTAL	**96**	**17**	**$873,564.99**	**$9,099.64**	**5.65**	**26.93%**
VISMODEGIB PRODUCTS						
ERIVEDGE CAP 150MG	65	13	$791,789.08	$12,181.37	5	24.40%
SUBTOTAL	**65**	**13**	**$791,789.08**	**$12,181.37**	**5**	**24.40%**
TRAMETINIB PRODUCTS						
MEKINIST TAB 2MG	37	9	$514,848.18	$13,914.82	4.11	15.87%
MEKINIST TAB 0.5MG	26	4	$266,884.46	$10,264.79	6.5	8.23%
SUBTOTAL	**63**	**13**	**$781,732.64**	**$12,408.45**	**4.85**	**24.10%**
COBIMETINIB PRODUCTS						
COTELLIC TAB 20MG	42	5	$279,366.59	$6,651.59	8.4	8.61%
SUBTOTAL	**42**	**5**	**$279,366.59**	**$6,651.59**	**8.4**	**8.61%**
VEMURAFENIB PRODUCTS						
ZELBORAF TAB 240MG	35	3	$243,336.96	$6,952.48	11.67	7.50%
SUBTOTAL	**35**	**3**	**$243,336.96**	**$6,952.48**	**11.67**	**7.50%**
BINIMETINIB PRODUCTS						
MEKTOVI TAB 15MG	14	4	$126,217.70	$9,015.55	3.5	3.89%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**14**	**4**	**$126,217.70**	**$9,015.55**	**3.5**	**3.89%**
ENCORAFENIB PRODUCTS						
BRAFTOVI CAP 75MG	10	3	$117,488.44	$11,748.84	3.33	3.62%
SUBTOTAL	**10**	**3**	**$117,488.44**	**$11,748.84**	**3.33**	**3.62%**
SONIDEGIB PRODUCTS						
ODOMZO CAP 200MG	5	1	$30,879.80	$6,175.96	5	0.95%
SUBTOTAL	**5**	**1**	**$30,879.80**	**$6,175.96**	**5**	**0.95%**
TOTAL	**330**	**39***	**$3,244,376.20**	**$9,831.44**	**8.46**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9271 PEMBROLIZUMAB INJ	1,642	304	$19,279,928.70	$11,741.73	5.4
J9299 NIVOLUMAB INJ	676	116	$5,828,621.39	$8,622.22	5.83
J9228 IPILIMUMAB INJ	120	45	$2,536,022.20	$21,133.52	2.67
J9119 CEMIPLIMAB-RWLC INJ	62	13	$590,292.50	$9,520.85	4.77
J9023 AVELUMAB INJ	11	2	$77,787.20	$7,071.56	5.5
TOTAL	**2,511**	**431**	**$28,312,651.99**	**$11,275.45**	**5.83**

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

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Appendix L

Fiscal Year 2023 Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Rystiggo® (Rozanolixizumab-noli), Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc), and Zilbrysq® (Zilucoplan)

Oklahoma Health Care Authority
December 2023

Current Prior Authorization Criteria

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

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Empaveli® must be prescribed by, or in consultation with, a gastroenterologist, hematologist, geneticist, or a specialist with expertise in the treatment of PNH; and
4. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and
5. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
7. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®.

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

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and

5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Enspryng® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
8. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
9. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
10. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
11. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
12. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and
13. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
14. 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.

Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS) Diagnosis]:

1. An FDA approved diagnosis of aHUS; and
2. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS.

Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

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

    a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
    b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIg); and
6. Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
7. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

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

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have a history of at least 2 NMOSD attacks in last 12 months or 3 attacks in the last 24 months, with at least 1 attack in the past 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤7; and
5. Soliris® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. 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.

Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or a specialist with expertise in the treatment of PNH.

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

1. An FDA approved diagnosis of aHUS; and
2. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS.

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

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapy (IST); and
7. Ultomiris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber must verify member is currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying Ultomiris® treatment outweigh the risks of developing a meningococcal infection; and
10. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

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

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Ultomiris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or a specialist with expertise in the treatment of PNH.

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

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months, or at least 2 attacks in the prior 24 months, requiring rescue therapy; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤8; and

5. Uplizna® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and
6. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
7. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
8. Prescriber must agree to monitor member for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
9. Prescriber must verify testing for quantitative serum immunoglobulins has been performed before the first dose and levels are acceptable to prescriber; and
10. Prescriber must agree to monitor the level of serum immunoglobulins during and after discontinuation of treatment with Uplizna® until B-cell repletion; and
11. The infusion must be administered under the supervision of a health care professional with access to appropriate medical support to manage potential severe reactions, and the patient must be observed for at least 1 hour after the completion of each infusion; and
12. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test prior to initiation of treatment; and
13. Female members of reproductive potential must use contraception while receiving Uplizna® and for 6 months after the last infusion; and
14. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
15. A quantity limit override for the loading dose will be approved upon meeting the Uplizna® approval criteria. A quantity limit of 30mL per 180 days will apply for the maintenance dose; and
16. 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.

Vyvgart® (Efgartigimod Alfa-fcab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

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

6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapy (IST); and
7. Vyvgart® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

Utilization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: 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	4	42	$1,368,017.73	$32,571.85	$1,252.76	5,137	1,092
2023	7	39	$2,200,272.11	$56,417.23	$1,312.81	3,419	1,676
% Change	**75.00%**	**-7.10%**	**60.80%**	**73.20%**	**4.80%**	**-33.40%**	**53.50%**
Change	**3**	**-3**	**$832,254.38**	**$23,845.38**	**$60.05**	**-1,718**	**584**

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

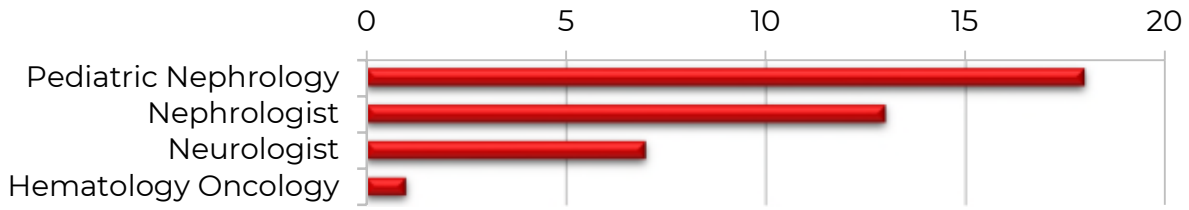
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2022	5	17	$933,019.50	$54,883.50	4,140
2023	15	117	$3,016,651.73	$25,783.35	48,574
% Change	**200%**	**588.24%**	**223.32%**	**-53.02%**	**1,073.29%**
Change	**10**	**100**	**$2,083,632.23**	**-$29,100.15**	**44,434**

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 Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Pharmacy Claims

- Due to the limited number of members utilizing complement inhibitors and miscellaneous immunomodulatory agents during fiscal year 2023, detailed demographic information could not be provided.

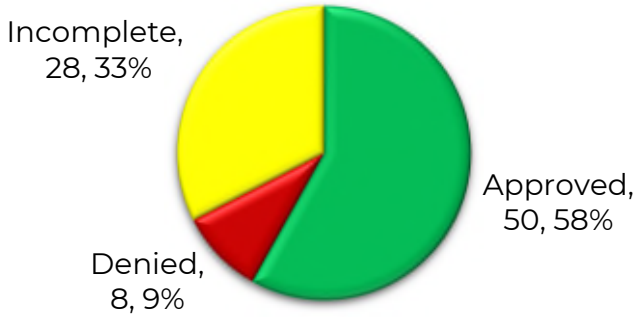
Top Prescriber Specialties of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Pharmacy Claims



Prior Authorization of Complement Inhibitors and Miscellaneous Immunomodulatory Agents

There were 86 prior authorization requests submitted for 27 unique members for complement inhibitors and miscellaneous immunomodulatory agents 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[1,2,3,4,5,6,7,8]

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

- **June 2021:** The FDA approved Ultomiris® (ravulizumab-cwvz) to treat patients 1 month of age or older with paroxysmal nocturnal hemoglobinuria (PNH). Previously, Ultomiris® was only indicated in adults for PNH.
- **July 2022:** The FDA approved a subcutaneous (sub-Q) formulation of Ultomiris® (ravulizumab-cwvz) for the treatment of adult patients with atypical hemolytic uremic syndrome (aHUS) and PNH. Ultomiris® was previously approved in an intravenous (IV) injection only. The IV product is also indicated for PNH or aHUS in pediatric patients and adults for generalized myasthenia gravis (gMG). The sub-Q formulation is not approved for these indications.
- **June 2023:** The FDA approved Rystiggo® (rozanolixizumab-noli) for the treatment of gMG in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

It is the only treatment approved by the FDA for both anti-AChR and anti-MuSK antibody positive gMG.

- **June 2023:** The FDA approved Vyvgart® Hytrulo (efgartigimod alfa/ hyaluronidase-qvfc) as a sub-Q injection for the treatment of gMG in adult patients who are AChR antibody positive. Previously, Vyvgart® (efgartigimod-alfa) was available as an IV product only. The addition of the recombinant human hyaluronidase PH20 (rHuPH20) helped facilitate the sub-Q delivery of efgartigimod-alfa.
- **September 2023:** The FDA approved Empaveli® Injector, a compact, single-use, on-body device designed for self-administration of Empaveli® (pegcetacoplan), which is FDA approved to treat adults with PNH. Previously, Empaveli® was given sub-Q through an infusion pump.
- **October 2023:** The FDA approved Zilbrysq® (zilucoplan) for the treatment of gMG in adults who are AChR antibody positive. It is a once-daily sub-Q, targeted C5 complement inhibitor for gMG that can be self-administered.

Pipeline:

- **Descartes-08:** A Phase 1b/2a study, MG-001, looked at the use of an RNA-based chimeric antigen receptor T-cell (rCAR-T) therapy, called Descartes-08, in 14 patients with gMG who previously received standard immunosuppressive therapies. The initial results showed patients tolerated Descartes-08 well and experienced improvement in disease severity scales. An ongoing Phase 2b randomized controlled study is currently enrolling patients.
- **Iptacopan:** Iptacopan is an orally administered targeted factor B inhibitor of the alternate complement pathway. Iptacopan is being studied for several complement-mediated diseases including aHUS and PNH.

Rystiggo® (Rozanolixizumab-noli) Product Summary[9]

Therapeutic Class: Neonatal Fc receptor blocker

Indication(s): Treatment of gMG in adult patients who are anti-AChR or anti-MuSK antibody positive

How Supplied: 280mg/2mL solution in a single-dose vial (SDV)

Dosing and Administration:

- The need to administer age-appropriate vaccines should be evaluated according to immunization guidelines before initiation of a new treatment cycle with Rystiggo®.
- The recommended dosage is administered as a sub-Q infusion using an infusion pump at a rate of up to 20mL/hour once weekly for 6 weeks (see Figure 1 for specific doses).

- Subsequent treatment cycles should be administered based on clinical evaluation; the safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established.
- Rystiggo® should only be prepared and infused by a health care provider.

Figure 1: Dose of Rystiggo® by Body Weight		
Body Weight	**Dose**	**Volume to be Infused**
Less than 50kg	420mg	3mL
50kg to less than 100kg	560mg	4mL
100kg and above	840mg	6mL

Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc) Product Summary[10]

Therapeutic Class: Neonatal Fc receptor blocker/endoglycosidase

Indication(s): Treatment of gMG in adult patients who are anti-AChR antibody positive

How Supplied: 1,008mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6mL (180mg/2,000 units per mL) in a SDV

Dosing and Administration:

- The need to administer age-appropriate vaccines should be evaluated according to immunization guidelines before initiation of a new treatment cycle with Vyvgart® Hytrulo.
- Vyvgart® Hytrulo should only be administered by a health care provider.
- The recommended dose is 1,008mg efgartigimod alfa and 11,200 units hyaluronidase administered as a fixed dose sub-Q over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks.
- Subsequent treatment cycles should be administered based on clinical evaluation; the safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

Zilbrysq® (Zilucoplan) Product Summary[11]

Therapeutic Class: Complement inhibitor

Indication(s): Treatment of gMG in adult patients who are anti-AChR antibody positive

How Supplied: 16.6mg/0.416mL, 23mg/0.574mL, or 32.4mg/0.81mL solution in single-dose prefilled syringes

Dosing and Administration:

- Before initiating Zilbrysq®, baseline lipase and amylase levels should be obtained.
- Meningococcal vaccination should be completed or updated at least 2 weeks prior to administering the first dose of Zilbrysq® unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection.
- The recommended dosage is given once daily as a sub-Q injection and is dependent on actual body weight (see Figure 2 below).
- Zilbrysq® should be given under the guidance and supervision of a health care provider; however, patients may self-inject Zilbrysq® after training in sub-Q injection technique.

