OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
February 8, 2023
4:00pm

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

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

DATE: February 1, 2023

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

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

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Enclosed are the following items related to the February meeting. Material is arranged in order of the agenda.

Call to Order

Public Comment Forum

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

Update on the Medication Coverage Authorization Unit/Use of Glucagon-Like Peptide 1 (GLP-1) Receptor Agonists and Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors with Cardiovascular (CV) Benefit in Members with Type 2 Diabetes (T2D) and High CV Risk or Established Atherosclerotic CV Disease (ASCVD) Mailing Update – Appendix B

Narrow Therapeutic Index (NTI) List – Appendix C

Action Item – Vote to Update the Approval Criteria for the Antihyperlipidemics – Appendix D

Action Item – Vote to Prior Authorize Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) and Update the Approval Criteria for the Amyotrophic Lateral Sclerosis (ALS) Medications – Appendix E

Action Item – Vote to Update the Approval Criteria for the Gonadotropin-Releasing Hormone (GnRH) Medications – Appendix F

Action Item – Vote to Prior Authorize Vyvgart® (Efgartigimod Alfa-fcab) and Update the Approval Criteria for Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon) – Appendix G

Action Item – Vote to Prior Authorize Omlonti® (Omidenepag Isopropyl) and Update the Approval Criteria for the Glaucoma Medications – Appendix H

Action Item – Vote to Prior Authorize Vabysmo™ (Faricimab-svoa) and Update the Approval Criteria for the Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitor Medications – Appendix I

Action Item – Vote to Prior Authorize Auvelity™ (Dextromethorphan/Bupropion) and Venlafaxine 112.5mg Extended-Release (ER) Tablet – Appendix J

Action Item – Vote to Prior Authorize Kimmtrak® (Tebentafusp-tebn) and Opdualag™ (Nivolumab/Relatlimab-rmbw) and Update the Approval Criteria for the Skin Cancer Medications – Appendix K

Action Item – Vote to Prior Authorize Lytgobi® (Futibatinib) and Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications – Appendix L

Action Item – Vote to Prior Authorize Pedmark® (Sodium Thiosulfate) and Vijoice® (Alpelisib) – Appendix M

Action Item – Vote to Prior Authorize Hyftor™ (Sirolimus Topical Gel) – Appendix N

Action Item – Annual Review of Anti-Migraine Medications – Appendix O

Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Rezlidhia™ (Olutasidenib) – Appendix P

Annual Review of Anticonvulsants and 30-Day Notice to Prior Authorize Zonisade™ (Zonisamide Oral Suspension) and Ztalmy® (Ganaxolone) – Appendix Q

Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Tadliq® (Tadalafil Oral Suspension) and Tyvaso® (Treprostinil Powder for Inhalation) – Appendix R

Annual Review of Dojolvi® (Triheptanoin) – Appendix S

Annual Review of Topical Acne, Psoriasis, and Rosacea Products and 30-Day Notice to Prior Authorize Brimonidine 0.33% Topical Gel (Generic Mirvaso®), Vtama® (Tapinarof), and Zoryve™ (Roflumilast) – Appendix T

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Meeting – February 8, 2023 @ 4:00pm
at the
Oklahoma Health Care Authority (OHCA)
4345 N. Lincoln Blvd.
Oklahoma City, Oklahoma 73105

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **Call to Order**

A. Roll Call – Dr. Wilcox

DUR Board Members:

Dr. Jennifer de los Angeles –	participating in person
Mr. Kenneth Foster –	participating in person
Dr. Megan Hanner –	participating in person
Dr. Lynn Mitchell –	participating in person
Dr. John Muchmore –	participating in person
Dr. Lee Muñoz –	participating in person
Dr. James Osborne –	participating in person

Viewing Access Only via Zoom:

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https://zoom.us/webinar/register/WN_73z8ERX7Sv-KeQGP3GVqPg
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: 952 7560 1667
Passcode: 69395211

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. December 14, 2022 DUR Board Meeting Minutes
   B. December 14, 2022 DUR Board Recommendations Memorandum
   C. January 11, 2023 DUR Board Recommendations Memorandum

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

4. **Update on Medication Coverage Authorization Unit/Use of Glucagon-Like Peptide 1 (GLP-1) Receptor Agonists and Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors with Cardiovascular (CV) Benefit in Members with Type 2 Diabetes (T2D) and High CV Risk or Established Atherosclerotic CV Disease (ASCVD) Mailing Update – See Appendix B**
   A. Pharmacy Help Desk Activity for January 2023
   B. Medication Coverage Activity for January 2023
   C. Use of GLP-1 Receptor Agonists and SGLT-2 Inhibitors with CV Benefit in Members with T2D and High CV Risk or Established ASCVD Mailing Update

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

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

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

6. **Action Item – Vote to Update the Approval Criteria for the Antihyperlipidemics – See Appendix D**
   A. College of Pharmacy Recommendations

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

7. **Action Item – Vote to Prior Authorize Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) and Update the Approval Criteria for the Amyotrophic Lateral Sclerosis (ALS) Medications – See Appendix E**
   A. Market News and Updates
   B. Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Product Summary
   C. College of Pharmacy Recommendations

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

8. **Action Item – Vote to Update the Approval Criteria for the Gonadotropin-Releasing Hormone (GnRH) Medications – See Appendix F**
   A. Market News and Updates
   B. College of Pharmacy Recommendations

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

9. **Action Item – Vote to Prior Authorize Vyvgart® (Efgartigimod Alfa-fcab) and Update the Approval Criteria for Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon) – See Appendix G**
   A. Market News and Updates
   B. Vyvgart® (Efgartigimod Alfa-fcab) Product Summary
   C. College of Pharmacy Recommendations

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

10. **Action Item – Vote to Prior Authorize Omlonti® (Omidenepag Isopropyl) and Update the Approval Criteria for the Glaucoma Medications – See Appendix H**
    A. Market News and Updates
    B. Omlonti® (Omidenepag Isopropyl) Product Summary
    C. College of Pharmacy Recommendations

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

11. **Action Item – Vote to Prior Authorize Vabysmo™ (Faricimab-svoa) and Update the Approval Criteria for the Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitor Medications – See Appendix I**
    A. Market News and Updates
    B. Vabysmo™ (Faricimab-svoa) Product Summary
    C. College of Pharmacy Recommendations

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

12. **Action Item – Vote to Prior Authorize Auvelity™ (Dextromethorphan/Bupropion) and Venlafaxine 112.5mg Extended-Release (ER) Tablet – See Appendix J**
    A. Market News and Updates
    B. Auvelity™ (Dextromethorphan/Bupropion) Product Summary
    C. College of Pharmacy Recommendations

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

13. **Action Item – Vote to Prior Authorize Kimmtrak® (Tebentafusp-tebn) and Opdualag™ (Nivolumab/Relatlimab-rmbw) and Update the Approval Criteria for the Skin Cancer Medications – See Appendix K**
    A. Market News and Updates
    B. Kimmtrak® (Tabentafusp-tebn) Product Summary
    C. Opdualag™ (Nivolumab/Relatlimab-rmbw) Product Summary
    D. College of Pharmacy Recommendations

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

14. **Action Item – Vote to Prior Authorize Lytgobi® (Futibatinib) and Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications – See Appendix L**
    A. Market News and Updates
    B. Lytgobi® (Futibatinib) Product Summary
    C. College of Pharmacy Recommendations

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

15. **Action Item – Vote to Prior Authorize Pedmark® (Sodium Thiosulfate) and Vijoice® (Alpelisib) – See Appendix M**
    A. Market News and Updates
    B. Product Summaries
    C. College of Pharmacy Recommendations

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

16. **Action Item – Vote to Prior Authorize Hyftor™ (Sirolimus Topical Gel) – See Appendix N**
    A. Market News and Updates
    B. Hyftor™ (Sirolimus Topical Gel) Product Summary
    C. College of Pharmacy Recommendations

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

17. **Action Item – Annual Review of Anti-Migraine Medications – See Appendix O**
    A. Current Prior Authorization Criteria
    B. Utilization of Anti-Migraine Medications
    C. Prior Authorization of Anti-Migraine Medications

D. Market News and Updates
E. College of Pharmacy Recommendations
F. Utilization Details of Anti-Migraine Medications

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

18. Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Rezlidhia™ (Olutasidenib) – See Appendix P

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

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

19. Annual Review of Anticonvulsants and 30-Day Notice to Prior Authorize Zonisade™ (Zonisamide Oral Suspension) and Ztalmy® (Ganaxolone) – See Appendix Q

A. Current Prior Authorization Criteria
B. Utilization of Anticonvulsants
C. Prior Authorization of Anticonvulsants
D. Market News and Updates
E. Ztalmy® (Ganaloxone) Product Summary
F. College of Pharmacy Recommendations
G. Utilization Details of Anticonvulsants

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

20. Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Tadliq® (Tadalafil Oral Suspension) and Tyvaso DPI® (Treprostinil Powder for Inhalation) – See Appendix R

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

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

21. Annual Review of Dojolvi® (Triheptanoin) – See Appendix S

A. Current Prior Authorization Criteria
B. Utilization of Dojolvi® (Triheptanoin)
C. Prior Authorization of Dojolvi® (Triheptanoin)
D. Market News and Updates
E. College of Pharmacy Recommendations

F. Utilization Details of Dojolvi® (Triheptanoin)

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

22. Annual Review of Topical Acne, Psoriasis, and Rosacea Products and 30-Day Notice to Prior Authorize Brimonidine 0.33% Topical Gel (Generic Mirvaso®), Vtama® (Tapinarof), and Zoryve™ (Roflumilast) – See Appendix T

A. Current Prior Authorization Criteria
B. Utilization of Topical Acne, Psoriasis, and Rosacea Products
C. Prior Authorization of Topical Acne, Psoriasis, and Rosacea Products
D. Market News and Updates
E. Product Summaries
F. College of Pharmacy Recommendations
G. Utilization Details of Topical Acne, Psoriasis, and Rosacea Products

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

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

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

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

A. Granulocyte Colony-Stimulating Factors (G-CSFs)
B. Growth Hormone Products
C. Lymphoma Medications
D. Multiple Sclerosis (MS) Medications

*Future product and class reviews subject to change.

25. 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 DECEMBER 14, 2022

DUR BOARD MEMBERS:	PRESENT	ABSENT
Jennifer de los Angeles, Pharm.D., BCOP	X	
Megan A. Hanner, D.O.	X	
Lynn Mitchell, M.D.; Vice Chairwoman		X
John Muchmore, M.D.; Ph.D.; Chairman	X	
Lee Muñoz, D.Ph.	X	
James Osborne, 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
Thara Kottoor, Pharm.D.; Pharmacy Resident	X	
Morgan Masterson, Pharm.D; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor		X
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
Oncology Pharmacists: Tad Autry Pharm.D., BCPS, BCOP		X
Allison Baxley, Pharm.D., BCOP		X
Emily Borders, Pharm.D., BCOP	X	
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.		X
Victoria Jones, Pharm.D.		X
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.		X
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief of Staff		X
Kevin Corbett, C.P.A.; 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, Interim 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:	
Dena Sessions, Immunogen	Robin Selsor, Aimmune
Scott Stepien, Ipsen	Wendi Chandler
Kimberly Brackett, AbbVie	Kevin Hinthorne, Leo Pharma
Todd Dickerson, Jazz Pharma	Robert Greely, Biogen
Craig Irwin, Acadia Pharm	Jason Smith, Gilead
Burl Beasley, OMES	Cindy Pennington, Rhythm Pharmaceuticals
Kevin Gallagher, Fennec Pharma	Aaron Austin, Takeda
Benjamin Skoog, Acadia Pharma	Paul Ford, Johnson & Johnson
Nima Nabavi, Amgen	Phillip Lohec, Viatris
Jamie Tobitt, Apellis	Marc Parker, Sunovion
Don Nopper, Apellis	

PRESENT FOR PUBLIC COMMENT:	
Jamie Tobitt, Apellis	

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

1A: ROLL CALL

Dr. Muchmore called the meeting to order at 4:00pm. Roll call by Dr. Wilcox established the presence of a quorum.

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 13 JAMIE TOBITT

ACTION: NONE REQUIRED

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

3A: NOVEMBER 9, 2022 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore

Dr. Muñoz moved to approve; seconded by Dr. de los Angeles

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/ACADEMIC DETAILING PROGRAM UPDATE**

4A: PHARMACY HELP DESK ACTIVITY FOR NOVEMBER 2022

4B: MEDICATION COVERAGE ACTIVITY FOR NOVEMBER 2022

4C: ACADEMIC DETAILING PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Kottoor, Dr. Travers

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **SOONERCARE MAINTENANCE DRUG LIST**

5A: INTRODUCTION

5B: SOONERCARE MAINTENANCE DRUG LIST

5C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE SKYSONA® (ELIVALDOGENE AUTOTEMCEL)**

6A: MARKET NEWS AND UPDATES
6B: SKYSONA® (ELIVALDOGENE AUTOTEMCEL) PRODUCT SUMMARY
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE TEZSPIRE® (TEZEPELUMAB-EKKO) AND UPDATE THE APPROVAL CRITERIA FOR THE ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS**

7A: MARKET NEWS AND UPDATES
7B: TEZSPIRE® (TEZEPELUMAB-EKKO) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE ADBRY™ (TRALOKINUMAB-LDRM) AND CIBINQO™ (ABROCITINIB) AND UPDATE THE APPROVAL CRITERIA FOR THE ATOPIC DERMATITIS (AD) MEDICATIONS**

8A: MARKET NEWS AND UPDATES
8B: ADBRY™ (TRALOKINUMAB-LDRM) PRODUCT SUMMARY
8C: CIBINQO™ (ABROCITINIB) PRODUCT SUMMARY
8D: COST COMPARISON
8E: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE CARVYKTI™ (CILTACABTAGENE AUTOLEUCEL) AND TECVAYLI™ (TECLISTAMAB-CQYV) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE MYELOMA MEDICATIONS**

9A: MARKET NEWS AND UPDATES
9B: CARVYKTI™ (CILTACABTAGENE AUTOLEUCEL) PRODUCT SUMMARY
9C: TECVAYLI™ (TECLISTAMAB-CQVY) PRODUCT SUMMARY
9D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Borders
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: **ANNUAL REVIEW OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS**

10A: CURRENT PRIOR AUTHORIZATION CRITERIA
10B: UTILIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
10C: PRIOR AUTHORIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
10D: MARKET NEWS AND UPDATES
10E: COLLEGE OF PHARMACY RECOMMENDATIONS
10F: UTILIZATION DETAILS OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS

Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> ANNUAL REVIEW OF CROHN'S DISEASE (CD) AND ULCERATIVE COLITIS (UC) MEDICATIONS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF CD AND UC MEDICATIONS
11C: PRIOR AUTHORIZATION OF CD AND UC MEDICATIONS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF CD AND UC MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> ANNUAL REVIEW OF SKIN CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KIMMTRAK® (TEBENTAFUSP-TEBN) AND OPDUALAG™ (NIVOLUMAB/RELATLIMAB-RMBW)
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF SKIN CANCER MEDICATIONS
12C: PRIOR AUTHORIZATION OF SKIN CANCER MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: KIMMTRAK® (TEBENTAFUSP-TEBN) PRODUCT SUMMARY
12F: OPDUALAG™ (NIVOLUMAB/RELATLIMAB-RMBW) PRODUCT SUMMARY
12G: COLLEGE OF PHARMACY RECOMMENDATIONS
12H: UTILIZATION DETAILS OF SKIN CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF EMPAVELI® (PEGCETACOPLAN), ENSPRYNG® (SATRALIZUMAB-MWGE), SOLIRIS® (ECULIZUMAB), ULTOMIRIS® (RAVULIZUMAB-CWVZ), AND UPLIZNA® (INEBILIZUMAB-CDON) AND 30-DAY NOTICE TO PRIOR AUTHORIZE VYVGART® (EFGARTIGIMOD ALFA-FCAB)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF EMPAVELI® (PEGCETACOPLAN), ENSPRYNG® (SATRALIZUMAB-MWGE), SOLIRIS® (ECULIZUMAB), ULTOMIRIS® (RAVULIZUMAB-CWVZ), AND UPLIZNA® (INEBILIZUMAB-CDON)
13C: PRIOR AUTHORIZATION OF EMPAVELI® (PEGCETACOPLAN), ENSPRYNG® (SATRALIZUMAB-MWGE), SOLIRIS® (ECULIZUMAB), ULTOMIRIS® (RAVULIZUMAB-CWVZ), AND UPLIZNA® (INEBILIZUMAB-CDON)
13D: MARKET NEWS AND UPDATES
13E: VYVGART® (EFGARTIGIMOD ALFA-FCAB) PRODUCT SUMMARY
13F: COST COMPARISON: GENERALIZED MYASTHENIA GRAVIS (GMG) THERAPIES
13G: COLLEGE OF PHARMACY RECOMMENDATIONS
13H: UTILIZATION DETAILS OF EMPAVELI® (PEGCETACOPLAN), ENSPRYNG® (SATRALIZUMAB-MWGE), SOLIRIS® (ECULIZUMAB), ULTOMIRIS® (RAVULIZUMAB-CWVZ), AND UPLIZNA® (INEBILIZUMAB-CDON)
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 14: **ANNUAL REVIEW OF ANTIDEPRESSANTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE AUVELITY™ (DEXTROMETHORPHAN/ BUPROPION) AND VENLAFAXINE 112.5MG EXTENDED-RELEASE (ER) TABLET**

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ANTIDEPRESSANTS
14C: PRIOR AUTHORIZATION OF ANTIDEPRESSANTS
14D: MARKET NEWS AND UPDATES
14E: AUVELITY™ (DEXTROMETHORPHAN/BUPROPION) PRODUCT SUMMARY
14F: VENLAFAXINE 112.5MG ER TABLET PRODUCT SUMMARY
14G: COLLEGE OF PHARMACY RECOMMENDATIONS
14H: UTILIZATION DETAILS OF ANTIDEPRESSANTS

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

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

AGENDA ITEM NO. 16: **FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)**
No live DUR meeting is scheduled for January 2023. January 2023 will be a packet-only meeting.

16A: AMYOTROPHIC LATERAL SCLEROSIS (ALS) MEDICATIONS
16B: ANTIHYPERLIPIDEMICS
16C: GLAUCOMA MEDICATIONS
16D: GONADOTROPIN-RELEASING HORMONE (GNRH) MEDICATIONS

*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 17: **ADJOURNMENT**
The meeting was adjourned at 5:23pm.

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

Memorandum

Date: December 15, 2022

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

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

Subject: DUR Board Recommendations from Meeting on December 14, 2022

Recommendation 1: Academic Detailing Program Update

NO ACTION REQUIRED.

Recommendation 2: SoonerCare Maintenance Drug List

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Skysona® (Elivaldogene Autotemcel)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Skysona® (elivaldogene autotemcel) with the following criteria:

Skysona® (Elivaldogene Autotemcel) Approval Criteria:

1. An FDA approved diagnosis of early, active cerebral adrenoleukodystrophy (CALD) in male members 4 to 17 years of age; and
2. Diagnosis must be confirmed by all of the following:
    a. Molecular genetic testing confirming a mutation in the *ABCD1* gene; and

        i. Members must not have a full deletion of the *ABCD1* gene; and
    b. Lab results indicating elevated very long-chain fatty acids (VLCFAs); and
    c. Active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating the following:
        i. Loes score between 0.5 and 9 on the 34-point scale; and
        ii. Gadolinium enhancement (GdE+) on MRI of demyelinating lesions; and
    d. Neurological Function Score (NFS) of ≤1; and
3. Skysona® must be prescribed by a neurologist, endocrinologist, or hematologist/oncologist with expertise in the treatment of CALD and the administration of Skysona®; and
4. Member must not have a known and available human leukocyte antigen (HLA)-matched sibling donor; and
5. Member must not have a prior history of hematopoietic stem cell transplantation (HSCT); and
6. Member must not be taking statins, Lorenzo's oil, or dietary regimens used to lower VLCFA levels; and
7. Member must not have an immediate family member with known or suspected familial cancer syndrome (FCS); and
8. Member must have a negative serology test for human immunodeficiency virus (HIV) prior to apheresis according to the package labeling; and
9. Prescriber must verify the member is clinically stable and eligible to undergo HSCT (HSCT must be appropriate for a member to be treated with Skysona®); and
10. Members of reproductive potential must use an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona®; and
11. Prescriber must verify members of reproductive potential have been counseled on the potential effects of myeloablative conditioning on fertility and the potential risk of infertility is acceptable to the member or member's caregiver; and
12. Prescriber must evaluate the potential for drug interactions, according to package labeling, prior to and after administration of Skysona®; and
13. Prescriber must verify member will be monitored for hematologic malignancies lifelong, with a complete blood count (with differential) performed at month 6 and month 12 after treatment with Skysona®, then at least annually thereafter for at least 15 years, and with integration site analysis at months 6, 12, and as warranted; and
14. Skysona® must be administered at a Skysona® qualified treatment center, and the receiving facility must have a mechanism in place to track the patient-specific Skysona® dose from receipt to storage to administration; and

15. Approvals will be for 1 dose per member per lifetime.

Recommendation 4: Vote to Prior Authorize Tezspire® (Tezepelumab-ekko) and Update the Approval Criteria for the Asthma and Chronic Obstructive Pulmonary Disease (COPD) Maintenance Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Tezspire® (tezepelumab-ekko) with the following criteria:

Tezspire® (Tezepelumab-ekko) Approval Criteria:

1. An FDA approved indication of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or that resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly for at least the past 12 months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium to high dose ICS compliantly for at least the past 3 months; and
6. Tezspire® must be administered by a health care provider prepared to manage anaphylaxis; and
7. Tezspire® must be prescribed by an allergist, pulmonologist, or pulmonary specialist, or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
8. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
9. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

Next, the College of Pharmacy recommends the addition of prior authorization criteria for Dupixent® (dupilumab) for a diagnosis of eosinophilic esophagitis (EoE) or prurigo nodularis (PN) based on the new FDA approved indications:

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

1. An FDA approved diagnosis of EoE; and
2. Member must be 12 years of age or older and weigh ≥40kg; and
3. Dupixent® must be prescribed by a gastroenterologist, allergist, or immunologist, or the member must have been evaluated by a

gastroenterologist, allergist, or immunologist within the last 12 months (or be an advanced care practitioner with a supervising physician who is a gastroenterologist, allergist, or immunologist); and
4. Member must have 2 or more episodes of dysphagia per week; and
5. Member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf); and
6. Member must have documented trials for a minimum of 8 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
    a. 1 high-dose proton pump inhibitor; and
    b. 1 swallowed inhaled respiratory corticosteroid (e.g., budesonide); and
7. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
8. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
9. A quantity limit of 8mL (4 syringes) every 28 days will apply.