Figure 2: Dose of Zilbrysq® by Body Weight	
Body Weight	**Dose**
Less than 56kg	16.6mg
56kg to less than 77kg	23mg
77kg and above	32.4mg

Cost Comparison: gMG Therapies

Medication	Cost Per mL	Cost Per Year
Rystiggo® (rozanolixizumab-noli) 280mg/2mL	**$3,025.00**	**$363,000α**
Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) 1,008mg/5.6mL	**$2,816.61**	**$441,644β**
Vyvgart® (efgartigimod alfa-fcab) 400mg/20mL	$303.45	$339,864+
Ultomiris® (ravulizumab-cwvz) 1,100mg/11mL	$2,134.67	$493,109*
Soliris® (eculizumab) 300mg/30mL	$217.43	$678,382±

Costs do not reflect rebated prices or net costs. Cost based on wholesale acquisition cost (WAC).
Cost information for Zilbrysq® is currently not available.
αCosts based on an 80kg patient receiving 560mg weekly for 6 infusions per cycle (5 cycles per year).
βCosts based on a fixed dose of 1,008mg/5.6mL with 4 infusions per cycle (7 cycles per year).
+Costs based on an 80kg patient receiving an 800mg dose with 4 infusions per cycle (7 cycles per year).
*Costs based on an 80kg patient receiving an IV maintenance dose of 3,300mg every 8 weeks.
±Costs based on recommended maintenance dosing of 1,200mg every 2 weeks.

Recommendations

The College of Pharmacy recommends the prior authorization of Rystiggo® (rozanolixizumab-noli) and Zilbrysq® (zilucoplan) with the following criteria (shown in red):

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

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

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

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

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Zilbrysq® must be prescribed by, or in consultation with, a neurologist, or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
9. Prescriber and pharmacy must be enrolled in the Zilbrysq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
10. Member must not be receiving Zilbrysq® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and

11. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Zilbrysq®; and
12. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

The College of Pharmacy also recommends the prior authorization of Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) with criteria similar to Vyvgart® (efgartigimod alfa-fcab) and recommends updating the Vyvgart® approval criteria to be consistent with clinical practice (new criteria and changes shown in red):

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

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

Additionally, the College of Pharmacy recommends the following changes to the Ultomiris® (ravulizumab-cwvz) prior authorization criteria based on the FDA approved age expansion, approval of the sub-Q formulation of Ultomiris®, and to be consistent with clinical practice (changes shown in red):

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

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

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

1. An FDA approved diagnosis of gMG; and
2. Member must be 18 years of age or older; and
3. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
4. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
5. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
6. Member must be on a stable dose of either an acetylcholinesterase (AChE) inhibitor or immunosuppressive therapies (ISTs) or a patient specific, clinically significant reason why the member cannot use an AChE inhibitor or an IST must be provided; and
7. Ultomiris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
8. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and

9. ~~Prescriber must verify member is currently vaccinated against *Neisseria meningitidis*, unless the risks of delaying Ultomiris® treatment outweigh the risks of developing a meningococcal infection; and~~
10. Prescriber must be enrolled in the Ultomiris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
11. The subcutaneous (sub-Q) formulation of Ultomiris® will not be approved for a diagnosis of gMG; and
12. Member must not be receiving Ultomiris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and
13. Initial approvals will be for the duration of 6 months, at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

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

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

Additionally, the College of Pharmacy recommends the following changes to the Soliris® (eculizumab) prior authorization criteria based on net cost and to be consistent with clinical practice (changes shown in red):

Soliris® (Eculizumab) Approval Criteria [Atypical Hemolytic Uremic Syndrome (aHUS)]:

1. An FDA approved diagnosis of aHUS; and
2. Prescriber must confirm the member does not have Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HS); and
3. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, nephrologist, or a specialist with expertise in the treatment of aHUS;
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Soliris® (Eculizumab) Approval Criteria [Generalized Myasthenia Gravis (gMG) Diagnosis]:

1. An FDA approved diagnosis of gMG; and
2. Member must have a positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies; and
3. Member must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV; and
4. Member must have a MG-Activities of Daily Living (MG-ADL) total score ≥6; and
5. Member must meet 1 of the following:
    a. Failed treatment over 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; or
    b. Failed at least 1 IST and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIg); and
6. Soliris® must be prescribed by, or in consultation with, a neurologist or a specialist with expertise in the treatment of gMG; and
7. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
8. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
9. Use of Soliris® will require a patient specific, clinically significant reason why the member cannot use Ultomiris® (ravulizumab-cwvz); and
10. Member must not be receiving Soliris® in combination with a neonatal Fc receptor blocker (i.e., Rystiggo®, Vyvgart®, Vyvgart® Hytrulo); and

11. Initial approvals will be for the duration of 6 months at which time an updated MG-ADL score must be provided. Continued authorization requires improvement in the MG-ADL score from baseline. Subsequent approvals will be for the duration of 1 year.

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

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

Soliris® (Eculizumab) Approval Criteria [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or a specialist with expertise in the treatment of PNH; and
4. Prescriber must verify member does not have unresolved *Neisseria meningitidis* infection; and
5. Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

Finally, the College of Pharmacy recommends the following changes to Empaveli® (pegcetacoplan), Enspryng® (satralizumab-mwge), and Uplizna®

(inebilizumab-cdon) to be consistent with clinical practice (changes shown in red):

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

1. An FDA approved diagnosis of PNH; and
2. Member must be 18 years of age or older; and
3. Empaveli® must be prescribed by, or in consultation with, a gastroenterologist, hematologist, geneticist, or a specialist with expertise in the treatment of PNH; and
4. For member self-administration or caregiver administration, the prescriber must verify the member or caregiver has been trained by a health care provider on proper administration and storage of Empaveli®; and
5. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
6. For members switching from Soliris® to Empaveli®, prescriber must verify the member will continue the current dose of Soliris® for 4 weeks before switching to Empaveli® as monotherapy; and
7. For members switching from Ultomiris® to Empaveli®, prescriber must verify that Empaveli® will be initiated no more than 4 weeks after the last dose of Ultomiris®; and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

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

1. An FDA approved indication of NMOSD in adult members who are anti-aquaporin-4 (AQP4) antibody positive; and
2. Member must be 18 years of age or older; and
3. Member must have experienced at least 1 acute NMOSD attack in the prior 12 months; and
4. Member must have an Expanded Disability Severity Scale (EDSS) score ≤6.5; and
5. Prescriber must verify hepatitis B virus (HBV) and tuberculosis (TB) screening are negative before the first dose; and
6. Approvals will not be granted for members with active HBV infection or active or untreated latent TB; and
7. Enspryng® must be prescribed by, or in consultation with, a neurologist, ophthalmologist, or a specialist with expertise in the treatment of NMOSD; and

8. Prescriber must verify liver function tests have been assessed prior to initiation of treatment with Enspryng® and levels are acceptable to prescriber; and
9. Prescriber must agree to counsel the member to monitor for clinically significant active infection(s) prior to each dose (for active infections, the dose should be delayed until the infection resolves); and
10. Prescriber must agree to monitor neutrophil counts 4 to 8 weeks after initiation of therapy and thereafter as clinically appropriate; and
11. Prescriber must verify member has not received any vaccinations within 4 weeks prior to initiation of therapy; and
12. Member and/or caregiver must be trained by a health care professional on subcutaneous administration and storage of Enspryng®; and
13. A quantity limit override for the loading dose will be approved upon meeting the Enspryng® approval criteria. A quantity limit of 1 syringe per 28 days will apply for the maintenance dose, according to the package labeling; and
14. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for 1 year.

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

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

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

Utilization Details of Complement Inhibitors and Miscellaneous Immunomodulatory Agents: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ULTOMIRIS INJ 300MG/3ML	20	4	$1,268,193.88	$63,409.69	5
SOLIRIS INJ 10MG/ML	11	1	$430,643.51	$39,149.41	11
ULTOMIRIS INJ 1,100MG/11ML	7	1	$493,188.92	$70,455.56	7
EMPAVELI INJ 54MG/ML	1	1	$8,245.80	$8,245.80	1
TOTAL	**39**	**7***	**$2,200,272.11**	**$56,417.23**	**5.57**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VYVGART INJ 400MG/20ML (J9332)	73	7	$1,251,051.73	$17,137.69	10.4
SOLIRIS INJ 10MG/ML (J1300)	29	4	$689,596.80	$24,089.54	7.25
ULTOMIRIS INJ 300MG/30ML (J1303)	15	5	$1,067,003.20	$71,133.55	3
TOTAL	**117⁺**	**15***	**$3,016,651.73**	**$25,783.35**	**7.8**

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

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Appendix M

Fiscal Year 2023 Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Exxua™ (Gepirone) and Zurzuvae™ (Zuranolone)

Oklahoma Health Care Authority
December 2023

Current Prior Authorization Criteria

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps*
escitalopram tabs & soln (Lexapro®)			fluoxetine tabs*
fluoxetine caps & soln (Prozac®)			fluoxetine DR (Prozac® Weekly™)*
fluvoxamine (Luvox®)			fluvoxamine CR (Luvox CR®)
paroxetine (Paxil®)			paroxetine CR (Paxil CR®)
sertraline tabs & soln (Zoloft®)			paroxetine (Pexeva®)
			sertraline 150mg & 200mg caps*
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron SolTab®)		nefazodone (Serzone®)	duloxetine (Drizalma Sprinkle™)*
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	duloxetine 40mg (Irenka™)*
venlafaxine tabs & ER caps (Effexor®, Effexor XR®)			trazodone 300mg tabs (Desyrel®)*
			venlafaxine besylate ER 112.5mg tablets*

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			venlafaxine ER tabs (Effexor XR®)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)*
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/ bupropion (Auvelity™)*
			esketamine nasal spray (Spravato®)*

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

Antidepressants Tier-2 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial of 2 Tier-1 medications at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response. Tier-1 selection must include at least 1 medication from the SSRI category; or
2. Prior stabilization on the Tier-2 medication documented within the last 100 days. A past history of success on the Tier-2 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by Tier-1 medications or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Tier-3 Approval Criteria:

1. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier 1 selection must include at least 1 medication from the SSRI category) and a trial of a Tier-2 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; or
2. Prior stabilization on the Tier-3 medication documented within the last 100 days. A past history of success on the Tier-3 medication will also be considered with adequate documentation; or
3. A unique FDA-approved indication not covered by a lowered tiered medication or other medications from a different therapeutic class; or
4. A petition may be submitted for consideration whenever a unique patient-specific situation exists.

Antidepressants Special Prior Authorization (PA) Approval Criteria:

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

Auvelity™ (Dextromethorphan/Bupropion) Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD); and
2. Member must be 18 years of age or older; and
3. Prescriber must agree that member's blood pressure will be assessed prior to treatment initiation and monitored periodically during treatment; and
4. Prescriber must agree to screen members for history of bipolar disorder, mania, or hypomania; and
5. Member must not be taking any other medications containing bupropion or dextromethorphan; and
6. Member must not have any contraindications to therapy (i.e., seizure disorder; current or prior diagnosis of bulimia or anorexia nervosa; abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs; concomitant use of a monoamine-oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI; known hypersensitivity to bupropion, dextromethorphan, or other components of Auvelity™); and
7. Member must not have severe hepatic or renal impairment; and
8. The maximum approvable dose is 1 tablet once daily if the member has moderate renal impairment, is taking a strong CYP2D6 inhibitor (e.g., paroxetine, fluoxetine, quinidine), or is a known poor CYP2D6 metabolizer; and
9. Prescriber must verify that female members are not currently pregnant and will use effective contraception while receiving treatment with Auvelity™; and
10. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier 1 selection must include bupropion as 1 of the 2 trials), 1 Tier-2 medication, and 1 Tier-3 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; or
11. Prior stabilization on the requested medication documented within the last 100 days. A history of success on the requested medication will also be considered with adequate documentation; and
12. A quantity limit of 60 tablets per 30 days will apply.