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

1. An FDA approved diagnosis of PN for at least 3 months; and
2. Member must have a Worst-Itch Numeric Rating Scale (WI-NRS) score of ≥7; and
3. Member must have ≥20 PN lesions; and
4. Member must be 18 years of age or older; and
5. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
6. Prescriber must verify that all other causes of pruritis have been ruled out; and
7. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following therapies (or have a contraindication or documented intolerance):
    a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
    b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
8. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require

patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

Additionally, the College of Pharmacy recommends updating the Xolair® (omalizumab) approval criteria with the following changes to be consistent with the criteria for the other asthma-indicated monoclonal antibodies (changes shown in red):

Xolair® (Omalizumab) 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 ≥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 high-dose inhaled corticosteroids (ICS) for at minimum the past 12 ~~3~~ months; and
7. Prescribed Xolair® dose must be an FDA approved regimen per Xolair® prescribing information; and
8. Xolair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
9. Xolair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or be an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past 12 months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and
11. Initial approvals will be for the duration of 6 ~~12~~ months after which time compliance will be evaluated for continued approval.

Finally, the College of Pharmacy recommends the following changes to the Asthma and COPD Maintenance Medications Product Based Prior Authorization (PBPA) category based on product discontinuations (changes noted in red in the following Tier chart and approval criteria; only criteria with changes are listed):

1. Removal of Aerospan® (flunisolide)
2. Removal of ArmonAir® RespiClick® (fluticasone propionate)
3. Removal of Utibron® Neohaler® (indacaterol/glycopyrrolate)
4. Removal of Arcapta® Neohaler® (indacaterol inhalation powder)
5. Removal of Seebri® Neohaler® (glycopyrrolate inhalation powder)

Inhaled Corticosteroids (ICS) and Combination Products	
Tier-1	**Tier-2***
budesonide (Pulmicort Flexhaler®)	beclomethasone dipropionate (QVAR® RediHaler®)
budesonide/formoterol (Symbicort®) – **Brand Preferred**	fluticasone furoate (Arnuity® Ellipta®)
ciclesonide (Alvesco®)	fluticasone furoate/vilanterol (Breo® Ellipta®)
~~**flunisolide (Aerospan®)**~~	fluticasone propionate (ArmonAir® Digihaler®)
fluticasone propionate (Flovent®)	~~**fluticasone propionate (ArmonAir® RespiClick®)**~~
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 applies to each Tier-2 product.
αDoes not include Wixela Inhub®; authorization of Wixela Inhub® requires a reason why the member cannot use the brand formulation (Advair®) or other generic formulations of fluticasone propionate/salmeterol.
¥Includes all strengths and formulations other than Asmanex® HFA 50mcg.
◊ Includes all strengths other than Dulera® 50mcg/5mcg.

Anoro® Ellipta® (Umeclidinium/Vilanterol), Bevespi Aerosphere® (Glycopyrrolate/Formoterol Fumarate), Duaklir® Pressair® (Aclidinium Bromide/Formoterol Fumarate), and Stiolto® Respimat® (Tiotropium/ Olodaterol)~~, and Utibron® Neohaler® (Indacaterol/Glycopyrrolate)~~ Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and

3. A patient-specific, clinically significant reason why the member cannot use Tier-1 long-acting beta$_2$ agonist (LABA) and long-acting muscarinic antagonist (LAMA) individual components must be provided.

Arnuity® Ellipta® (Fluticasone Furoate) ~~and ArmonAir® RespiClick® (Fluticasone Propionate)~~ 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.

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®)
	~~**indacaterol inhalation powder (Arcapta® Neohaler®)**~~
	olodaterol inhalation spray (Striverdi® Respimat®)
Long-Acting Muscarinic Antagonists (LAMA)	
tiotropium inhalation powder (Spiriva® HandiHaler®)	aclidinium inhalation powder (Tudorza® PressAir®)
tiotropium soft mist inhaler (Spiriva® Respimat®)	~~**glycopyrrolate inhalation powder (Seebri® Neohaler)**~~
	glycopyrrolate inhalation solution (Lonhala® Magnair®)
	revefenacin inhalation solution (Yupelri®)
	umeclidinium inhalation powder (Incruse® Ellipta®)

*Tier-1 combination products that contain a long-acting beta$_2$ agonist (LABA) qualify for the LABA trial requirement.
Tier-1 medications do not require prior authorization.
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).

Recommendation 5: Vote to Prior Authorize Adbry™ (Tralokinumab-ldrm) and Cibinqo™ (Abrocitinib) and Update the Approval Criteria for the Atopic Dermatitis (AD) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes and additions to the AD medications approval criteria (shown in red):

1. The prior authorization of Adbry™ (tralokinumab-ldrm); and
2. The prior authorization of Cibinqo™ (abrocitinib) with criteria similar to Rinvoq® (upadacitinib) for AD; and
3. Updating the approval criteria for Dupixent® (dupilumab) for AD based on the recent FDA approved age expansion; and
4. The addition of prior authorization criteria for Opzelura™ (ruxolitinib 1.5% cream) for a diagnosis of vitiligo based on the new FDA approved indication.

Adbry™ (Tralokinumab-ldrm Injection) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable; and
2. Member must be 18 years of age or older; and
3. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
4. Adbry™ must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
5. Requests for concurrent use of Adbry™ with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Adbry™ has not been studied in combination with other biologic therapies); and
6. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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

1. An FDA approved diagnosis of moderate-to-severe AD not adequately controlled with other systemic drug products, including biologics, or when those therapies are not advisable; and
2. For Cibinqo™, member must be 18 years of age or older; and
3. For Rinvoq®, member must be 12 years of age or older; and
4. Member must have a documented trial within the last 6 months for a minimum of 2 weeks that resulted in failure with both of the following topical therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid; and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
5. Member must have a documented 16-week trial with Adbry™ (tralokinumab-ldrm) or Dupixent® (dupilumab) that resulted in inadequate response (or have a contraindication or documented intolerance); and
6. Requested medication must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
7. For Cibinqo™, prescriber must verify the member will not use antiplatelet therapies (e.g., clopidogrel, prasugrel, ticagrelor) concurrently with Cibinqo™, except for low-dose aspirin, during the first 3 months of treatment; and
8. Cibinqo™ and Rinvoq® will not be approved for use in combination with other Janus kinas (JAK) inhibitors, biologic immunomodulators, or with other immunosuppressant medications; and
9. Initial approvals will be for the duration of 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval; and
10. For Rinvoq®, the maximum approvable dose for AD is 30mg once daily.

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

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

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

4. Dupixent® must be prescribed by a dermatologist, allergist, or immunologist or the member must have been evaluated by a dermatologist, allergist, or immunologist within the last 12 months (or an advanced care practitioner with a supervising physician who is a dermatologist, allergist, or immunologist); and
5. Requests for concurrent use of Dupixent® with other biologic medications will be reviewed on a case-by-case basis and will require patient-specific information to support the concurrent use (Dupixent® has not been studied in combination with other biologic therapies); and
6. Initial approvals will be for the duration of 16 weeks. Reauthorization may be granted if the prescriber documents the member is responding well to treatment. Additionally, compliance will be evaluated for continued approval.

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

1. An FDA approved diagnosis of nonsegmental vitiligo; and
2. The member's body surface area (BSA) involvement must be provided and must be ≤10%; and
3. Member must be 12 to 20 years of age; and
4. Member must have documented trials within the last 6 months for a minimum of 12 weeks that resulted in failure with all of the following therapies (or have a contraindication or documented intolerance):
   a. 1 medium potency to very-high potency Tier-1 topical corticosteroid (used continuously or intermittently); and
   b. 1 topical calcineurin inhibitor [e.g., Elidel® (pimecrolimus), Protopic® (tacrolimus)]; and
5. Concurrent use with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants (e.g., azathioprine, cyclosporine) will not generally be approved; and
6. Prescriber must verify female members are not breastfeeding; and
7. If the member is pregnant or becomes pregnant, prescriber must verify member has been counseled on potential risks of this medication and will report the exposure to the Opzelura™ pregnancy registry; and
8. Initial approvals will be for a duration of 24 weeks of treatment; and
9. Reauthorization for an additional 28 weeks of treatment (to complete 1 year of treatment) may be considered if the prescriber documents both of the following:
   a. Member had a positive response to and tolerated previous treatment with Opzelura™; and
   b. Member has been evaluated by the prescriber and continues to require treatment with Opzelura™; and

10. Further approval beyond 1 year of treatment will require patient-specific, clinically significant information to support the member's need for additional treatment.

Recommendation 6: Vote to Prior Authorize Carvykti™ (Ciltacabtagene Autoleucel) and Tecvayli™ (Teclistamab-cqyv) and Update the Approval Criteria for the Multiple Myeloma Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Carvykti™ (ciltacabtagene autoleucel) and Tecvayli™ (teclistamab-cqyv) with the following criteria:

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

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

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

1. Diagnosis of relapsed or refractory multiple myeloma; and

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

The College of Pharmacy also recommends the removal of the Farydak® (panobinostat) approval criteria based on the withdrawal of the New Drug Application (NDA) approval by the FDA:

~~**Farydak® (Panobinostat) Approval Criteria [Multiple Myeloma Diagnosis]:**~~

~~1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and~~
~~2. Used in combination with bortezomib and dexamethasone after 1 or more lines of therapy; or~~
~~3. Used in combination with carfilzomib or dexamethasone and lenalidomide after 2 or more lines of therapy (including bortezomib and an immunomodulatory agent).~~

Finally, the College of Pharmacy recommends updating the Abecma® (idecabtagene vicleucel) approval criteria to be consistent with the other chimeric antigen receptor (CAR) T-cell therapies (changes shown in red):

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

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

of cytokine release syndrome (CRS), neurologic toxicities, and comply with the risk evaluation and mitigation strategy (REMS) requirements; and
3. Approvals will be for 1 dose per member per lifetime.

Recommendation 7: Annual Review of Anticoagulants and Platelet Aggregation Inhibitors

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Xarelto® (rivaroxaban) approval criteria based on the new FDA approved indications and formulation (changes noted in red):

Xarelto® (Rivaroxaban) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Non-valvular atrial fibrillation (NVAF); or
   b. Treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), or to reduce the risk of recurrent DVT and PE; or
   c. Prophylaxis of DVT, which may lead to PE in members undergoing knee or hip replacement surgery; or
   d. In combination with aspirin, to reduce the risk of major cardiovascular (CV) events [CV death, myocardial infarction (MI), and stroke] in members with chronic coronary artery disease (CAD) or peripheral artery disease (PAD); or
   e. Prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding; or
   f. Treatment of VTE and the reduction in the risk of recurrent VTE in pediatric members from birth to younger than 18 years of age after at least 5 days of initial parenteral anticoagulant treatment; or
   g. Thromboprophylaxis in pediatric members 2 years of age and older with congenital heart disease who have undergone the Fontan procedure; and

~~2. For Xarelto® (rivaroxaban) 15mg and 20mg:~~
   ~~a. Treatment of NVAF, DVT, or PE; or~~
   ~~b. Prophylaxis of recurrent DVT or PE; or~~

~~3. For Xarelto® (rivaroxaban) 10mg:~~
   ~~a. One prescription for up to 39 days of therapy is allowed without prior authorization every 6 months to allow for DVT prophylaxis in members following hip or knee replacement surgery or for prophylaxis of VTE in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding; or~~
   ~~b. Secondary prophylaxis of recurrent DVT or PE; or~~

~~4. For Xarelto® (rivaroxaban) 2.5mg:~~

~~a. Must be used in combination with aspirin 75 to 100mg to reduce the risk of major CV events in members with chronic CAD or PAD.~~

5. Approvals will be based on the recommended dosing per package labeling based on the member's diagnosis, age, and recent weight, if applicable. The member's recent weight must be provided on the prior authorization request for all pediatric members; and
6. For Xarelto® (rivaroxaban) 1mg/mL oral suspension, a patient-specific, clinically significant reason why the member requires the oral suspension and cannot use the oral tablet formulation, even when tablets are crushed, must be provided.

Additionally, the College of Pharmacy recommends the following changes to the Savaysa® (edoxaban) approval criteria based on net costs in comparison to other available direct oral anticoagulants (DOACs) (changes noted in red):

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. For the 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.

Recommendation 8: Annual Review of Crohn's Disease (CD) and Ulcerative Colitis (UC) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of generic Pentasa® based on net cost and recommends updating the approval criteria for Pentasa® with the following changes (shown in red):

Pentasa® (Mesalamine Extended-Release Capsule) ~~Quantity Limit~~ Approval Criteria:

1. Brand name Pentasa® does not require prior authorization for the first 8 weeks of treatment. Approval of the generic formulation requires a patient-specific, clinically significant reason the member cannot use

the brand formulation (Pentasa®) and all other mesalamine products that do not require prior authorization; and

2. A quantity limit of 480 capsules per 30 days will apply for the 250mg strength and a quantity limit of 240 capsules per 30 days will apply for the 500mg strength; and
3. ~~The first 8 weeks of treatment do not require prior authorization.~~
4. After 8 weeks of treatment:
    a. Provider must document a patient-specific, clinically significant reason the member needs a longer duration of treatment.

The following medications do not require prior authorization: Colazal® (balsalazide) capsules, Cortenema® (hydrocortisone) enemas, Apriso® (mesalamine) extended-release (ER) capsules, Canasa® (mesalamine) suppositories, Delzicol® (mesalamine) delayed-release (DR) capsules, Lialda® (mesalamine) DR capsules, brand name Pentasa® (mesalamine) ER capsules, Rowasa® (mesalamine) rectal suspension enemas, Dipentum® (olsalazine) capsules, sulfasalazine 500mg tablets, and sulfasalazine DR 500mg tablets.

Recommendation 9: Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Kimmtrak® (Tebentafusp-tebn) and Opdualag™ (Nivolumab/Relatlimab-rmbw)

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

Recommendation 10: Annual Review of Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon) and 30-Day Notice to Prior Authorize Vyvgart® (Efgartigimod Alfa-fcab)

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

Recommendation 11: Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Auvelity™ (Dextromethorphan/Bupropion) and Venlafaxine 112.5mg Extended-Release (ER) Tablet

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

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

NO ACTION REQUIRED.

Recommendation 13: Future Business

No live DUR Board meeting is scheduled for January 2023. January 2023 will be a packet-only meeting.

NO ACTION REQUIRED.

The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: January 13, 2023

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

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

Subject: DUR Board Recommendations from Packet Meeting on January 11, 2023

Recommendation 1: U.S. Food and Drug Administration (FDA) Safety Alerts

NO ACTION REQUIRED.

Recommendation 2: Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications

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

Recommendation 3: Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications and 30-day Notice to Prior Authorize Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol)

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

Recommendation 4: Annual Review of Antihyperlipidemics

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

Recommendation 5: Annual Review of Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitor Medications and 30-Day Notice to Prior Authorize Vabysmo™ (Faricimab-svoa)

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

Recommendation 6: Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize Omlonti® (Omidenepag Isopropyl)

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

Recommendation 7: 30-Day Notice to Prior Authorize Hyftor™ (Sirolimus Topical Gel)

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

Recommendation 8: Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Pedmark® (Sodium Thiosulfate) and Vijoice® (Alpelisib)

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

Recommendation 9: Annual Review of Gastrointestinal (GI) Cancer Medications and 30-Day Notice to Prior Authorize Lytgobi® (Futibatinib)

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

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

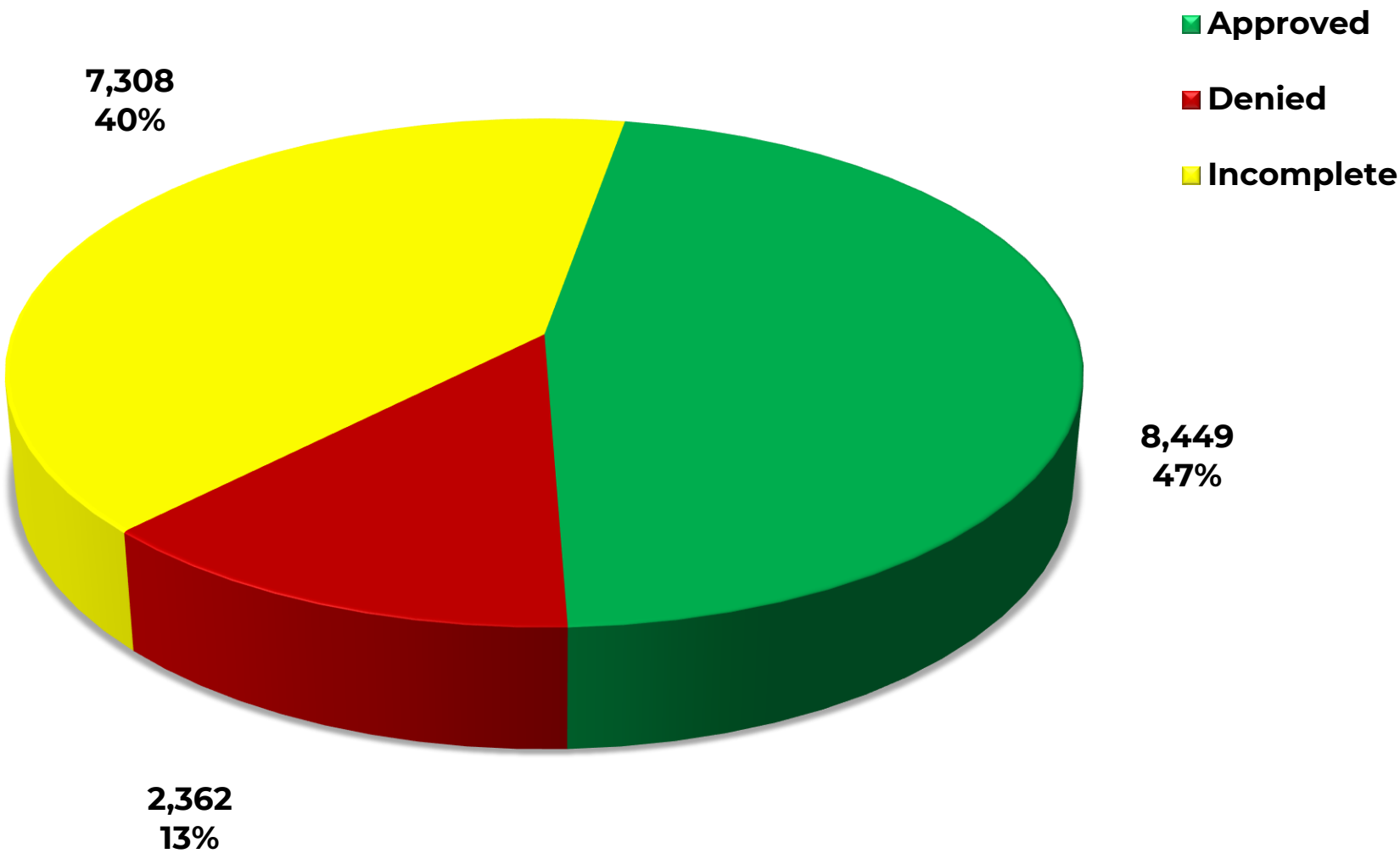
NO ACTION REQUIRED.

Recommendation 11: Future Business

NO ACTION REQUIRED.

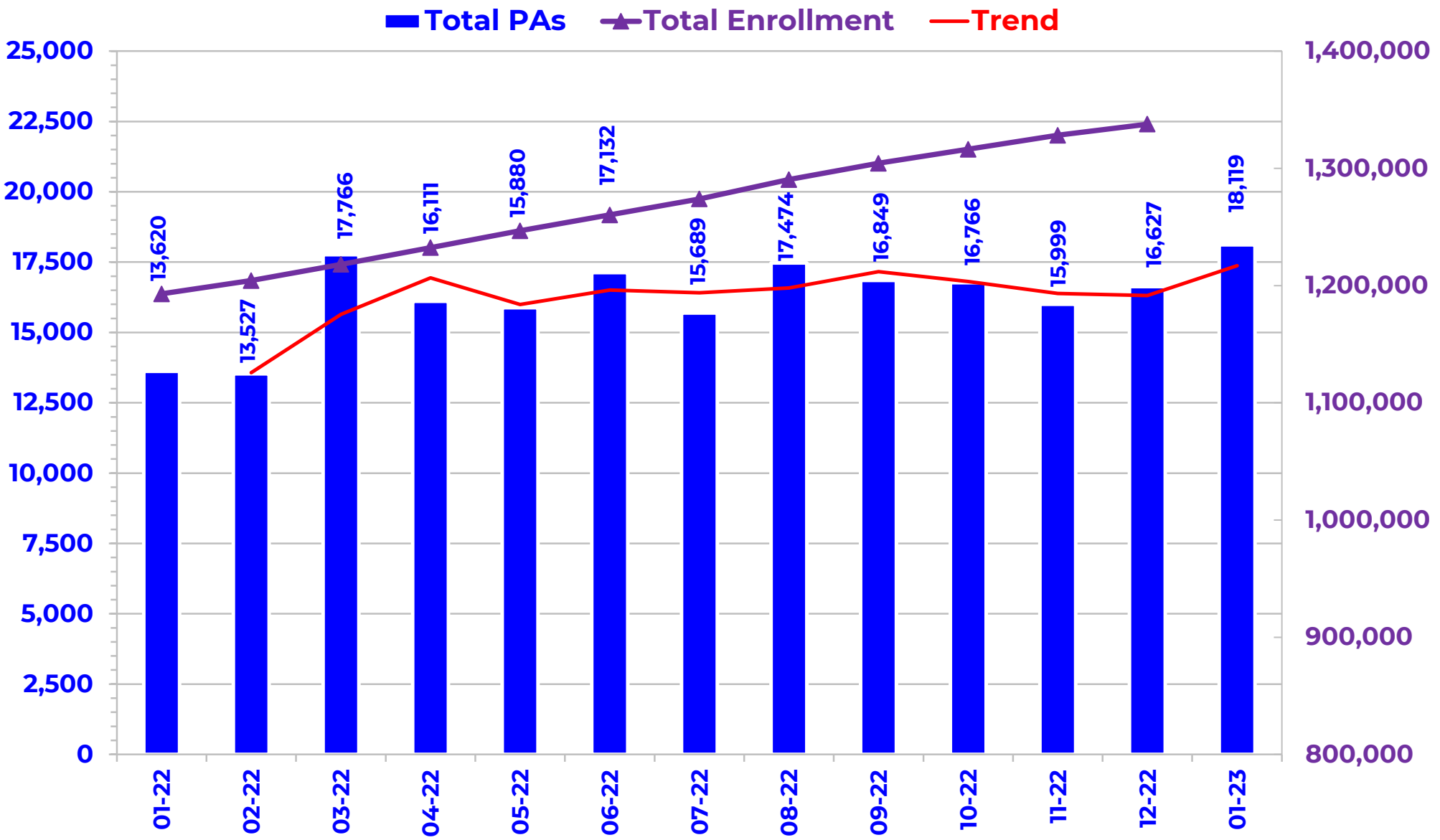
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JANUARY 2023