Citalopram Capsule Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD) in adults; and
2. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use citalopram tablets, which are available without a prior authorization, in place of the capsule formulation must be provided; and
4. Citalopram capsules will not be approved for members 60 years of age or older; and
5. A quantity limit of 30 capsules per 30 days will apply.

Desyrel® (Trazodone 300mg Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use other available generic Tier-1 products including 2 trazodone 150mg tablets or 3 trazodone 100mg tablets to achieve a 300mg dose must be provided.

Drizalma Sprinkle™ (Duloxetine Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:

1. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
2. A patient-specific, clinically significant reason why the member cannot use generic duloxetine 20mg, 30mg, or 60mg capsules, which are available without prior authorization, in place of Drizalma Sprinkle™ must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply.

Fluoxetine Tablet Approval Criteria:

1. Fluoxetine capsules are available without a prior authorization. The tablet formulation will require prior authorization and a patient-specific, clinically significant reason why the tablet formulation is required in place of the capsule formulation.

Irenka™ (Duloxetine 40mg Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:

1. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
2. A patient-specific, clinically significant reason why the member cannot use 2 duloxetine 20mg capsules in place of Irenka™ 40mg capsules must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply; and

Marplan® (Isocarboxazid) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use any of the Tier-3 monoamine oxidase inhibitors (MAOIs) or other cost-effective, lower tiered alternatives in place of Marplan® must be provided.

Sertraline Capsule Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD) in adults or obsessive-compulsive disorder (OCD) in adults and pediatric members 6 years of age and older; and
2. Member must have initiated treatment with sertraline tablets for dose titration up to the 150mg or 200mg dose; and
3. A patient-specific, clinically significant reason why the member cannot use sertraline tablets, which are available without a prior authorization, in place of the capsule formulation must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Depressive Symptoms in Adults with Major Depressive Disorder (MDD) with Acute Suicidal Ideation or Behavior Diagnosis]:

1. An FDA approved indication of depressive symptoms in adults with MDD with acute suicidal ideation or behavior; and
2. Member must be 18 years of age or older; and
3. Spravato® must be used in conjunction with an oral antidepressant; and
4. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
5. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with package labeling; and
6. Member must not have any contraindications to therapy [i.e., aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and
7. Member must not have severe hepatic impairment (Child Pugh C); and
8. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
9. Prescriber must verify female member is not breastfeeding; and
10. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
11. Member must be enrolled in the Spravato® REMS program; and
12. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and

13. For initial approval, the number of doses the member received while hospitalized, if applicable, and the dates of these doses must be provided to allow authorization of the appropriate quantity for the initial 4 weeks of treatment; and
14. For continued authorization, prescriber must verify member demonstrated an adequate response during the initial 4 weeks of treatment, verify member is using Spravato® in combination with an oral antidepressant, and provide patient-specific, clinically significant information to support continued use of Spravato®; and
15. A quantity limit of 8 kits per 28 days will apply.

Spravato® (Esketamine Nasal Spray) Approval Criteria [Treatment-Resistant Depression Diagnosis]:

1. An FDA approved diagnosis of treatment-resistant depression in adults; and
2. Member must be 18 years of age or older; and
3. Spravato® must be used in conjunction with an oral antidepressant; and
4. Member must have had an inadequate response to at least 2 different antidepressants from different classes at least 4 weeks in duration each and titrated to recommended dosing during the current depressive episode, unless contraindicated or clinically significant adverse effects; and
5. Prescriber must agree that member will be monitored by a health care provider for at least 2 hours after each administration; and
6. Prescriber must agree that member's blood pressure will be monitored prior to and after administration of Spravato® in accordance with package labeling; and
7. Member must not have any contraindications to therapy [e.g., aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation; intracerebral hemorrhage; hypersensitivity to esketamine, ketamine, or any of the excipients]; and
8. Member must not have severe hepatic impairment (Child Pugh C); and
9. Prescriber must verify that female member is not currently pregnant and will use effective contraception while receiving treatment with Spravato®; and
10. Prescriber must verify female member is not breastfeeding; and
11. Pharmacy and health care setting must be certified in the Spravato® Risk Evaluation and Mitigation Strategy (REMS) program; and
12. Member must be enrolled in the Spravato® REMS program; and
13. Spravato® must be administered under the direct observation of a health care provider in a REMS certified health care setting; and
14. Initial approvals will be for the duration of the induction phase. For continued authorization, prescriber must verify member demonstrated

an adequate response during the induction phase and verify member is using Spravato® in combination with an oral antidepressant; and

15. A quantity limit of 4 kits per 28 days will apply for maintenance dosing.

Approval Criteria for Atypical Antipsychotics as Adjunctive Treatment of Major Depressive Disorder (MDD):*

1. For Rexulti® (brexpiprazole), Symbyax® (olanzapine/fluoxetine), or Vraylar® (cariprazine), a diagnosis of MDD requires current use of an antidepressant and requires previous trials with at least 2 other antidepressants from both categories (an SSRI and a dual-acting antidepressant) and a trial of aripiprazole tablets that did not yield adequate response; and
2. Tier structure rules still apply.

*Rexulti® (brexpiprazole), Symbyax® (olanzapine/fluoxetine), and Vraylar® (cariprazine) are reviewed annually with the atypical antipsychotic medications. A full review of these medications, including utilization data, can be found in the June 2023 Drug Utilization Review (DUR) Board packet.

Utilization of Antidepressants: Fiscal Year 2023

Comparison of Fiscal Years

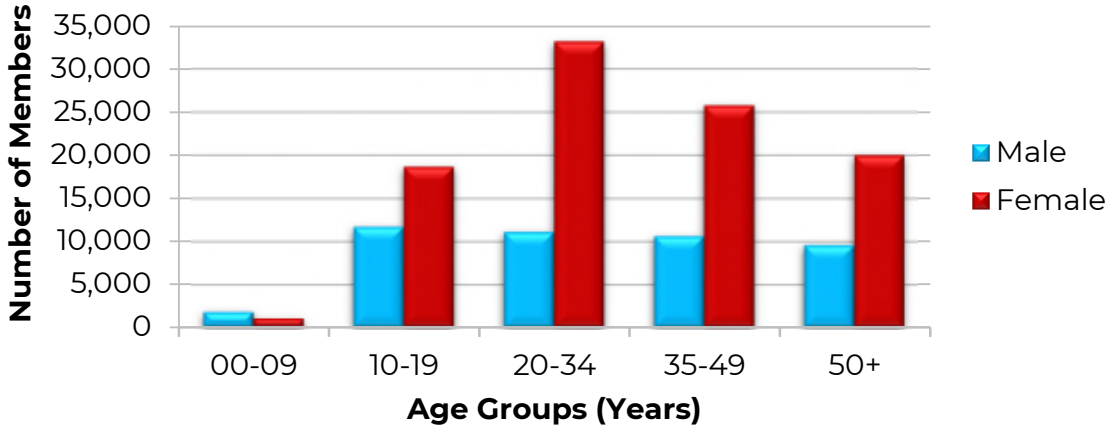
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	119,877	612,837	$10,349,946.35	$16.89	$0.43	27,659,629	23,931,353
2023	142,912	718,878	$12,822,729.54	$17.84	$0.43	34,351,763	29,836,452
% Change	**19.2%**	**17.3%**	**23.9%**	**5.6%**	**0.0%**	**24.2%**	**24.7%**
Change	**23,035**	**106,041**	**$2,472,783.19**	**$0.95**	**$0.00**	**6,692,164**	**5,905,099**

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

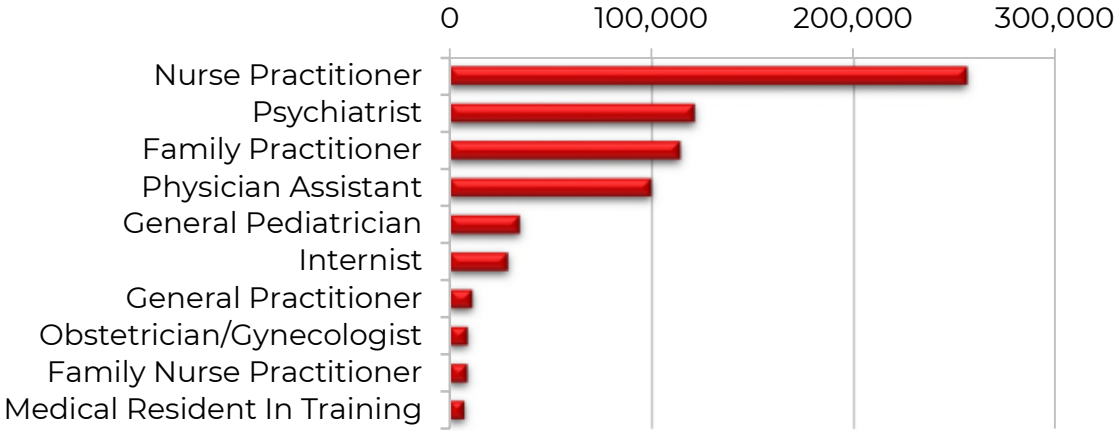
- There were no SoonerCare paid medical claims for antidepressants in fiscal year 2023 (07/01/2022 to 06/30/2023).
- Aggregate drug rebates collected during fiscal year 2023 for antidepressants totaled $2,203,707.62.[Δ] Rebates are collected after reimbursement for the medication and are not reflected 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.

Demographics of Members Utilizing Antidepressants



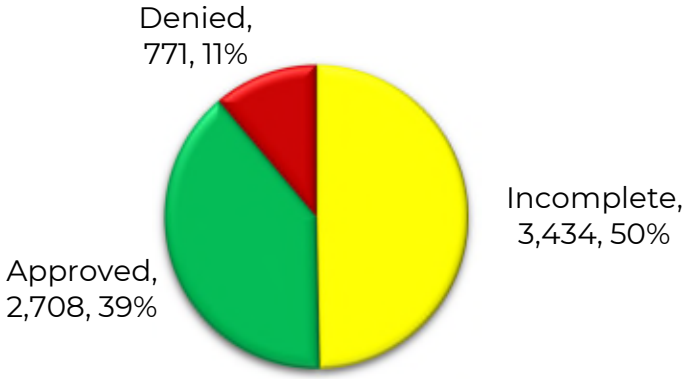
Top Prescriber Specialties of Antidepressants by Number of Claims



Prior Authorization of Antidepressants

There were 6,913 prior authorization requests submitted for antidepressants 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[1,2,3,4,5,6,7]

Anticipated Patent Expiration(s):

- Exxua™ [gepirone extended-release (ER) tablets]: September 2025
- Aplenzin® (bupropion ER) tablets]: June 2026
- Forfivo XL® (bupropion ER tablets): June 2027
- Trintellix® (vortioxetine tablets): March 2032
- Fetzima® (levomilnacipran ER capsules): May 2032
- Spravato® (esketamine nasal spray): September 2035
- Drizalma Sprinkle™ [duloxetine delayed-release (DR) capsules]: April 2037
- Zurzuvae™ (zuranolone capsules): August 2037
- Auvelity™ (dextromethorphan/bupropion ER tablets): January 2040

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

- **August 2023:** The FDA approved Zurzuvae™ (zuranolone) as the first oral medication for the treatment of postpartum depression (PPD) in adults. Previously, the only FDA approved treatment option for PPD was an intravenous (IV) injection given in a health care facility for over 60 hours.
- **September 2023:** Exxua™ (gepirone) was approved by the FDA for the treatment of major depressive disorder (MDD) in adults. Exxua™ is the first antidepressant that selectively targets the serotonin 1A ($5\text{-}HT_{1A}$) receptor.

News:

- **May 2023:** Sebela Pharmaceuticals stated that all strengths of Pexeva® (paroxetine) will be discontinued and no longer available.
- **August 2023:** Biogen and Sage Therapeutics received a complete response letter (CRL) for Zurzuvae™ for the diagnosis of MDD in adults. The CRL stated that there was not substantial evidence to support the effectiveness of Zurzuvae™ for the treatment of MDD.