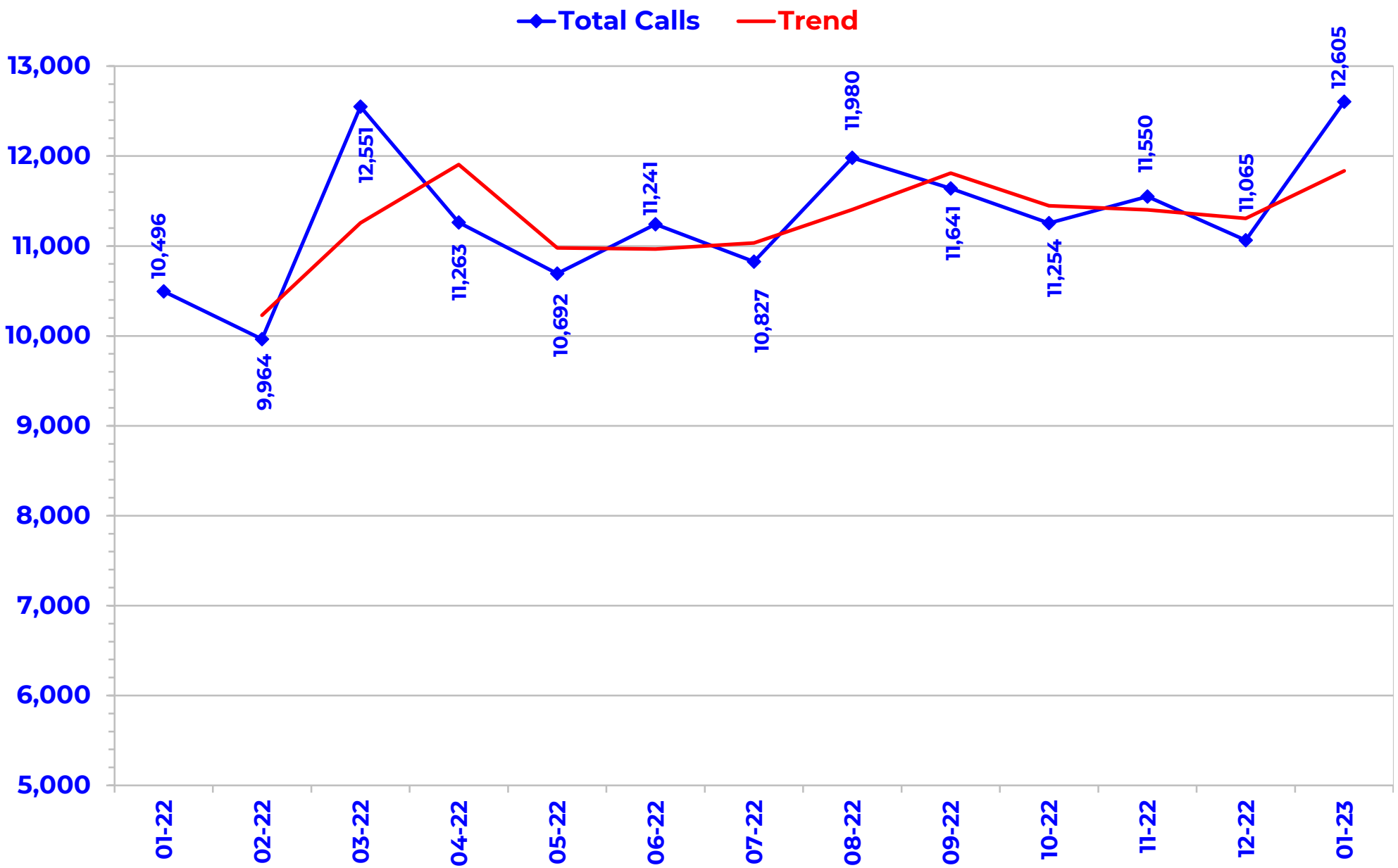
PA totals include approved/denied/incomplete/overrides

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JANUARY 2022 – JANUARY 2023



Prior Authorization Activity

1/1/2023 Through 1/31/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	120	29	8	83	357
Analgesic - NonNarcotic	19	0	4	15	0
Analgesic, Narcotic	385	152	53	180	143
Antiasthma	81	29	17	35	239
Antibiotic	50	21	3	26	159
Anticonvulsant	283	123	21	139	323
Antidepressant	416	97	50	269	323
Antidiabetic	2,204	656	541	1,007	356
Antifungal	10	2	1	7	101
Antigout	14	7	1	6	326
Antihemophilic Factor	11	10	0	1	259
Antihistamine	52	17	7	28	357
Antimalarial Agent	158	115	3	40	355
Antimigraine	578	91	157	330	261
Antineoplastic	340	226	13	101	170
Antiobesity	46	8	21	17	305
Antiparasitic	55	21	5	29	29
Antiulcers	42	7	6	29	233
Anxiolytic	47	5	6	36	223
Atypical Antipsychotics	680	303	52	325	353
Benign Prostatic Hypertrophy	31	1	16	14	85
Biologics	378	199	31	148	274
Bladder Control	132	16	39	77	320
Blood Thinners	769	494	18	257	342
Botox	91	46	26	19	340
Buprenorphine Medications	127	45	17	65	89
Calcium Channel Blockers	22	1	1	20	358
Cardiovascular	212	118	14	80	333
Chronic Obstructive Pulmonary Disease	358	78	78	202	352
Constipation/Diarrhea Medications	286	68	73	145	225
Contraceptive	57	20	13	24	319
Dermatological	619	239	146	234	220
Diabetic Supplies	1,068	373	187	508	245
Endocrine & Metabolic Drugs	82	42	4	36	210
Erythropoietin Stimulating Agents	32	17	3	12	105
Estrogen Derivative	10	2	1	7	360
Fibric Acid Derivatives	13	2	2	9	359
Fibromyalgia	1	0	0	1	0
Fish Oils	33	5	10	18	357
Gastrointestinal Agents	191	45	29	117	180

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Genitourinary Agents	11	2	5	4	359
Glaucoma	19	5	1	13	250
Growth Hormones	105	72	15	18	149
Hematopoietic Agents	33	6	13	14	137
Hepatitis C	46	18	10	18	9
HFA Rescue Inhalers	33	10	2	21	359
Insomnia	163	15	40	108	218
Insulin	299	102	33	164	345
Miscellaneous Antibiotics	53	7	14	32	22
Multiple Sclerosis	87	42	6	39	224
Muscle Relaxant	81	8	19	54	205
Nasal Allergy	35	0	14	21	0
Neurological Agents	182	54	30	98	208
Neuromuscular Agents	18	11	2	5	292
NSAIDs	55	2	8	45	360
Ocular Allergy	21	2	3	16	359
Ophthalmic	21	3	5	13	268
Ophthalmic Anti-infectives	27	10	1	16	122
Ophthalmic Corticosteroid	13	3	0	10	39
Osteoporosis	40	14	4	22	359
Other*	358	112	42	204	283
Otic Antibiotic	25	6	1	18	11
Pediculicide	24	3	4	17	5
Respiratory Agents	57	35	1	21	298
Statins	39	7	12	20	137
Stimulant	2,586	1,789	92	705	348
Synagis	217	118	50	49	35
Testosterone	185	48	43	94	333
Thyroid	51	17	6	28	328
Topical Antifungal	51	7	12	32	134
Topical Corticosteroids	44	1	19	24	176
Vitamin	144	46	58	40	121
Pharmacotherapy	101	88	2	11	306
Emergency PAs	0	0	0	0	
Total	**15,327**	**6,393**	**2,244**	**6,690**	

* 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	91	60	2	29	147
Compound	11	9	0	2	15
Cumulative Early Refill	4	4	0	0	16
Diabetic Supplies	2	2	0	0	52
Dosage Change	459	424	1	34	15
High Dose	4	2	0	2	192
IHS-Brand	3	3	0	0	360
Ingredient Duplication	12	6	1	5	38
Lost/Broken Rx	126	116	0	10	16
MAT Override	322	264	8	50	88
NDC vs. Age	365	239	40	86	264
NDC vs. Sex	14	11	1	2	104
Nursing Home Issue	59	58	0	1	15
Opioid MME Limit	120	41	5	74	316
Opioid Quantity	59	47	2	10	158
Other	71	46	10	15	14
Quantity vs. Days Supply	922	622	45	255	258
STBS/STBSM	24	19	2	3	114
Step Therapy Exception	10	9	0	1	359
Stolen	16	15	0	1	21
Temporary Unlock	2	2	0	0	1
Third Brand Request	96	57	1	38	24
Overrides Total	**2,792**	**2,056**	**118**	**618**	
Total Regular PAs + Overrides	**18,119**	**8,449**	**2,362**	**7,308**	

Denial Reasons	
Unable to verify required trials.	6,168
Does not meet established criteria.	2,422
Lack required information to process request.	1,084
Other PA Activity	
Duplicate Requests	1,785
Letters	41,072
No Process	3
Changes to Existing PAs	1,544
Helpdesk Initiated Prior Authorizations	1,369
PAs Missing Information	2,757

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

Use of Glucagon-Like Peptide-1 (GLP-1) Agonists or Sodium-Glucose Co-Transporter-2 (SGLT-2) Inhibitors with Cardiovascular (CV) Benefit in Members with Type 2 Diabetes (T2D) and High CV Risk or Established Atherosclerotic CV Disease (ASCVD) Mailing Update

Oklahoma Health Care Authority
February 2023

Introduction[1,2,3,4,5,6,7,8]

ASCVD is the leading cause of morbidity and mortality for individuals with diabetes, and an estimated $37.3 billion is spent annually on CV-related issues associated with diabetes. Co-existing conditions like hypertension (HTN) and hyperlipidemia (HLD) are risk factors for ASCVD, while diabetes itself confers independent risk. The 2023 American Diabetes Association (ADA) *Standards of Medical Care in Diabetes* guidelines include a dedicated decision pathway for individuals with indicators of high CV risk or established ASCVD. For these individuals, either a GLP-1 agonist or an SGLT-2 inhibitor with known CV benefit should be considered independent of baseline hemoglobin A1C target or metformin use. Per the 2023 ADA guidelines, indicators of high CV risk include ≥55 years of age with 2 or more additional risk factors, including obesity, HTN, smoking, dyslipidemia, or albuminuria. The GLP-1 agonists with U.S. Food and Drug Administration (FDA) approved CV benefit include Victoza® (liraglutide), Trulicity® (dulaglutide), and Ozempic® (injectable semaglutide). The SGLT-2 inhibitors with FDA approved CV benefit include Jardiance® (empagliflozin), Farxiga® (dapagliflozin), and Invokana® (canagliflozin).

Mailing Summary

In February 2021, the College of Pharmacy (COP) and the Oklahoma Health Care Authority (OHCA) sent an educational letter to 120 providers regarding 944 unique members with a diagnosis of type 2 diabetes (T2D) with high CV risk or established ASCVD who were not receiving treatment with 1 of the above GLP-1 agonists or SGLT-2 inhibitors based on their SoonerCare pharmacy claims history. The number of members associated with these top 120 providers ranged from 39 members to 3 members per provider. High CV risk was determined using the indicators suggested in the 2021 ADA guidelines (≥55 years of age with left ventricular hypertrophy or with >50% coronary, carotid, or lower-extremity artery stenosis) or a diagnosis of HTN and HLD as evidenced in the member's SoonerCare claims history. The

purpose of the educational mailing was to encourage providers to evaluate evidence-based prescribing practices for SoonerCare members with diabetes and high CV risk or established ASCVD and determine if they may benefit from therapy with a GLP-1 agonist or SGLT-2 inhibitor with FDA approved CV benefit. Providers were selected for this mailing if they were the most recent prescriber for at least 1 SoonerCare member with concurrent diagnoses of T2D and ASCVD or high CV risk factors in the last year who did not have any SoonerCare pharmacy paid claims for a GLP-1 agonist or SGLT-2 inhibitor with CV benefit. Members with a diagnosis of end-stage renal disease (ESRD), heart failure (HF), or pregnancy were excluded.

Mailing Results

In May 2021, 2.5 months after the letters were sent out, the first post-mailing claims analysis was performed and found 23 members (2.44%) included in the mailing had a paid claim for a GLP-1 agonist or SGLT-2 inhibitor with CV benefit. A second post-mailing analysis was performed in January 2022 and found 132 members (13.98%) had a paid claim for a GLP-1 agonist or SGLT-2 inhibitor with CV benefit resulting in an 11.54% increase from the first analysis in May 2021. It was also found that of the 120 providers included in the mailing, 70 providers had at least 1 member who was previously included for evaluation of therapy with a GLP-1 agonist or an SGLT-2 inhibitor with FDA approved CV benefit who has now started on therapy with 1 of the indicated medications.

In January 2023, another post-mailing claims analysis was performed and found 214 members (22.67%) included in the original mailing had a paid claim for 1 of the above mentioned GLP-1 agonists or SGLT-2 inhibitors with CV benefit. This resulted in a 20.23% increase from the first claims analysis in May 2021 and an 8.69% increase from the January 2022 analysis. Of the 120 original providers included in the mailing, 93 providers now have had 1 member who was previously included for evaluation of therapy with a GLP-1 agonist or an SGLT-2 inhibitor with FDA approved CV benefit who has now started on therapy with 1 of the indicated medications.

Conclusions

The third post-mailing claims analysis in January 2023 showed 22.67% of members with a diagnosis of T2D with high CV risk or established ASCVD who were not previously receiving treatment with a GLP-1 agonist or SGLT-2 inhibitor with CV benefit before the mailing in February 2021 were now receiving treatment at 22 months after the initial mailing.

The May 2021 post-mailing analysis performed had limitations including only 2.5 months had passed between the letter being mailed out and the claims analysis which is shorter than a 90-day medication supply; therefore, some

members may not have been due for a prescription refill. A limitation the first 2 analyses have in common is that they occurred during a global pandemic in which members may not have been seen by their primary care provider. The third claims analysis now gives a better picture of the results of the mailing now that 22 months have passed and members may have been able to resume seeing their primary care providers regularly. Additionally, it is important to note that the recommended GLP-1 agonists and SGLT-2 inhibitors with CV benefit require prior authorization that could delay the time to filling the medication. However, while these medications do require prior authorization, there is a clinical exception that applies for members who require the medication for its CV benefit (tier structure still applies).

Overall, the purpose of this mailing was not to see all of the members started on therapy with a GLP-1 agonist or SGLT-2 inhibitor with CV benefit, but rather to ensure the providers were evaluating these members for appropriate therapy. As of January 2023, there are currently 5,537 unique SoonerCare members with a diagnosis of T2D with high CV risk or established ASCVD who are not receiving treatment with a GLP-1 agonist or SGLT-2 inhibitor with CV benefit. The COP will continue to work with OHCA to improve the quality of care for SoonerCare members with T2D including educational mailings and the future addition of system edits to detect T2D and ASCVD or other diagnoses conferring high CV risk in the member's SoonerCare claims history to generate automated prior authorizations where possible for GLP-1 agonist or SGLT-2 inhibitor medications with CV benefit to prevent further delay of treatment caused by the requirement for submission of a manual prior authorization request. New interventions will be implemented where appropriate, and results will be reported to the DUR Board when available.

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[1] Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes – 2021. *Diabetes Care* 2021; 44(1):S125–S150.
[2] Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes – 2023. *Diabetes Care* 2023; 46(1):S158–S190.
[3] Marso SP, Daniels GH, Brown-Frandsen K, et al. LEADER Steering Committee; LEADER Trial Investigators. Liraglutide and Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med* 2016; 375:311-322.
[4] Gerstein HC, Colhoun HM, Dagenais GR, et al. REWIND Investigators. Dulaglutide and Cardiovascular Outcomes in Type 2 Diabetes (REWIND): A Double-blind, Randomized Placebo-controlled Trial. *Lancet* 2019; 394:121-130.
[5] Marso SP, Bain SC, Consoli A, et al. SUSTAIN-6 Investigators. Semaglutide and Cardiovascular Outcomes in Patients with Type 2 Diabetes. *N Engl J Med* 2016; 375:1834-1844.
[6] Zinman B, Wanner C, Lachin JM, et al. EMPGA-REG OUTCOME Investigators. Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. *N Engl J Med* 2015; 373:2117-2128.
[7] Wiviott SD, Raz I, Bonaca MP, et al. Dapagliflozin and Cardiovascular Outcomes in Type 2 Diabetes. *N Engl J Med* 2019; 380:347-357.
[8] Neal B, Perkovic V, Mahaffey KW, et al. CANVAS Program Collaborative Group. Canagliflozin and Cardiovascular and Renal Events in Type 2 Diabetes. *N Engl J Med* 2017; 377:644-657.

Appendix C

Narrow Therapeutic Index (NTI) Drug List

Oklahoma Health Care Authority
February 2023

Introduction[1,2,3]

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

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

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

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

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

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

SoonerCare NTI Drug List

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

Recommendations

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

[1] U.S. Food and Drug Administration (FDA). FY2015 Regulatory Science Research Report: Narrow Therapeutic Index Drugs. Available online at: https://www.fda.gov/industry/generic-drug-user-fee-amendments/fy2015-regulatory-science-research-report-narrow-therapeutic-index-drugs. Last revised 05/09/2017. Last accessed 01/04/2023.
[2] U.S. FDA. Building Confidence in Generic Narrow Therapeutic Index (NTI) Drugs. Available online at: https://www.fda.gov/about-fda/fda-pharmacy-student-experiential-program/building-confidence-generic-narrow-therapeutic-index-nti-drugs. Last revised 04/10/2020. Last accessed 01/04/2023.
[3] Jiang, Wenlei. FDA Drug Topics: Understanding Generic Narrow Therapeutic Index Drugs. *U.S. FDA*. Available online at: https://www.fda.gov/media/162779/download Issued 11/01/2022. Last accessed 01/04/2023.

Appendix D

Vote to Update the Approval Criteria for the Antihyperlipidemics

Oklahoma Health Care Authority
February 2023

Recommendations

The College of Pharmacy recommends the following changes to the Juxtapid® (lomitapide) approval criteria to be consistent with the other antihyperlipidemic medications with similar indications (changes noted in red):

Juxtapid® (Lomitapide) Approval Criteria:

1. An FDA approved diagnosis of homozygous familial hypercholesterolemia (HoFH) defined by the presence of at least 1 of the following criteria:
    a. Documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing; or
    b. Untreated LDL >500mg/dL and triglycerides <300mg/dL and at least 1 of the following:
        i. Documented evidence of definite HeFH in both parents ~~Documentation that both parents have untreated total cholesterol >250mg/dL;~~ or
        ii. Presence of tendinous/cutaneous xanthoma prior to 10 years of age; and
2. Documented trial of high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy at least 12 weeks in duration; and
3. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
4. Documented trial of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®) ~~Repatha® (evolocumab)~~ at least 12 weeks in duration; and

5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
6. Prescriber must be certified with Juxtapid® Risk Evaluation and Mitigation Strategy (REMS) program.

Additionally, the College of Pharmacy recommends the following changes to the antihyperlipidemics approval criteria based on net costs (changes shown in red):

Welchol® (Colesevelam) Chewable Bar and Welchol® (Colesevelam) Packets for Oral Suspension Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the oral tablet ~~other~~ formulation~~s~~ of colesevelam, ~~including oral tablets and packets for oral suspension,~~ which is ~~are~~ available without prior authorization, must be provided; and

~~3. A quantity limit of 30 chewable bars per 30 days will apply.~~

4. The following quantity limits will apply:
    a. 30 chewable bars per 30 days; and
    b. 30 packets for oral suspension per 30 days.

Appendix E

Vote to Prior Authorize Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) and Update the Approval Criteria for the Amyotrophic Lateral Sclerosis (ALS) Medications

Oklahoma Health Care Authority
February 2023

Market News and Updates[1,2,3]

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

- **May 2022:** The FDA approved Radicava ORS® (edaravone oral suspension) for the treatment of ALS. Radicava® was initially FDA approved for the treatment of ALS in 2017 as a formulation for intravenous (IV) administration. The FDA approval of Radicava ORS® was based on a bioavailability study comparing Radicava® and Radicava ORS®, which demonstrated an equivalent area under the curve (AUC) for the 105mg oral dose compared to the 60mg IV dose, with similar pharmacokinetics for oral administration and administration via feeding tubes. Radicava® and Radicava ORS® are administered using the same dosing schedule, with an initial treatment cycle of daily dosing for the first 14 days, followed by a 14-day drug-free period. Subsequent cycles consist of daily dosing for 10 days out of the 14-day period, followed by a 14-day drug-free period.
- **September 2022:** The FDA approved Relyvrio™ (sodium phenylbutyrate/taurursodiol) for the treatment of adults with ALS. Relyvrio™ contains a fixed-dose combination of sodium phenylbutyrate and taurursodiol for oral administration and was studied as monotherapy or in combination with other FDA approved treatments for ALS.

Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Product Summary[4,5]

Indication(s): Treatment of adults with ALS

How Supplied: Powder for oral suspension containing 3g sodium phenylbutyrate and 1g taurursodiol in single-dose packets

Dosing and Administration:

- Recommended initial dose is 1 packet daily for the first 3 weeks
- Recommended maintenance dose is 1 packet twice daily
- Should be administered before a snack or meal

- Packet contents should be emptied into a cup containing 8 ounces of room temperature water and should be stirred vigorously prior to administration
- Should be taken orally or administered via feeding tube within 1 hour of preparation

Mechanism of Action: The specific mechanism by which sodium phenylbutyrate/ taurursodiol exerts its therapeutic effects in patients with ALS is unknown; however, it is thought that Relyvrio™ targets pathways in the mitochondria and endoplasmic reticulum that lead to neuronal death and degradation, and that sodium phenylbutyrate and taurursodiol help to reduce neuronal death by mitigating endoplasmic reticulum stress and mitochondrial dysfunction.