Pipeline:

- **Psilocybin:** Psilocybin is a tryptamine alkaloid found in a species of psilocybe mushrooms. It was found to have potential antidepressant efficacy from preliminary studies of patients with life-threatening cancer. A Phase 2b study was completed and showed that a single 25mg dose was associated with a statistically significant reduction in depression symptoms after 3 weeks in patients with treatment-resistant depression. Psilocybin has been granted FDA Breakthrough Therapy designation and Innovative Licensing and Access Pathway designation and a Phase 3 study is currently ongoing.
- **Rel-1017:** Relmada Therapeutic's Rel-1017, also known as esmethadone, is 1 component of the medication methadone that lacks significant

abuse and respiratory effects. Rel-1017 has been shown to potentially increase plasma levels of brain-derived neurotrophic factor and enhance the neural plasticity in the brain in MDD. It is thought that impaired neural plasticity can increase depression relapse or limit the effects of other therapies. Phase 2 data showed sustained antidepressant effects in those with an inadequate response to standard antidepressants. Phase 3 trials of Rel-1017 are currently ongoing.

Exxua™ (Gepirone) Product Summary[8]

Therapeutic Class: Selective 5-HT_{1A} receptor agonist

Indication(s): MDD in adults

How Supplied: 18.2mg, 36.3mg, 54.5mg, and 72.6mg ER tablets

Dosing and Administration:

- The recommended starting dose is 18.2mg orally once daily with food.
- Depending on tolerability and clinical response, the dose can be increased to 36.3mg daily on day 4, 54.5mg on day 7, and then 72.6mg after an additional week.
- Prior to initiating treatment, electrolyte abnormalities should be corrected, and an electrocardiogram (ECG) should be performed.
- Exxua™ should not be initiated if QTc is >450msec.

Cost: Cost information for Exxua™ is not available at this time.

Zurzuvae™ (Zuranolone) Product Summary[9]

Therapeutic Class: Neuroactive gamma-aminobutyric acid (GABA) A receptor positive modulator

Indication(s): PPD in adults

How Supplied: 20mg, 25mg, and 30mg capsules

Dosing and Administration:

- The recommended dose is 50mg once daily in the evening for 14 days.
- Zurzuvae™ should be administered with a fat-containing food.
- If central nervous system (CNS) depressant effects occur, the dose may be reduced to 40mg once daily.
- The dose should be reduced to 30mg once daily for the following:
  - Severe hepatic impairment
  - Moderate to severe renal impairment
  - Concomitant use with strong CYP3A4 inhibitors

Cost: The Wholesale Acquisition Cost (WAC) of Zurzuvae™ is $567.86 per capsule, regardless of strength. This results in an estimated cost of $15,900 for the recommended dose of 50mg once daily for 14 days.

Recommendations

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

1. Prior authorization of Exxua™ (gepirone) and placement into the Special PA Tier with the following additional criteria; and
2. Prior authorization of Zurzuvae™ (zuranolone) and placement into the Special PA Tier with the following additional criteria; and
3. Moving venlafaxine ER (Effexor XR) 75mg and 150mg tablets to Tier-1 based on net costs; and
4. The removal of Pexeva® (paroxetine) due to product discontinuation.

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram tabs & soln (Celexa®)			citalopram 30mg caps*
escitalopram tabs & soln (Lexapro®)			fluoxetine tabs*
fluoxetine caps & soln (Prozac®)			fluoxetine DR (Prozac® Weekly™)*
fluvoxamine (Luvox®)			fluvoxamine CR (Luvox CR®)
paroxetine (Paxil®)			paroxetine CR (Paxil CR®)
sertraline tabs & soln (Zoloft®)			~~**paroxetine (Pexeva®)**~~
			sertraline 150mg & 200mg caps*
Dual-Acting Antidepressants			
bupropion (Wellbutrin®, Wellbutrin SR®, XL®)	desvenlafaxine (Pristiq®)	desvenlafaxine (Khedezla®)	bupropion ER (Aplenzin®)
duloxetine (Cymbalta®)		levomilnacipran (Fetzima®)	bupropion ER (Forfivo XL®)
mirtazapine (Remeron®, Remeron SolTab®)		nefazodone (Serzone®)	duloxetine (Drizalma Sprinkle™)*

Antidepressants			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
trazodone 50mg, 100mg, & 150mg tabs (Desyrel®)		vilazodone (Viibryd®)	duloxetine 40mg (Irenka™)*
venlafaxine tabs & ER caps (Effexor®, Effexor XR®)			trazodone 300mg tabs (Desyrel®)*
venlafaxine 75mg & 150mg ER tabs (Effexor XR®)			venlafaxine besylate ER 112.5mg tablets*
			venlafaxine ER **225mg** tabs (Effexor XR®)
Monoamine Oxidase Inhibitors (MAOIs)			
		phenelzine (Nardil®)	isocarboxazid (Marplan®)*
		selegiline (Emsam®)	
		tranylcypromine (Parnate®)	
Unique Mechanisms of Action			
		vortioxetine (Trintellix®)	dextromethorphan/ bupropion (Auvelity™)*
			esketamine nasal spray (Spravato®)*
			gepirone (Exxua™)*
			zuranolone (Zurzuvae™)*

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

Exxua™ (Gepirone) Approval Criteria:

1. An FDA approved diagnosis of major depressive disorder (MDD); and
2. Member must be 18 years of age or older; and
3. Member must have a documented, recent (within 6 months) trial with 2 Tier-1 medications (Tier-1 selection must include at least 1 medication from the SSRI category), 1 Tier-2 medication, and 1 Tier-3 medication at least 4 weeks in duration each and titrated to recommended dosing, that did not provide an adequate response; and
4. Member must not have any contraindications to Exxua™, including:
    a. Prolonged QTc interval >450msec; and
    b. Congenital long QT syndrome; and
    c. Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin); and
    d. Severe hepatic impairment; and

e. Concomitant use of a monoamine-oxidase inhibitor (MAOI) or within 14 days of discontinuing an MAOI; and

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

Zurzuvae™ (Zuranolone) Approval Criteria:

1. An FDA approved diagnosis of moderate to severe postpartum depression (PPD); and
2. Member must be ≤12 months postpartum and the date of delivery must be provided; and
3. Member must be a female 18 years of age or older; and
4. Prescriber must verify the following:
   a. Member is not currently pregnant and will use effective contraception while receiving treatment and for 7 days after the last dose of Zurzuvae™; and
   b. Member is not breastfeeding or has agreed to temporarily hold breastfeeding during Zurzuvae™ therapy and for 7 days after the last dose; and
   c. Member has been counseled on the proper administration of Zurzuvae™ including taking with a fat-containing meal; and
   d. Member has been counseled on the central nervous system (CNS) depression effects of Zurzuvae™ and the member agrees not to drive or engage in other potentially hazardous activities until at least 12 hours after administration; and
5. Dosing and approval duration will be limited to the following:
   a. 50mg once daily for 14 days; or
   b. For members with severe hepatic impairment, moderate to severe renal impairment, or concomitant use with CYP3A4 inhibitors:
      i. 30mg once daily for 14 days; and
   c. If a dose reduction to 40mg once daily is required due to CNS depression effects, the manufacturer should be contacted to provide the 20mg capsules for the remainder of the member's treatment course; and
6. Approvals will be for 1 treatment course.