Contraindication(s): None

Safety:

- Risk in Patients with Enterohepatic Circulation Disorders, Pancreatic Disorders, or Intestinal Disorders: Taurursodiol is a bile acid. In patients with disorders that interfere with bile acid circulation, there may be an increased risk for worsening diarrhea. Patients should be monitored appropriately for this adverse reaction. Pancreatic insufficiency, intestinal malabsorption, or intestinal diseases that may alter the concentration of bile acids may also lead to decreased absorption of sodium phenylbutyrate or taurursodiol. Patients with enterohepatic circulation disorders, severe pancreatic disorders, and intestinal disorders that may alter concentrations of bile acids were excluded from clinical studies of sodium phenylbutyrate and taurursodiol, so there is no clinical experience in these conditions.
- Use in Patients Sensitive to High Sodium Intake: Relyvrio™ contains a high salt content. Each packet contains 464mg of sodium, resulting in 928mg of sodium daily for the maintenance dose of 2 packets daily. In patients sensitive to salt intake (e.g., with heart failure, hypertension, renal impairment), the amount of sodium in each dose should be considered and patients should be monitored appropriately.
- Pregnancy: There are no data available on sodium phenylbutyrate/ taurursodiol use in pregnant women to evaluate a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In rats, administration of sodium phenylbutyrate/ taurursodiol throughout pregnancy and lactation resulted in increased offspring mortality at all doses tested, which were less than or similar to the clinical doses.
- Lactation: There are no data available on the presence of sodium phenylbutyrate/taurursodiol in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. The

developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for sodium phenylbutyrate/taurursodiol and any potential adverse effects on the breastfed child from the medication or the underlying maternal condition.

- Pediatric Use: The safety and efficacy of sodium phenylbutyrate/taurursodiol have not been established in pediatric patients.
- Geriatric Use: Of the 89 patients with ALS treated with sodium phenylbutyrate/taurursodiol in a Phase 2 study, 25 (28%) were 65 years of age or older and 4 (4.5%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between younger patients and those 65 years of age or older.

Adverse Reactions: The most common adverse reactions in a Phase 2 study (occurring in >5% of patients treated with sodium phenylbutyrate/taurursodiol and at a greater incidence than placebo) were diarrhea (25%), abdominal pain (21%), nausea (18%), upper respiratory tract infection (18%), fatigue (12%), salivary hypersecretion (11%), and dizziness (10%).

Efficacy: The efficacy of sodium phenylbutyrate/taurursodiol for the treatment of ALS was assessed in a Phase 2 study (CENTAUR) which was a 24-week, multicenter, randomized, double-blind, placebo-controlled study in 137 adult patients with ALS. Patients were randomized 2:1 to receive treatment with sodium phenylbutyrate/taurursodiol or placebo for 24 weeks.

- Inclusion Criteria: Patients were required to have a definite diagnosis of sporadic or familial ALS as defined by the World Federation of Neurology El Escorial criteria. Additionally, eligible patients had symptom onset within the past 18 months and a slow vital capacity (SVC) >60% of predicted at screening.
- Primary Endpoint: The primary efficacy endpoint was a comparison of the rate of reduction in the revised ALS Functional Rating Scale (ALSFRS-R) total score from baseline to week 24. The ALSFRS-R consists of 12 questions that evaluate fine motor, gross motor, bulbar, and respiratory function in patients with ALS, with each item scored from 0-4 and higher scores representing greater functional ability.
- Results: At baseline, the average ALSFRS-R total score was 35.7 in the sodium phenylbutyrate/taurursodiol group and 36.7 in the placebo group. At week 24, the least squares mean ALSFRS-R total score had declined to 29.06 in the sodium phenylbutyrate/taurursodiol group and 26.73 in the placebo group [treatment difference: 2.32; 95% confidence interval (CI): 0.18, 4.47; P=0.034]. Additionally, a post hoc, long-term survival analysis suggested longer median overall survival in patients originally randomized to receive sodium phenylbutyrate/taurursodiol compared to patients originally randomized to placebo.

Cost: The Wholesale Acquisition Cost (WAC) of Relyvrio™ is $223.29 per packet, resulting in a cost of $12,504.24 per 28 days and $162,555.12 per year based on the recommended maintenance dose of 1 packet twice daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Relyvrio™ (sodium phenylbutyrate/taurursodiol) with the following criteria (shown in red):

Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Member must be 18 years of age or older; and
3. Disease duration of 18 months or less (for initial approval); or
    a. A prior authorization request with patient-specific information may be submitted for consideration of Relyvrio™ for members with disease duration >18 months, including but not limited to disease progression, specific symptoms related to the disease, activities of daily living currently affected by the disease, or prognosis; and
4. Must be prescribed by a neurologist or other specialist with expertise in the treatment of ALS (or an advanced care practitioner with a supervising physician who is a neurologist or other specialist with expertise in the treatment of ALS); and
5. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression; and
6. A quantity limit of 56 packets per 28 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Radicava ORS® (edaravone oral suspension) with criteria similar to Radicava® (edaravone) (changes noted in red):

Radicava® (Edaravone) and Radicava ORS® (Edaravone Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. Member must have been evaluated by a physician specializing in the treatment of ALS within the last 3 months; and
3. Disease duration of 2 years or less (for initial approval); or
    a. A prior authorization request with patient-specific information may be submitted for consideration of edaravone for members with disease duration >2 years, including but not limited to disease progression, specific symptoms related to the disease, activities of daily living currently affected by the disease, or prognosis; and

4. Approvals will be for the duration of 6 months. For each subsequent approval, the prescriber must document that the member is responding to the medication, as indicated by a slower progression in symptoms and/or slower decline in quality of life compared to the typical ALS disease progression.

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[1] Mitsubishi Tanabe Pharma America, Inc. Mitsubishi Tanabe Pharma America Announces FDA Approval of Radicava ORS® (Edaravone) for the Treatment of ALS. Available online at: https://www.prnewswire.com/news-releases/mitsubishi-tanabe-pharma-america-announces-fda-approval-of-radicava-ors-edaravone-for-the-treatment-of-als-301546937.html. Issued 05/13/2022. Last accessed 01/25/2023.

[2] Radicava ORS® (Edaravone Oral Suspension) Prescribing Information. Mitsubishi Tanabe Pharma America, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209176s012lbl.pdf. Last revised 11/2022. Last accessed 01/25/2023.

[3] Amylyx Pharmaceuticals, Inc. Amylyx Pharmaceuticals Announces FDA Approval of Relyvrio™ for the Treatment of ALS. Available online at: https://www.amylyx.com/media/amylyx-pharmaceuticals-announces-fda-approval-of-relyvriotm-for-the-treatment-of-als. Issued 09/29/2022. Last accessed 01/25/2023.

[4] Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Prescribing Information. Amylyx Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216660s000lbledt.pdf. Last revised 09/2022. Last accessed 01/25/2023.

[5] Paganoni S, Macklin EA, Hendrix S, et al. Trial of Sodium Phenylbutyrate–Taurursodiol for Amyotrophic Lateral Sclerosis. *N Engl J Med* 2020; 383:919-930.

Appendix F

Vote to Update the Approval Criteria for the Gonadotropin-Releasing Hormone (GnRH) Medications

Oklahoma Health Care Authority
February 2023

Market News and Updates[1,2,3]

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

- **August 2022:** The FDA approved Myfembree® (relugolix/estradiol/norethindrone) for a new indication for the treatment of premenopausal women with moderate-to-severe pain associated with endometriosis. Myfembree® was previously FDA approved in May 2021 for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Treatment for either indication should be limited to 24 months due to the risk of continued bone loss which may not be reversible. The approval for the new indication was based on data from the Phase 3 SPIRIT 1 and SPIRIT 2 studies which were replicate, 24-week, randomized, double-blind, placebo-controlled studies conducted in 829 premenopausal women with moderate-to-severe pain associated with endometriosis. Pain was assessed daily using a numerical rating scale (NRS) ranging from 0 (indicating "no pain") to 10 (indicating "pain as bad as you can imagine") for both dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP). To be eligible for study participation, patients were required to have a DYS NRS score ≥4 on at least 2 days during the placebo run-in period and a mean NMPP NRS score ≥2.5 or a mean NMPP NRS score ≥1.25 with NMPP NRS score ≥5 on at least 4 days during the run-in period. The co-primary efficacy endpoints were the proportion of patients who were DYS responders (defined as a reduction from baseline in the DYS NRS of at least 2.8 points over the last 35 days of treatment without an increase in analgesic use) and the proportion of patients who were NMPP responders (defined as a reduction from baseline in NMPP NRS score of at least 2.1 points over the last 35 days of treatment without an increase in analgesic use). In SPIRIT 1 and SPIRIT 2 respectively, a higher proportion of patients treated with Myfembree® were DYS responders (74.5% and 75.1%) compared to placebo (26.9% and 30.5%). The difference from placebo in DYS responders in both studies was statistically significant (P≤0.0001). Additionally, a higher proportion of patients treated with Myfembree® were NMPP responders (58.5% and 65.9%) compared to placebo (39.6% and 42.5%). The difference from placebo in NMPP responders in both studies was statistically significant (P≤0.0001).

Recommendations

The College of Pharmacy recommends updating the current Myfembree® approval criteria based on the new FDA approved indication for endometriosis pain with the following changes and additions (shown in red):

Myfembree® (Relugolix/Estradiol/Norethindrone) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women; or
    b. Moderate-to-severe pain associated with endometriosis in premenopausal women; and
2. Member must be 18 years of age or older; and
3. Member must not have any contraindications to therapy including:
    a. Osteoporosis; and
    b. Pregnancy; and
        i. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
        ii. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment and for at least 1 week after discontinuing treatment; and
    c. Hepatic impairment or disease; and
    d. Undiagnosed abnormal uterine bleeding; and
    e. High risk of arterial, venous thrombotic, or thromboembolic disease, including uncontrolled hypertension; and
    f. Current or history of breast cancer or other hormonally-sensitive malignancies; and
    g. Known hypersensitivity to ingredients in Myfembree®; and
4. Must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of uterine leiomyomas (fibroids) or endometriosis; and
5. A failed trial at least 1 month in duration with nonsteroidal anti-inflammatory drugs (NSAIDs) or a patient-specific, clinically significant reason why the member cannot use NSAIDs; and
6. A failed trial at least 3 months in duration of hormonal contraceptives or a patient-specific, clinically significant reason why the member cannot use hormonal contraceptives; and
7. A quantity limit of 28 tablets per 28 days will apply; and
8. Lifetime approval duration will be limited to a maximum of 24 months. For members previously approved for Oriahnn® or Orilissa®, a combined cumulative maximum treatment duration of 24 months will apply.

[1] Myovant Sciences and Pfizer, Inc. Myovant Sciences and Pfizer Receive U.S. FDA Approval of Myfembree®, a Once-Daily Treatment for the Management of Moderate to Severe Pain Associated with Endometriosis. Available online at: https://www.pfizer.com/news/press-release/press-release-detail/myovant-sciences-and-pfizer-receive-us-fda-approval. Issued 08/05/2022. Last accessed 01/25/2023.

[2] Myfembree® (Relugolix/Estradiol/Norethindrone) Prescribing Information. Myovant Sciences, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214846s002lbl.pdf. Last revised 08/2022. Last accessed 01/25/2023.

[3] Giudice LC, As-Sanie S, Arjona Ferreira JC, et al. Once Daily Oral Relugolix Combination Therapy versus Placebo in Patients with Endometriosis-Associated Pain: Two Replicate Phase 3, Randomised, Double-Blind, Studies (SPIRIT 1 and 2). *Lancet* 2022; 399(10343):2267-2279.