Utilization Details of Antidepressants: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 MEDICATIONS						
SERTRALINE PRODUCTS						
SERTRALINE TAB 100MG	49,875	13,246	$634,381.62	$12.72	3.77	4.95%
SERTRALINE TAB 50MG	49,852	18,943	$604,113.03	$12.12	2.63	4.71%
SERTRALINE TAB 25MG	25,553	10,691	$297,461.07	$11.64	2.39	2.32%
SERTRALINE 20MG/ML	859	243	$42,553.56	$49.54	3.53	0.33%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ZOLOFT TAB 50MG	1	1	$408.73	$408.73	1	0.00%
ZOLOFT TAB 100MG	1	1	$1,117.56	$1,117.56	1	0.01%
ZOLOFT TAB 25MG	1	1	$1,169.95	$1,169.95	1	0.01%
SUBTOTAL	**126,142**	**43,126**	**$1,581,205.52**	**$12.54**	**2.92**	**12.33%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 50MG	50,530	17,410	$526,022.25	$10.41	2.90	4.10%
TRAZODONE TAB 100MG	39,270	10,966	$452,804.88	$11.53	3.58	3.53%
TRAZODONE TAB 150MG	19,956	5,084	$271,569.84	$13.61	3.93	2.12%
SUBTOTAL	**109,756**	**33,460**	**$1,250,396.97**	**$11.39**	**3.28**	**9.75%**
FLUOXETINE PRODUCTS						
FLUOXETINE CAP 20MG	47,443	16,402	$492,736.57	$10.39	2.89	3.84%
FLUOXETINE CAP 40MG	26,699	7,792	$311,261.66	$11.66	3.43	2.43%
FLUOXETINE CAP 10MG	23,532	9,353	$283,571.99	$12.05	2.52	2.21%
FLUOXETINE SOL 20MG/5ML	1,772	423	$82,584.08	$46.61	4.19	0.64%
PROZAC CAP 20MG	12	2	$21,162.78	$1,763.57	6	0.17%
PROZAC CAP 40MG	8	1	$10,163.78	$1,270.47	8	0.08%
SUBTOTAL	**99,466**	**33,973**	**$1,201,480.86**	**$12.08**	**2.93**	**9.37%**
ESCITALOPRAM PRODUCTS						
ESCITALOPRAM TAB 10MG	44,427	17,425	$533,097.59	$12.00	2.55	4.16%
ESCITALOPRAM TAB 20MG	37,224	10,642	$495,885.83	$13.32	3.50	3.87%
ESCITALOPRAM TAB 5MG	9,417	4,175	$114,129.07	$12.12	2.26	0.89%
ESCITALOPRAM 5MG/5ML	421	97	$37,640.82	$89.41	4.34	0.29%
SUBTOTAL	**91,489**	**32,339**	**$1,180,753.31**	**$12.91**	**2.83**	**9.21%**
BUPROPION PRODUCTS						
BUPROPION TAB 150MG XL	31,485	12,025	$492,668.36	$15.65	2.62	3.84%
BUPROPION TAB 300MG XL	22,280	6,555	$364,816.59	$16.37	3.40	2.85%
BUPROPION TAB 150MG SR	12,191	4,578	$207,714.28	$17.04	2.66	1.62%
BUPROPION TAB 100MG SR	5,119	1,995	$74,326.97	$14.52	2.57	0.58%
BUPROPION TAB 75MG	2,957	1,177	$42,280.63	$14.30	2.51	0.33%
BUPROPION TAB 200MG SR	2,841	807	$46,564.40	$16.39	3.52	0.36%
BUPROPION TAB 100MG	2,147	749	$34,896.65	$16.25	2.87	0.27%
WELLBUTRIN TAB 150MG XL	19	2	$69,295.62	$3,647.14	9.50	0.54%
SUBTOTAL	**79,039**	**27,888**	**$1,332,563.50**	**$16.86**	**2.83**	**10.39%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 60MG	31,992	8,803	$520,156.61	$16.26	3.63	4.06%
DULOXETINE CAP 30MG	22,581	8,930	$332,672.12	$14.73	2.53	2.59%
DULOXETINE CAP 20MG	5,950	2,538	$89,269.35	$15.00	2.34	0.70%
CYMBALTA CAP 60MG	12	2	$6,721.40	$560.12	6	0.05%
CYMBALTA CAP 30MG	1	1	$273.12	$273.12	1	0.00%
SUBTOTAL	**60,536**	**20,274**	**$949,092.60**	**$15.68**	**2.99**	**7.40%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE CAP 150MG ER	14,840	3,848	$244,829.44	$16.50	3.86	1.91%
VENLAFAXINE CAP 75MG ER	13,818	4,897	$203,198.77	$14.71	2.82	1.58%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VENLAFAXINE CAP 37.5 ER	7,151	3,441	$96,160.67	$13.45	2.08	0.75%
VENLAFAXINE TAB 75MG	2,347	718	$33,064.24	$14.09	3.27	0.26%
VENLAFAXINE TAB 37.5MG	1,251	602	$15,817.37	$12.64	2.08	0.12%
VENLAFAXINE TAB 100MG	748	203	$11,025.16	$14.74	3.68	0.09%
VENLAFAXINE TAB 50MG	350	129	$4,733.72	$13.52	2.71	0.04%
VENLAFAXINE TAB 25MG	227	110	$2,752.99	$12.13	2.06	0.02%
EFFEXOR CAP 75MG XR	13	1	$6,663.01	$512.54	13	0.05%
EFFEXOR CAP 150MG XR	5	2	$7,713.47	$1,542.69	2.5	0.06%
SUBTOTAL	**40,750**	**13,951**	**$625,958.84**	**$15.36**	**2.92**	**4.88%**
CITALOPRAM PRODUCTS						
CITALOPRAM TAB 20MG	17,989	6,621	$174,526.16	$9.70	2.72	1.36%
CITALOPRAM TAB 40MG	11,811	3,371	$118,146.63	$10.00	3.5	0.92%
CITALOPRAM TAB 10MG	8,859	3,622	$86,564.48	$9.77	2.45	0.68%
CITALOPRAM 10MG/5ML	186	33	$10,269.78	$55.21	5.64	0.08%
SUBTOTAL	**38,845**	**13,647**	**$389,507.05**	**$10.03**	**2.85**	**3.04%**
MIRTAZAPINE PRODUCTS						
MIRTAZAPINE TAB 15MG	18,259	6,076	$220,357.91	$12.07	3.01	1.72%
MIRTAZAPINE TAB 30MG	9,903	2,988	$127,881.77	$12.91	3.31	1.00%
MIRTAZAPINE TAB 7.5MG	3,509	1,244	$120,057.69	$34.21	2.82	0.94%
MIRTAZAPINE TAB 45MG	3,382	835	$47,342.70	$14.00	4.05	0.37%
MIRTAZAPINE TAB 15MG ODT	399	145	$10,165.17	$25.48	2.75	0.08%
MIRTAZAPINE TAB 30MG ODT	180	52	$4,932.89	$27.40	3.46	0.04%
MIRTAZAPINE TAB 45MG ODT	146	47	$4,644.40	$31.81	3.11	0.04%
SUBTOTAL	**35,778**	**11,387**	**$535,382.53**	**$14.96**	**3.14**	**4.19%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 20MG	7,242	2,794	$79,779.22	$11.02	2.59	0.62%
PAROXETINE TAB 40MG	5,063	1,401	$71,244.68	$14.07	3.61	0.56%
PAROXETINE TAB 10MG	4,233	1,867	$53,609.68	$12.66	2.27	0.42%
PAROXETINE TAB 30MG	2,614	803	$34,965.14	$13.38	3.26	0.27%
PAROXETINE 10MG/5ML	94	24	$37,740.25	$401.49	3.92	0.29%
PAXIL 10MG/5ML	15	3	$4,978.55	$331.90	5	0.04%
SUBTOTAL	**19,261**	**6,892**	**$282,317.52**	**$14.66**	**2.79**	**2.20%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE TAB 100MG	2,162	394	$54,570.88	$25.24	5.49	0.43%
FLUVOXAMINE TAB 50MG	1,887	497	$39,467.43	$20.92	3.8	0.31%
FLUVOXAMINE TAB 25MG	727	222	$13,556.33	$18.65	3.27	0.11%
SUBTOTAL	**4,776**	**1,113**	**$107,594.64**	**$22.53**	**4.29**	**0.85%**
TIER-1 SUBTOTAL	**705,838**	**238,050**	**$9,436,253.34**	**$13.37**	**2.97**	**73.61%**
TIER-2 MEDICATIONS						
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE TAB 50MG ER	2,698	850	$78,261.92	$29.01	3.17	0.61%
DESVENLAFAXINE TAB 100MG ER	2,523	575	$77,364.58	$30.66	4.39	0.60%
DESVENLAFAXINE TAB 25MG ER	746	329	$21,316.93	$28.57	2.27	0.17%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PRISTIQ TAB 100MG	4	1	$5,072.34	$1,268.09	4	0.04%
SUBTOTAL	**5,971**	**1,755**	**$182,015.77**	**$30.48**	**3.4**	**1.42%**
TIER-2 SUBTOTAL	**5,971**	**1,755**	**$182,015.77**	**$30.48**	**3.4**	**1.42%**
TIER-3 MEDICATIONS						
VORTIOXETINE PRODUCTS						
TRINTELLIX TAB 20MG	2,050	322	$871,748.92	$425.24	6.37	6.80%
TRINTELLIX TAB 10MG	1,318	326	$553,517.09	$419.97	4.04	4.32%
TRINTELLIX TAB 5MG	266	91	$115,853.70	$435.54	2.92	0.90%
SUBTOTAL	**3,634**	**739**	**$1,541,119.71**	**$424.08**	**4.92**	**12.02%**
VILAZODONE PRODUCTS						
VILAZODONE TAB 40MG	967	163	$74,799.10	$77.35	5.93	0.58%
VILAZODONE TAB 20MG	502	122	$35,358.94	$70.44	4.11	0.28%
VIIBRYD TAB 40MG	246	65	$75,653.22	$307.53	3.78	0.59%
VIIBRYD TAB 20MG	138	46	$48,212.08	$349.36	3	0.38%
VILAZODONE TAB 10MG	119	36	$9,897.98	$83.18	3.31	0.08%
VIIBRYD TAB 10MG	19	11	$5,202.65	$273.82	1.73	0.04%
SUBTOTAL	**1,991**	**443**	**$249,123.97**	**$125.13**	**4.49**	**1.95%**
LEVOMILNACIPRAN PRODUCTS						
FETZIMA CAP 120MG	74	9	$33,076.21	$446.98	8.22	0.26%
FETZIMA CAP 80MG	58	9	$26,458.94	$456.19	6.44	0.21%
FETZIMA CAP 40MG	17	5	$7,003.59	$411.98	3.4	0.05%
FETZIMA CAP 20MG	8	6	$3,248.74	$406.09	1.33	0.03%
SUBTOTAL	**157**	**29**	**$69,787.48**	**$444.51**	**5.41**	**0.55%**
DESVENLAFAXINE PRODUCTS						
DESVENLAFAXINE TAB 100MG ER	44	24	$9,799.36	$222.71	1.83	0.08%
DESVENLAFAXINE TAB 50MG ER	42	19	$5,786.66	$137.78	2.21	0.05%
SUBTOTAL	**86**	**43**	**$15,586.02**	**$181.23**	**2**	**0.13%**
TRANYLCYPROMINE PRODUCTS						
TRANYLCYPROMINE TAB 10MG	17	2	$2,703.17	$159.01	8.5	0.02%
SUBTOTAL	**17**	**2**	**$2,703.17**	**$159.01**	**8.5**	**0.02%**
SELEGILINE PRODUCTS						
EMSAM PATCH 6MG/24HR	3	2	$3,741.28	$1,247.09	1.5	0.03%
SUBTOTAL	**3**	**2**	**$3,741.28**	**$1,247.09**	**1.5**	**0.03%**
TIER-3 SUBTOTAL	**5,888**	**1,258**	**$1,882,061.63**	**$319.64**	**4.68**	**14.70%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
FLUOXETINE PRODUCTS						
FLUOXETINE TAB 10MG	349	102	$4,495.42	$12.88	3.42	0.04%
FLUOXETINE TAB 20MG	129	38	$2,429.12	$18.83	3.39	0.02%
FLUOXETINE CAP 90MG DR	38	6	$5,040.26	$132.64	6.33	0.04%
FLUOXETINE TAB 60MG	3	1	$72.81	$24.27	3	0.00%
SUBTOTAL	**519**	**147**	**$12,037.61**	**$23.19**	**3.53**	**0.10%**
ESKETAMINE PRODUCTS						
SPRAVATO SOL 84MG DOSE	229	81	$1,164,634.18	$5,085.74	2.83	9.08%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SPRAVATO SOL 56MG DOSE	51	48	$100,740.23	$1,975.30	1.06	0.79%
SUBTOTAL	**280**	**129**	**$1,265,374.41**	**$4,519.19**	**2.17**	**9.87%**
PAROXETINE PRODUCTS						
PAROXETINE TAB 25MG ER	112	17	$3,868.43	$34.54	6.59	0.03%
PAROXETINE ER TAB 37.5MG	77	10	$2,594.95	$33.70	7.7	0.02%
PAROXETINE ER TAB 12.5MG	18	4	$617.57	$34.31	4.5	0.00%
SUBTOTAL	**207**	**31**	**$7,080.95**	**$34.21**	**6.68**	**0.05%**
FLUVOXAMINE PRODUCTS						
FLUVOXAMINE CAP 150MG ER	112	14	$27,720.98	$247.51	8	0.22%
FLUVOXAMINE CAP 100MG ER	24	4	$7,049.59	$293.73	6	0.05%
SUBTOTAL	**136**	**18**	**$34,770.57**	**$255.67**	**7.56**	**0.27%**
DULOXETINE PRODUCTS						
DULOXETINE CAP 40MG	20	7	$2,139.72	$106.99	2.86	0.02%
SUBTOTAL	**20**	**7**	**$2,139.72**	**$106.99**	**2.86**	**0.02%**
VENLAFAXINE PRODUCTS						
VENLAFAXINE TAB 225MG ER	6	3	$320.99	$53.50	2	0.00%
VENLAFAXINE TAB 75MG ER	3	3	$173.26	$57.75	1	0.00%
VENLAFAXINE TAB 37.5 ER	2	2	$112.74	$56.37	1	0.00%
SUBTOTAL	**11**	**8**	**$606.99**	**$55.18**	**1.38**	**0.00%**
TRAZODONE PRODUCTS						
TRAZODONE TAB 300MG	7	3	$230.14	$32.88	2.33	0.00%
SUBTOTAL	**7**	**3**	**$230.14**	**$32.88**	**2.33**	**0.00%**
CITALOPRAM PRODUCTS						
CITALOPRAM CAP 30MG	1	1	$158.41	$158.41	1	0.00%
SUBTOTAL	1	1	$158.41	$158.41	1	0.00%
SPECIAL PA SUBTOTAL	**1,181**	**344**	**$1,322,398.80**	**$1,119.73**	**3.43**	**10.31%**
TOTAL	**718,878**	**142,912***	**$12,822,729.54**	**$17.84**	**5.03**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; ER = extended-release; ODT = orally disintegrating tablet; SR = sustained-release; TAB = tablet; XL = extended-release
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

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Appendix N

Fiscal Year 2023 Annual Review of Lysosomal Storage Disease Medications and 30-Day Notice to Prior Authorize Elfabrio® (Pegunigalsidase Alfa-iwxj), Opfolda™ (Miglustat), and Pombiliti™ (Cipaglucosidase Alfa-atga)

Oklahoma Health Care Authority
December 2023

Current Prior Authorization Criteria

Aldurazyme® (Laronidase) Approval Criteria:

1. An FDA approved diagnosis of Hurler, Hurler-Scheie, or Scheie syndrome (mucopolysaccharidosis type I; MPS I) confirmed by:
   a. Enzyme assay demonstrating a deficiency of alpha-L-iduronidase (IDUA) enzyme activity; or
   b. Molecular genetic testing to confirm pathogenic mutations in the *IDUA* gene; and
2. For Scheie syndrome, the prescriber must document that the member has moderate-to-severe symptoms; and
3. Aldurazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
4. 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
5. 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.

Brineura® (Cerliponase Alfa) Approval Criteria:

1. An FDA approved diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) also known as tripeptidyl peptidase-1 (TPP-1) deficiency; and
2. Member must have confirmed TPP-1 enzymatic deficiency via enzyme assay, confirmed by molecular analysis; and
3. Member must be 3 years of age or older; and
4. Brineura® must be prescribed by a specialist with expertise in the treatment of CLN2 (or an advanced care practitioner with a supervising physician who is a specialist with expertise in treating CLN2); and
5. Brineura® must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration; and

6. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
7. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
8. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
9. Prescriber must be willing to perform regular 12-lead electrocardiogram (ECG) evaluation at baseline and at least every 6 months and verify that they are acceptable to the prescriber; and
10. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
11. Initial authorizations will be for the duration of 6 months, at which time compliance will be required for continued approval. After 12 months of utilization, the prescriber must verify the member is responding to the medication as demonstrated by ≤2 point decline in Motor plus Language CLN2 score from baseline; and
12. Approval quantity will be based on package labeling and FDA approved dosing regimen.

Cerdelga® (Eliglustat) Approval Criteria:

1. An FDA approved diagnosis of type 1 Gaucher disease (GD1); and
2. Member is classified as 1 of the following as detected by an FDA-cleared test:
    a. CYP2D6 extensive metabolizers (EMs); or
    b. CYP2D6 intermediate metabolizers (IMs); or
    c. CYP2D6 poor metabolizers (PMs); and
3. Prescriber must verify the member will not take Cerdelga® concurrently with another therapy for GD1; and
4. For CYP2D6 EMs and IMs, a quantity limit of 56 capsules per 28 days will apply. For CYP2D6 PMs, a quantity limit of 28 capsules per 28 days will apply; and
5. Approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication.

Cerezyme® (Imiglucerase), Elelyso® (Taliglucerase Alfa), and Vpriv® (Velaglucerase Alfa) Approval Criteria:

1. Diagnosis of symptomatic (e.g., anemia, thrombocytopenia, bone disease, splenomegaly, hepatomegaly) type 1 or type 3 Gaucher disease (GD); and
2. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing; and

3. Prescriber must verify the member will not take the requested therapy concurrently with another therapy for GD; and
4. Approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication.

Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of corneal cystine crystal accumulation in members with cystinosis; and
2. The requested medication must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has been counseled on the proper storage of the requested medication; and
4. For Cystadrops®, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Cystaran® must be provided; and
5. A quantity limit of 4 bottles per month will apply.

Elaprase® (Idursulfase) Approval Criteria:

1. An FDA approved diagnosis of Hunter syndrome (mucopolysaccharidosis type II; MPS II) confirmed by:
    a. Enzyme assay demonstrating a deficiency of iduronate-2-sulfatase enzyme activity; or
    b. Molecular genetic testing confirming a hemizygous pathogenic variant in the *IDS* gene; and
2. 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.

Fabrazyme® (Agalsidase Beta) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease. Diagnosis must be confirmed by 1 of the following:
    a. Genetic testing confirming positive galactosidase alpha (*GLA*) gene mutation; or
    b. Decreased plasma levels of alpha-galactosidase A (<5% of normal); and
2. Fabrazyme® will initially be approved for 6 months. After that time, compliance will be required for continued authorization; and
3. 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.

Galafold® (Migalastat) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease with a confirmed amenable galactosidase alpha (*GLA*) gene variant based on *in vitro* assay data; and
2. Galafold® must be prescribed by, or in consultation with, a geneticist or an advanced care practitioner with a supervising physician who is a geneticist; and
3. Member must have an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2; and
4. Galafold® will not be approved for concomitant use with enzyme replacement therapy (ERT); and
5. Galafold® will initially be approved for 6 months. After that time, compliance will be required for continued approval; and
6. A quantity limit of 14 capsules per 28 days will apply.

Kanuma® (Sebelipase Alfa) Approval Criteria:

1. An FDA approved diagnosis of lysosomal acid lipase (LAL) deficiency; and
2. Kanuma® (sebelipase alfa) must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
3. 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.

Lamzede® (Velmanase Alfa-tycv) Approval Criteria:

1. An FDA approved diagnosis of alpha-mannosidosis confirmed by:
    a. Documented lab results verifying alpha-mannosidase activity <11% of normal; or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *MAN2B1* gene; and
2. Member's recent weight (kg) taken within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
3. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Lamzede®; and
4. Lamzede® must be administered in a health care setting by a health care provider with appropriate equipment and personnel to manage anaphylaxis. Approvals will not be granted for self-administration; and
    a. Lamzede® must be shipped via cold chain supply to the health care setting where the member is scheduled to receive treatment; and
5. Lamzede® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; and

6. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents the member is responding well to treatment.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Infantile-Onset Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of infantile-onset Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Lumizyme® must be prescribed by a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Late-Onset (Non-Infantile) Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Provider must document presence of symptoms of Pompe disease; and
4. Lumizyme® must be prescribed by a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

Mepsevii® (Vestronidase Alfa-vjbk) Approval Criteria:

1. An FDA approved diagnosis of Sly syndrome (mucopolysaccharidosis VII; MPS VII) confirmed by:
   a. Enzyme assay demonstrating a deficiency of beta-glucuronidase activity; or
   b. Genetic testing to confirm diagnosis of MPS VII; and
2. Mepsevii® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and

4. 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.

Naglazyme® (Galsulfase) Approval Criteria:

1. An FDA approved diagnosis of Maroteaux-Lamy syndrome (mucopolysaccharidosis type VI; MPS VI) confirmed by:
   a. Enzyme assay demonstrating a deficiency of arylsulfatase B (ASB) enzyme activity; or
   b. Genetic testing to confirm diagnosis of MPS VI; and
2. Naglazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
3. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
4. 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.

Nexviazyme® (Avalglucosidase Alfa-ngpt) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency]; and
2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Nexviazyme® must be prescribed by a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

Procysbi® (Cysteamine Bitartrate) Delayed-Release Capsule and Granule Approval Criteria:

1. An FDA approved diagnosis of nephropathic cystinosis; and
2. A patient specific, clinically significant reason why the member cannot use the short-acting formulation, Cystagon® (cysteamine bitartrate), must be provided; and

3. Use of Procysbi® granules will also require a patient specific, clinically significant reason why the member cannot use the capsule formulation of Procysbi®.

Vimizim® (Elosulfase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Morquio A syndrome (mucopolysaccharidosis type IVA; MPS IVA) confirmed by:
   a. Enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity; or
   b. Molecular genetic testing to confirm biallelic pathogenic variants in the *GALNS* gene; and
2. Vimizim® must be administered by a health care professional prepared to manage anaphylaxis; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Xenpozyme® (Olipudase Alfa-rpcp) Approval Criteria:

1. An FDA approved diagnosis of acid sphingomyelinase deficiency (ASMD) type B or A/B confirmed by:
   a. Documented lab results verifying <10% of acid sphingomyelinase (ASM) activity from control; or
   b. Molecular genetic testing confirming a mutation in the *SMPD1* gene; and
2. Documentation of baseline AST and ALT within 1 month prior to treatment initiation or within 72 hours prior to treatment escalation; and
3. Member's weight (kg) and body mass index (BMI) within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
   a. BMI ≤30: The dosage is based on actual body weight (kg); or
   b. BMI >30: The dosage is based on adjusted body weight; and
4. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Xenpozyme®; and
5. Prescriber must verify ALT and AST will be assessed to manage the risk of elevated transaminases as directed by package labeling; and
6. Xenpozyme® must be administered by a health care provider prepared to manage anaphylaxis. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Xenpozyme® will be administered; and

a. Xenpozyme® must be shipped via cold chain supply to the health care facility where the member is scheduled to receive treatment; or
b. Xenpozyme® must be shipped via cold chain supply to the member's home and administered by a home health care provider prepared to manage anaphylaxis, and the member or member's caregiver must be trained on the proper storage of Xenpozyme®; and
    i. For consideration of home administration by a home health care provider, prescriber must verify member is receiving the maintenance dose and is tolerating the Xenpozyme® infusion well; and

7. Xenpozyme® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; 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.

Zavesca® (Miglustat) Approval Criteria:

1. An FDA approved diagnosis of mild/moderate type 1 Gaucher disease (GD1); and
2. A patient-specific, clinically significant reason why the member cannot use 1 of the following enzyme replacement therapies must be provided:
    a. Cerezyme® (imiglucerase); or
    b. Elelyso® (taliglucerase alfa); or
    c. Vpriv® (velaglucerase alfa); and
3. Prescriber must verify the member will not take Zavesca® concurrently with another therapy for GD1; and
4. A quantity limit of 90 capsules per 30 days will apply; and
5. Approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication.

Utilization of Lysosomal Storage Disease 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	10	109	$2,379,486.54	$21,830.15	$873.53	4,391	2,724
2023	12	134	$3,628,997.28	$27,082.07	$1,137.26	5,428	3,191
% Change	**20.00%**	**22.90%**	**52.50%**	**24.10%**	**30.20%**	**23.60%**	**17.10%**
Change	**2**	**25**	**$1,249,510.74**	**$5,251.92**	**$263.73**	**1,037**	**467**

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	5	114	$1,281,888.64	$11,244.64	22.8
2023	6	124	$1,829,954.57	$14,757.70	20.67
% Change	**20.00%**	**8.77%**	**42.75%**	**31.24%**	**-9.34%**
Change	**1**	**10**	**$548,065.93**	**$3,513.06**	**-2.13**

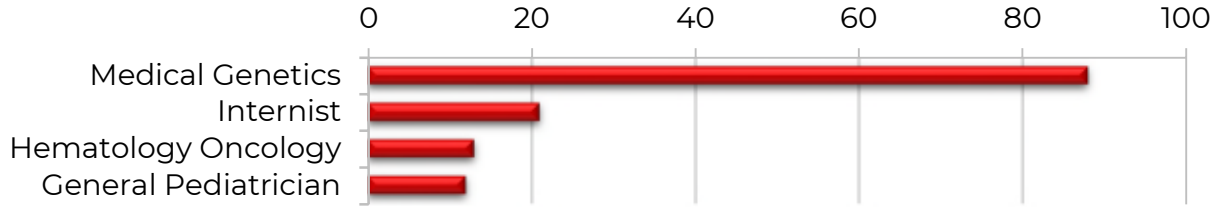
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

- Aggregate drug rebates collected during fiscal year 2023 for lysosomal storage disease medications totaled $886,106.08.[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 Lysosomal Storage Disease Medications: Pharmacy Claims

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

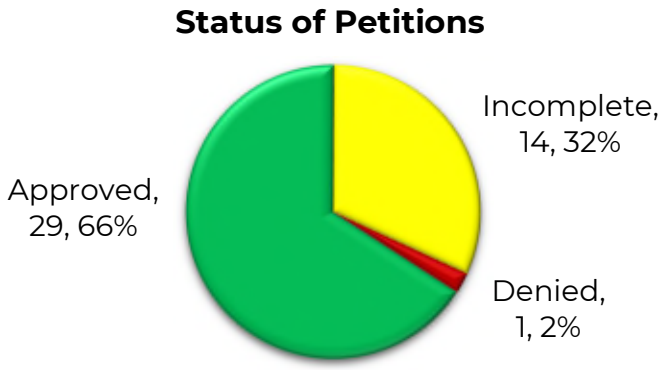
Top Prescriber Specialties of Lysosomal Storage Disease Medications: Pharmacy Claims



Prior Authorization of Lysosomal Storage Disease Medications

There were 44 prior authorization requests submitted for 16 unique members for lysosomal storage disease medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

[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.



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Procysbi® (cysteamine bitartrate): February 2037
- Opfolda™ (miglustat): August 2037
- Cerdelga® (eliglustat): December 2038
- Galafold® (migalastat): March 2039

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

- **May 2023:** The FDA approved Elfabrio® (pegunigalsidase alfa-iwxj) for the treatment of adults with confirmed Fabry disease.
- **September 2023:** The FDA approved Pombiliti™ (cipaglucosidase alfa-atga) in combination with Opfolda™ (miglustat) for the treatment of adult patients with late-onset Pompe disease [lysosomal acid alpha-glucosidase (GAA) deficiency] weighing ≥40kg and who are not improving on their current enzyme replacement therapy (ERT).

Elfabrio® (Pegunigalsidase Alfa-iwxj) Product Summary[4]

Therapeutic Class: Hydrolytic lysosomal neutral glycosphingolipid-specific enzyme

Indication(s): Treatment of adults with confirmed Fabry disease

How Supplied: 20mg/10mL solution in a single-dose vial (SDV)

Dosing and Administration:

- 1mg/kg (based on actual body weight) by intravenous (IV) infusion every 2 weeks
- Initial recommended infusion rates vary for ERT-experienced and ERT-naïve patients. Please refer to the full *Prescribing Information* for the complete infusion rate recommendations, including modifications to the infusion rate for hypersensitivity and/or infusion-associated reactions.

Cost Comparison: Fabry Disease Products

Product	Cost Per Unit	Cost Per 28 Days*	Cost Per Year
Elfabrio® (pegunigalsidase alfa-iwxj) 20mg/10mL vial	**$413.51**	**$33,080.80**	**$430,050.40**
Fabrazyme® (agalsidase beta) 35mg vial	$7,237.60	$33,085.48	$430,111.24
Fabrazyme® (agalsidase beta) 5mg vial	$1,033.77	$33,085.48	$430,111.24
Galafold® (migalastat) 123mg capsule	$2,062.86	$28,880.04	$375,440.52

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = each mL for Elfabrio®, each vial for Fabrazyme®, or each capsule for Galafold®
*Cost per 28 days based on FDA approved dosing for each product for a member weighing 80kg. Elfabrio® would require 4 vials (20mL) every 2 weeks. Fabrazyme® would require (2) 35mg vials and (2) 5mg vials every 2 weeks.

Opfolda™ (Miglustat) Product Summary[5]

Therapeutic Class: Enzyme stabilizer

Indication(s): Treatment of adult patients with late-onset Pompe disease (lysosomal GAA deficiency) weighing ≥40kg and who are not improving on their current ERT, in combination with Pombiliti™ (cipaglucosidase alfa-atga)

How Supplied: 65mg oral capsule

Dosing and Administration:

- Administered orally in combination with Pombiliti™ (based on actual body weight):
  - Weight ≥50kg: 260mg [(4) 65mg capsules] every other week
  - Weight <50kg: 195mg [(3) 65mg capsules] every other week
- Should be taken with an unsweetened beverage approximately 1 hour before the start of Pombiliti™ infusion
- Other beverages or food should not be consumed for at least 2 hours prior to and 2 hours after taking Opfolda™

Pombiliti™ (Cipaglucosidase Alfa-atga) Product Summary[6]

Therapeutic Class: Hydrolytic lysosomal glycogen-specific enzyme

Indication(s): Treatment of adult patients with late-onset Pompe disease (lysosomal GAA deficiency) weighing ≥40kg and who are not improving on their current ERT, in combination with Opfolda™ (miglustat)

How Supplied: 105mg SDV containing lyophilized powder for reconstitution

Dosing and Administration:

- 20mg/kg (based on actual body weight) by IV infusion over 4 hours every 2 weeks

- Infusion should begin approximately 1 hour after oral administration of Opfolda™

Cost Comparison: Pompe Disease Products

Product	Cost Per Unit	Cost Per 28 Days*	Cost Per Year
Pombiliti™ (cipaglucosidase alfa-atga) 105mg vial	**$1,785.00**	**$57,120.00**	**$742,560.00**
Opfolda™ (miglustat) 65mg capsule	**$32.50**	**$260.00**	**$3,380.00**
Lumizyme® (alglucosidase alfa) 50mg vial	$936.34	$59,925.76	$779,034.88
Nexviazyme® (avalglucosidase alfa-ngpt) 100mg vial	$1,800.65	$57,620.80	$749,070.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = each vial or capsule
*Cost per 28 days based on FDA approved dosing for each product for a member weighing 80kg. Pombiliti™ would require 16 vials every 2 weeks. Lumizyme® would require 32 vials every 2 weeks. Nexviazyme® would require 16 vials every 2 weeks.

Recommendations

The College of Pharmacy recommends the prior authorization of Elfabrio® (pegunigalsidase alfa-iwxj) with criteria similar to Fabrazyme® (agalsidase beta) and recommends updating the Fabrazyme® approval criteria to be consistent with clinical practice (new criteria and changes shown in red):

Elfabrio® (Pegunigalsidase Alfa-iwxj) and Fabrazyme® (Agalsidase Beta) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease confirmed by 1 of the following:
   a. Molecular genetic testing confirming ~~positive~~ a pathogenic variant in the galactosidase alpha (*GLA*) gene ~~mutation~~ (results of genetic testing must be submitted); or
   b. ~~Decreased plasma levels of~~ Enzyme assay demonstrating a deficiency of alpha-galactosidase A enzyme activity (<5% of normal) (results of assay must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Fabry disease; and
3. Requests for Elfabrio® will require a patient-specific, clinically significant reason why the member cannot use Fabrazyme®; and
4. Member will not be approved for concomitant use with Galafold® (migalastat); and
5. Member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and

6. ~~Fabrazyme® (agalsidase beta) will initially be approved for~~ Initial approvals will be for the duration of 6 months. After that time, compliance will be required for continued authorization and prescriber must verify the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

The College of Pharmacy also recommends the prior authorization of Opfolda™ (miglustat) and Pombiliti™ (cipaglucosidase alfa-atga) with the following criteria (shown in red):

Opfolda™ (Miglustat) and Pombiliti™ (Cipaglucosidase Alfa-atga) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
    a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
2. Member must be 18 years of age or older and weigh ≥40kg; and
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Member must be receiving a different enzyme replacement therapy (ERT) for Pompe disease and not experiencing improvement on the current ERT product; and
5. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for at least 60 days after the final dose; and
6. Must be administered in a health care setting by a health care provider with appropriate equipment and personnel to manage anaphylaxis. Approvals will not be granted for self-administration; and
    a. Must be shipped via cold chain supply to the health care setting where the member is scheduled to receive treatment; and
7. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease; and
8. Opfolda™ must be used in combination with Pombiliti™; and
    a. A separate, completed prior authorization request must be received for both medications; and
9. Member will not be approved for concomitant use with other ERT products for Pompe disease; and

10. Member's recent weight must be provided in order to authorize the appropriate amount of drug required according to package labeling; and
11. For Opfolda™, the following quantity limits will apply:
    a. Weight ≥50kg: 8 capsules per 28 days; or
    b. Weight 40kg to <50kg: 6 capsules per 28 days; and
12. Initial approvals will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Additionally, the College of Pharmacy recommends updating the approval criteria for other lysosomal storage disease medications (Aldurazyme®, Brineura®, Cerdelga®, Cerezyme®, Cystadrops®, Cystaran®, Elaprase®, Elelyso®, Galafold®, Kanuma®, Lamzede®, Lumizyme®, Mepsevii®, Naglazyme®, Nexviazyme®, Procysbi®, Vimizim®, Vpriv®, Xenpozyme®, and Zavesca®) based on clinical practice and net cost (changes shown in red):

Aldurazyme® (Laronidase) Approval Criteria:

1. An FDA approved diagnosis of Hurler, Hurler-Scheie, or Scheie syndrome (mucopolysaccharidosis type I; MPS I) confirmed by:
    a. Enzyme assay demonstrating a deficiency of alpha-L-iduronidase (IDUA) enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing to confirm biallelic pathogenic mutations in the *IDUA* gene (results of genetic testing must be submitted); and
2. For Scheie syndrome, the prescriber must document that the member has moderate-to-severe symptoms; and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS I; and
4. Aldurazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
6. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Brineura® (Cerliponase Alfa) Approval Criteria:

1. An FDA approved diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) also known as tripeptidyl peptidase-1 (TPP-1) deficiency confirmed by:
   a. Enzyme assay demonstrating a deficiency of TPP-1 enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *TPP1* gene (results of genetic testing must be submitted); and
2. ~~Member must have confirmed TPP-1 enzymatic deficiency via enzyme assay, confirmed by molecular analysis; and~~
3. Member must be 3 years of age or older; and
4. Brineura® must be prescribed by a specialist with expertise in the treatment of CLN2 (or an advanced care practitioner with a supervising physician who is a specialist with expertise in treating CLN2); and
5. Brineura® must be administered in a health care facility by a prescriber who is knowledgeable in intraventricular administration; and
6. Member must not have ventriculoperitoneal shunts or acute intraventricular access device-related complications; and
7. Member must not have documented generalized status epilepticus within 4 weeks of initiating treatment; and
8. Prescriber must verify member's blood pressure and heart rate will be monitored prior to each infusion, during infusion, and post-infusion; and
9. Prescriber must be willing to perform regular 12-lead electrocardiogram (ECG) evaluation at baseline and at least every 6 months and verify that they are acceptable to the prescriber; and
10. A baseline assessment must be performed to assess the Motor plus Language CLN2 score; and
11. Initial authorizations will be for the duration of 6 months, at which time compliance will be required for continued approval. After 12 months of utilization, the prescriber must verify the member is responding to the medication as demonstrated by ≤2 point decline in Motor plus Language CLN2 score from baseline. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment; and
12. Approval quantity will be based on package labeling and FDA approved dosing regimen.

Cerdelga® (Eliglustat) Approval Criteria:

1. An FDA approved diagnosis of type 1 Gaucher disease (GD1) confirmed by:

   a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. Member is classified as 1 of the following as detected by an FDA-cleared test:
   a. CYP2D6 extensive metabolizers (EMs); or
   b. CYP2D6 intermediate metabolizers (IMs); or
   c. CYP2D6 poor metabolizers (PMs); and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD1; and
4. Prescriber must verify the member will not take Cerdelga® concurrently with another therapy for GD1; and
5. For CYP2D6 EMs and IMs, a quantity limit of 56 capsules per 28 days will apply. For CYP2D6 PMs, a quantity limit of 28 capsules per 28 days will apply; and
6. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Cerezyme® (Imiglucerase), Elelyso® (Taliglucerase Alfa), and Vpriv® (Velaglucerase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Gaucher disease (GD) confirmed by:
   a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. ~~Diagnosis of~~ Prescriber must confirm member has symptomatic (e.g., anemia, thrombocytopenia, bone disease, splenomegaly, hepatomegaly) type 1 or type 3 GD; and
3. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD; and
4. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing; and
5. Prescriber must verify the member will not take the requested therapy concurrently with another therapy for GD; and
6. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the

medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of corneal cystine crystal accumulation in members with cystinosis confirmed by 1 of the following:
   a. Identification of cystine crystals in the cornea on slit lamp examination; or
   b. Identification of elevated cystine concentration in polymorphonuclear leukocytes; or
   c. Molecular genetic testing confirming biallelic pathogenic variants in the *CTNS* gene (results of genetic testing must be submitted); and
2. The requested medication must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has been counseled on the proper storage of the requested medication; and
4. For Cystadrops®, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Cystaran® must be provided; and
5. A quantity limit of 4 bottles per month will apply.

Elaprase® (Idursulfase) Approval Criteria:

1. An FDA approved diagnosis of Hunter syndrome (mucopolysaccharidosis type II; MPS II) confirmed by:
   a. Enzyme assay demonstrating a deficiency of iduronate-2-sulfatase enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming a hemizygous pathogenic variant in the *IDS* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS II; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Galafold® (Migalastat) Approval Criteria:

1. An FDA approved diagnosis of Fabry disease with a confirmed amenable galactosidase alpha (*GLA*) gene variant based on *in vitro* assay data (results of genetic testing must be submitted); and
2. Galafold® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Fabry disease (or an advanced care practitioner with a supervising physician who is a geneticist or other specialist with expertise in the treatment of Fabry disease); and
3. Member must have an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2; and
4. Galafold® will not be approved for concomitant use with enzyme replacement therapy (ERT); and
5. Galafold® will initially be approved for 6 months. After that time, compliance will be required for continued approval and prescriber must verify the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment; and
6. A quantity limit of 14 capsules per 28 days will apply.

Kanuma® (Sebelipase Alfa) Approval Criteria:

1. An FDA approved diagnosis of lysosomal acid lipase (LAL) deficiency confirmed by:
    a. Enzyme assay demonstrating a deficiency of LAL enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *LIPA* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of LAL deficiency; and
3. Kanuma® (sebelipase alfa) must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
4. 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
5. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Lamzede® (Velmanase Alfa-tycv) Approval Criteria:

1. An FDA approved diagnosis of alpha-mannosidosis confirmed by:

a. ~~Documented lab results~~ Enzyme assay verifying alpha-mannosidase enzyme activity <11% of normal (results of assay must be submitted); or
b. Molecular genetic testing confirming biallelic pathogenic variants in the *MAN2B1* gene (results of genetic testing must be submitted); and

2. Member's recent weight (kg) taken within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
3. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Lamzede®; and
4. Lamzede® must be administered in a health care setting by a health care provider with appropriate equipment and personnel to manage anaphylaxis. Approvals will not be granted for self-administration; and
   a. Lamzede® must be shipped via cold chain supply to the health care setting where the member is scheduled to receive treatment; and
5. Lamzede® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; and
6. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Infantile-Onset Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of infantile-onset Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
   a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and

~~2. Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and~~

3. Lumizyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
4. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing.

Lumizyme® (Alglucosidase Alfa) Approval Criteria [Late-Onset (Non-Infantile) Pompe Disease Diagnosis]:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
    a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
2. ~~Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and~~
3. Provider must document presence of symptoms of Pompe disease; and
4. Lumizyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

Mepsevii® (Vestronidase Alfa-vjbk) Approval Criteria:

1. An FDA approved diagnosis of Sly syndrome (mucopolysaccharidosis VII; MPS VII) confirmed by:
    a. Enzyme assay demonstrating a deficiency of beta-glucuronidase enzyme activity (results of assay must be submitted); or
    b. Molecular genetic testing to confirm ~~diagnosis of MPS VII~~ biallelic pathogenic variants in the *GUSB* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS VII; and
3. Mepsevii® must be administered by a health care professional prepared to manage anaphylaxis; and
4. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Naglazyme® (Galsulfase) Approval Criteria:

1. An FDA approved diagnosis of Maroteaux-Lamy syndrome (mucopolysaccharidosis type VI; MPS VI) confirmed by:
   a. Enzyme assay demonstrating a deficiency of arylsulfatase B (ASB) enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing to confirm ~~diagnosis of MPS VI~~ biallelic pathogenic variants in the *ARSB* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS VI; and
3. Naglazyme® must be administered by a health care professional prepared to manage anaphylaxis; and
4. 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
5. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Nexviazyme® (Avalglucosidase Alfa-ngpt) Approval Criteria:

1. An FDA approved diagnosis of late-onset (non-infantile) Pompe disease [acid alpha-glucosidase (GAA) deficiency] confirmed by:
   a. Enzyme assay demonstrating a deficiency of GAA enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GAA* gene (results of genetic testing must be submitted); and
2. ~~Documentation of diagnosis confirmation of GAA enzyme deficiency through specific genetic laboratory test(s); and~~
3. Prescriber must document presence of symptoms of Pompe disease; and
4. Nexviazyme® must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of Pompe disease and/or inherited genetic disorders; and
5. Member's weight must be provided and have been taken within the last 4 weeks to ensure accurate dosing; and
6. Initial approval will be for the duration of 6 months, at which time compliance and information regarding efficacy, such as improvement or stabilization in forced vital capacity (FVC) and/or 6-minute walk test (6MWT), will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

Procysbi® (Cysteamine Bitartrate) Delayed-Release Capsule and Granule Approval Criteria:

1. An FDA approved diagnosis of nephropathic cystinosis confirmed by 1 of the following:
   a. Identification of elevated cystine concentration in polymorphonuclear leukocytes; or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *CTNS* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a nephrologist or other specialist with expertise in the treatment of cystinosis; and
3. A patient specific, clinically significant reason why the member cannot use the short-acting formulation, Cystagon® (cysteamine bitartrate), must be provided; and
4. Use of Procysbi® granules will also require a patient specific, clinically significant reason why the member cannot use the capsule formulation of Procysbi®.

Vimizim® (Elosulfase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Morquio A syndrome (mucopolysaccharidosis type IVA; MPS IVA) confirmed by:
   a. Enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity (results of assay must be submitted); or
   b. Molecular genetic testing to confirm biallelic pathogenic variants in the *GALNS* gene (results of genetic testing must be submitted); and
2. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of MPS IVA; and
3. Vimizim® must be administered by a health care professional prepared to manage anaphylaxis; and
4. 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
5. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Xenpozyme® (Olipudase Alfa-rpcp) Approval Criteria:

1. An FDA approved diagnosis of acid sphingomyelinase deficiency (ASMD) type B or A/B confirmed by:
   a. Documented lab results verifying <10% of acid sphingomyelinase (ASM) activity from control (results of assay must be submitted); or

   b. Molecular genetic testing confirming ~~a mutation~~ biallelic pathogenic variants in the *SMPD1* gene (results of genetic testing must be submitted); and
2. Documentation of baseline AST and ALT within 1 month prior to treatment initiation or within 72 hours prior to treatment escalation; and
3. Member's weight (kg) and body mass index (BMI) within the last 3 weeks must be provided to ensure accurate weight-based dosing; and
   a. BMI ≤30: The dosage is based on actual body weight (kg); or
   b. BMI >30: The dosage is based on adjusted body weight; and
4. Female members of reproductive potential must have a negative pregnancy test prior to initiation and must agree to use effective contraception during treatment and for 2 weeks after the final dose of Xenpozyme®; and
5. Prescriber must verify ALT and AST will be assessed to manage the risk of elevated transaminases as directed by package labeling; and
6. Xenpozyme® must be administered by a health care provider prepared to manage anaphylaxis. Approvals will not be granted for self-administration. Prior authorization requests must indicate how Xenpozyme® will be administered; and
   a. Xenpozyme® must be shipped via cold chain supply to the health care facility where the member is scheduled to receive treatment; or
   b. Xenpozyme® must be shipped via cold chain supply to the member's home and administered by a home health care provider prepared to manage anaphylaxis, and the member or member's caregiver must be trained on the proper storage of Xenpozyme®; and
      i. For consideration of home administration by a home health care provider, prescriber must verify member is receiving the maintenance dose and is tolerating the Xenpozyme® infusion well; and
7. Xenpozyme® must be prescribed by, or in consultation with, a specialist with expertise in the treatment of lysosomal storage disorders; 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. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Zavesca® (Miglustat) Approval Criteria:

1. An FDA approved diagnosis of mild/moderate type 1 Gaucher disease (GD1) confirmed by:

   a. Enzyme assay demonstrating a deficiency of glucocerebrosidase enzyme activity (≤15% of normal) (results of assay must be submitted); or
   b. Molecular genetic testing confirming biallelic pathogenic variants in the *GBA1* gene (results of genetic testing must be submitted); and
2. A patient-specific, clinically significant reason why the member cannot use 1 of the following enzyme replacement therapies must be provided:
   a. Cerezyme® (imiglucerase); or
   b. Elelyso® (taliglucerase alfa); or
   c. Vpriv® (velaglucerase alfa); and
3. Zavesca® is brand preferred. Requests for generic miglustat will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
4. Must be prescribed by, or in consultation with, a geneticist or other specialist with expertise in the treatment of GD1; and
5. Prescriber must verify the member will not take Zavesca® concurrently with another therapy for GD1; and
6. A quantity limit of 90 capsules per 30 days will apply; and
7. Initial approvals will be for the duration of 6 months, at which time the prescriber must verify the member is responding well to the medication. Subsequent approvals will be for the duration of 1 year if the member is responding well to treatment.

Utilization Details of Lysosomal Storage Disease Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ELAPRASE INJ 6MG/3ML	34	3	$962,394.43	$28,305.72	11.33	26.52%
GALAFOLD CAP 123MG	32	3	$906,063.12	$28,314.47	10.67	24.97%
FABRAZYME INJ 5MG	24	1	$222,764.31	$9,281.85	24	6.14%
CEREZYME INJ 400 UNIT	21	3	$960,008.25	$45,714.68	7	26.45%
VPRIV INJ 400 UNIT	13	1	$336,576.27	$25,890.48	13	9.27%
MIGLUSTAT CAP 100MG	10	1	$241,190.90	$24,119.09	10	6.65%
TOTAL	**134**	**12***	**$3,628,997.28**	**$27,082.07**	**11.17**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VPRIV INJ J3385	46	2	$577,660.68	$12,557.84	23	31.57%
LUMIZYME INJ J0221	44	1	$669,570.65	$15,217.51	44	36.59%
FABRAZYME INJ J0180	33	2	$579,695.00	$17,566.52	16.5	31.68%
XENPOZYME INJ J0218	1	1	$3,028.24	$3,028.24	1	0.17%
TOTAL	**124**	**6**	**$1,829,954.57**	**$14,757.70**	**20.67**	**100%**

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

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[2] Chiesi Global Rare Diseases. Chiesi Global Rare Diseases and Protalix BioTherapeutics Announce FDA Approval of Elfabrio® (Pegunigalsidase Alfa-iwxj) for the Treatment of Fabry Disease. Available online at: https://protalixbiotherapeutics.gcs-web.com/news-releases/news-release-details/chiesi-global-rare-diseases-and-protalix-biotherapeutics-1. Issued 05/10/2023. Last accessed 11/10/2023.
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[6] Pombiliti™ (Cipaglucosidase Alfa-atga) Prescribing Information. Amicus Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761204s000lbl.pdf. Last revised 09/2023. Last accessed 11/10/2023.

Appendix O

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: November 27, 2023

FDA Approves First Therapy for Rare Type of Non-Cancerous Tumors

The FDA approved Ogsiveo™ (nirogacestat) tablets for adult patients with progressing desmoid tumors who require systemic treatment. Ogsiveo™ is the first drug to be approved for the treatment of patients with desmoid tumors, a rare subtype of soft tissue sarcomas.

The effectiveness of Ogsiveo™ was evaluated in an international, multicenter, randomized, double-blind, placebo-controlled trial in 142 adult patients with progressing desmoid tumors not amenable to surgery. Patients were randomized to receive 150mg of Ogsiveo™ or placebo orally, twice daily, until disease progression or unacceptable toxicity. The main efficacy outcome measure was progression-free survival. Objective response rate (a measure of tumor shrinkage) was an additional efficacy outcome measure.

The pivotal clinical trial demonstrated that Ogsiveo™ provided clinically meaningful and statistically significant improvement in progression-free survival compared to placebo. Additionally, the objective response rate was also statistically different between the 2 arms with a response rate of 41% in the Ogsiveo™ arm and 8% in the placebo arm. The progression-free survival results were also supported by an assessment of patient-reported pain favoring the Ogsiveo™ arm.

The most common side effects seen in at least 15% of the patients in the trial were diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection, and dyspnea.

The FDA granted the approval of Ogsiveo™ to SpringWorks Therapeutics Inc.

FDA NEWS RELEASE

For Immediate Release: November 09, 2023

FDA Approves First Vaccine to Prevent Disease Caused by Chikungunya Virus

The FDA approved Ixchiq®, the first chikungunya vaccine. Ixchiq® is approved for individuals 18 years of age and older who are at increased risk of exposure to chikungunya virus.

Ixchiq® is administered as a single-dose intramuscular (IM) injection. It contains a live, weakened version of the chikungunya virus and may cause symptoms in the vaccine recipient similar to those experienced by people who have chikungunya disease.

The safety of Ixchiq® was evaluated in 2 clinical studies conducted in North America in which about 3,500 participants 18 years of age and older received a dose of the vaccine with 1 study including about 1,000 participants who received a placebo. The most commonly reported side effects by vaccine recipients were headache, fatigue, muscle pain, joint pain, fever, nausea, and tenderness at the injection site.

In addition, although not commonly reported, severe chikungunya-like adverse reactions that prevented daily activity and/or required medical intervention occurred in 1.6% of Ixchiq® recipients and none of the placebo recipients. Two recipients with severe chikungunya-like adverse reactions were hospitalized. In addition, some recipients had prolonged chikungunya-like adverse reactions that lasted for at least 30 days. The

Prescribing Information includes a warning to inform that the vaccine may cause severe or prolonged chikungunya-like adverse reactions.

The FDA is requiring the company to conduct a postmarketing study to assess the serious risk of severe chikungunya-like adverse reactions following administration of Ixchiq®.

The FDA granted approval of Ixchiq® to Valneva Austria GmbH.

FDA NEWS RELEASE

For Immediate Release: November 09, 2023

FDA Approves First Treatment for Patients with Rare Inherited Blood Clotting Disorder

The FDA approved Adzynma, the first recombinant protein product indicated for prophylactic or on-demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).

Treatment for cTTP typically involves prophylactic plasma-based therapy for individuals with chronic disease to reduce the risk of clotting/bleeding by replenishing the absent/low ADAMTS13 enzyme. Adzynma is a purified recombinant form of the ADAMTS13 enzyme that works by providing a replacement for the low levels of the deficient enzyme in patients with cTTP used as prophylaxis to reduce the risk of disease symptoms or as treatment for an acute event. Adzynma is administered intravenously once every other week for prophylactic ERT, and once daily for on-demand ERT.
The safety and effectiveness of Adzynma were demonstrated in a global study evaluating prophylactic and on-demand ERT with Adzynma compared to plasma-based therapies in patients with cTTP.

The efficacy of Adzynma in the prophylactic treatment of patients with cTTP was evaluated in 46 patients who were randomized to receive 6 months of treatment with either Adzynma or plasma-based therapies (Period 1), then crossed over to the other treatment for 6 months (Period 2). The efficacy was demonstrated based on the incidence of thrombotic thrombocytopenic purpura (TTP) events and TTP manifestations, as well as the incidence of the need for supplemental doses. The efficacy of on-demand ERT was evaluated based on the proportion of acute TTP events responding to Adzynma in both the prophylactic and the on-demand cohorts throughout the duration of the study. All acute and subacute TTP events resolved after treatment with either Adzynma or plasma-based therapies.

The most common side effects associated with Adzynma include headache, diarrhea, migraine, abdominal pain, nausea, upper respiratory tract infection, dizziness and vomiting. During the clinical studies, no adverse events, including allergic reactions, were observed during the administration of Adzynma.

The application was awarded a Rare Pediatric Disease Priority Review Voucher, and granted Priority Review, Fast Track and Orphan designations.

The FDA granted approval of Adzynma to Takeda Pharmaceuticals U.S.A. Inc.

Current Drug Shortages Index (as of November 29, 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***
Cromolyn Sodium Concentrate	***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***