Appendix G

Vote to Prior Authorize Vyvgart® (Efgartigimod Alfa-fcab) and Update the Approval Criteria for Empaveli® (Pegcetacoplan), Enspryng® (Satralizumab-mwge), Soliris® (Eculizumab), Ultomiris® (Ravulizumab-cwvz), and Uplizna® (Inebilizumab-cdon)

Oklahoma Health Care Authority
February 2023

Market News and Updates[1,2,3]

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

- **December 2021:** The FDA approved Vyvgart® (efgartigimod alfa-fcab) for the treatment of generalized myasthenia gravis (gMG) in adults who test positive for the anti-acetylcholine receptor (AChR) antibody. In gMG, the immune system produces AChR antibodies that interfere with communication between nerves and muscles, resulting in muscle weakness. Vyvgart® is the first approval of a new class of medications. It is an antibody fragment that binds to the neonatal Fc receptor (FcRn), preventing FcRn from recycling immunoglobulin G (IgG) back into the blood. The medication causes a reduction in overall levels of IgG, including the abnormal AChR antibodies that are present in gMG.
- **April 2022:** The FDA approved Ultomiris® (ravulizumab-cwvz) for the treatment of adult patients with gMG who are anti-AChR antibody positive. Ultomiris® is the first and only long-acting C5 complement inhibitor approved for the treatment of gMG. Ultomiris® is a humanized monoclonal antibody that specifically binds with high affinity to the human terminal complement protein C5, preventing disruption of neuromuscular transmission, presumably by inhibiting membrane attack complex-mediated destruction of the neuromuscular junction. Ultomiris® was engineered to maintain therapeutic serum concentrations over an 8-week dosing interval. The approval for gMG was based on positive results from the CHAMPION-MG Phase 3, randomized, double-blind, placebo-controlled study in which Ultomiris® was superior to placebo. In total, 175 patients were enrolled. Ultomiris® significantly increased the magnitude of mean changes from baseline to week 26 versus placebo in the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) (−3.1 vs. −1.4; P<0.001) and Quantitative Myasthenia Gravis (QMG) (−2.8 vs. −0.8; P<0.001) total scores. Improvements in both measures occurred within 1 week of Ultomiris® initiation and were sustained through week 26. QMG total scores improved by ≥5 points in a significantly greater proportion of Ultomiris®

treated patients compared to those receiving placebo (30.0% vs. 11.3%; P=0.005). No notable differences in adverse events were observed. The most common adverse reactions in patients receiving Ultomiris® were upper respiratory tract infection and diarrhea.

Vyvgart® (Efgartigimod Alfa-fcab) Product Summary[4,5]

Indication(s): Vyvgart® (efgartigimod alfa-fcab) is a FcRn blocker indicated for the treatment of gMG in adult patients who are anti-AChR antibody positive.

How Supplied: 400mg in 20mL (20mg/mL) solution single-dose vial (SDV) for intravenous (IV) infusion

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®.
- The recommended dosage is 10mg/kg administered as an IV infusion over 1 hour via a 0.2 micron in-line filter once weekly for 4 weeks.
- In patients weighing ≥120kg, the recommended dose is 1,200mg per infusion.
- 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.

Mechanism of Action: Efgartigimod alfa-fcab is a human IgG1 antibody fragment that binds to the FcRn, resulting in the reduction of circulating IgG.

Warnings and Precautions:

- Infections: Vyvgart® may increase the risk of infection. The most common infections observed were urinary tract infections and respiratory infections. A higher frequency of patients who received Vyvgart® versus placebo were observed to have below normal levels of white blood cell counts, lymphocyte counts, and neutrophil counts. Most infections and hematologic abnormalities were mild to moderate in severity. Administration of Vyvgart® should be delayed in patients with an active infection until the infection is resolved. During treatment with Vyvgart®, patients should be monitored for clinical signs and symptoms of infections. If serious infection occurs, appropriate treatment should be administered and withholding Vyvgart® until the infection has resolved should be considered.
- Immunization: Administration of vaccines during Vyvgart® treatment has not been studied. The safety of immunization with live or live-attenuated vaccines and the response to immunization with any vaccine are unknown. Because Vyvgart® causes a reduction in IgG

levels, patients should not receive live-attenuated or live vaccines during treatment with Vyvgart®. The need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with Vyvgart® should be considered.

- Hypersensitivity Reactions: Angioedema, dyspnea, and rash have occurred in patients treated with Vyvgart®. Patients should be monitored during administration and for 1 hour after the infusion for clinical signs and symptoms of hypersensitivity reactions. If a hypersensitivity reaction occurs during administration, therapy should be discontinued, and appropriate supportive measures should be used, if needed.
- Drug Interactions: Concomitant use of Vyvgart® with medications that bind to the human FcRn (e.g., immunoglobulin products, monoclonal antibodies, antibody derivates containing the human Fc domain of the IgG subclass) may lower systemic exposures and reduce effectiveness of such medications. Patients should be monitored closely for reduced effectiveness of medications that bind to the human FcRn. When concomitant long-term use of such medications is essential for patient care, discontinuing Vyvgart® and using alternative therapies should be considered.

Contraindication(s): None

Adverse Reactions: The most common adverse reactions (≥10%) occurring in patients with gMG treated with Vyvgart® were respiratory tract infection, headache, and urinary tract infection.

Efficacy: The safety and efficacy of Vyvgart® were established in a 26-week, multicenter, randomized, double-blind, placebo-controlled study. A total of 167 patients were enrolled in the study and met the following criteria at screening:

- Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV; and
- MG-ADL total score ≥5; and
- On stable dose of gMG therapy prior to screening [i.e., acetylcholinesterase (AChE) inhibitors, corticosteroids, or non-steroidal immunosuppressive therapies (NSISTs), either in combination or alone]; and
- IgG level ≥6g/L.

Patients were randomized to receive either Vyvgart® (n=84) or placebo (n=83). The median MG-ADL total score was 9, and the median QMG total score was 16. Most patients (n=65 for Vyvgart®; n=64 for placebo) were positive for AChR antibodies.

- Primary Endpoint: Comparison of the percentage of MG-ADL responders (≥2-point MG-ADL improvement sustained for ≥4 weeks)

during the first treatment cycle between treatment groups in the AChR antibody positive population

- Secondary Endpoint: Comparison of the percentage of QMG responders (≥3-point QMG improvement sustained for ≥4 weeks) during the first treatment cycle between both treatment groups in the AChR antibody positive population
- Results: For both endpoints, a statistically significant difference favoring Vyvgart® was observed. The MG-ADL responder rate, during the first treatment cycle, was 67.7% in the Vyvgart®-treated group vs. 29.7% in the placebo-treated group (P<0.0001). The QMG responder rate, during the first treatment cycle, was 63.1% in the Vyvgart®-treated group vs. 14.1% in the placebo-treated group (P<0.0001).

Cost: The Wholesale Acquisition Cost (WAC) of Vyvgart® is $5,950 per 400mg/20mL SDV, resulting in an estimated annual cost of $333,200 based on the recommended dose for an 80kg patient of 800mg once weekly for 4 weeks with subsequent cycles not being dosed sooner than 50 days from the start of the previous treatment cycle.

Cost Comparison: gMG Therapies

Medication	Cost for First Year	Cost Per Year for Maintenance
Vyvgart® (efgartigimod alfa-fcab)⁺	**$333,200**	**$333,200**
Ultomiris® (ravulizumab-cwvz)*	$550,744	$493,108
Soliris® (eculizumab)	$704,484	$678,392

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).
⁺Costs based on recommended dose for patients weighing 80kg.
*Costs based on recommended dosing for patients weighing 60kg to <100kg with gMG.

Recommendations

The College of Pharmacy recommends the prior authorization of Vyvgart® (efgartigimod alfa-fcab) with the following criteria (shown in red):

Vyvgart® (Efgartigimod Alfa-fcab) Approval Criteria:

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 (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.

Next, the College of Pharmacy recommends the addition of prior authorization criteria for Ultomiris® for a diagnosis of gMG based on the new FDA approved indication (shown in red):

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.

Additionally, the College of Pharmacy recommends updating the current prior authorization criteria for the following medications 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. ~~Must have an established diagnosis of PNH via international classification of disease (ICD) coding in member's medical claims history; and~~
3. Member must be 18 years of age or older; and
4. Empaveli® must be prescribed by, or in consultation with, a gastroenterologist, hematologist, geneticist, or a specialist with expertise in the treatment of PNH; and
5. 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
6. Prescriber and pharmacy must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. 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
8. 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:

1. An FDA approved diagnosis of neuromyelitis optica spectrum disorder (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. ~~Member must have an established diagnosis of aHUS or PNH via international classification of disease (ICD) coding in member's medical claims history; and~~
3. ~~For members younger than 18 years of age, approval can be granted with a documented diagnosis of aHUS; and~~
4. 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 [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. An FDA approved diagnosis of PNH; and
2. ~~Member must have an established diagnosis of aHUS or PNH via international classification of disease (ICD) coding in member's medical claims history; and~~
3. Member must be 18 years of age or older; and
4. Soliris® must be prescribed by, or in consultation with, a gastroenterologist, geneticist, hematologist, or a specialist with expertise in the treatment of PNH.

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 diagnosis 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.

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

1. ~~Member must have a documented~~ 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 [Paroxysmal Nocturnal Hemoglobinuria (PNH) Diagnosis]:

1. ~~Member must have an established~~ An FDA approved diagnosis of PNH ~~via international classification of disease (ICD) coding in member's medical claims history~~; 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:

1. An FDA approved diagnosis of neuromyelitis optica spectrum disorder (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.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves New Treatment for Myasthenia Gravis. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-myasthenia-gravis. Issued 12/17/2021. Last accessed 01/10/2023.
[2] AstraZeneca, Inc. Ultomiris® (Ravulizumab-cwvz) Approved in the U.S. for Adults with Generalized Myasthenia Gravis. Available online at: https://www.astrazeneca-us.com/media/press-releases/2022/ultomiris-approved-in-the-us-for-adults-with-generalized-myasthenia-gravis.html. Issued 04/28/2022. Last accessed 01/10/2023.
[3] Vu T, Meisel A, Mantegazza R, et al. Terminal Complement Inhibitor Ravulizumab in Generalized Myasthenia Gravis. *NEJM Evid* 2022; 1(5). doi: 10.1056/EVIDoa2100066.
[4] Vyvgart® (Efgartigimod Alfa-fcab) Prescribing Information. Argenx US, Inc. Available online at: https://www.argenx.com/product/vyvgart-prescribing-information.pdf. Last revised 04/2022. Last accessed 01/10/2023.
[5] Howard JF, Bril V, Vu T, et al. Safety, Efficacy, and Tolerability of Efgartigimod in Patients with Generalized Myasthenia Gravis (ADAPT): a Multicenter, Randomized, Placebo-controlled, Phase 3 Trial. *Lancet Neurol* 2021; 20: 526-36. doi: 10.1016/S1474-4422(21)00159-9.

Appendix H

Vote to Prior Authorize Omlonti® (Omidenepag Isopropyl) and Update the Approval Criteria for the Glaucoma Medications

Oklahoma Health Care Authority
February 2023

Market News and Updates[1]

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

- **September 2022:** The FDA approved Omlonti® (omidenepag isopropyl) for the reduction of elevated intraocular pressure (IOP) in patients with primary open-angle glaucoma (OAG) or ocular hypertension (OHT). Omlonti® is a relatively selective prostaglandin E2 (EP2) receptor agonist designed to increase aqueous humor drainage through the conventional (or trabecular) and uveoscleral outflow pathways and is the only product with this pharmacological action. The approval was based on data from 3 randomized controlled clinical trials.

Omlonti® (Omidenepag Isopropyl) Product Summary[2,3]

Indication(s): Omidenepag isopropyl is a relatively selective EP2 receptor agonist indicated for the reduction of elevated IOP in patients with OAG or OHT.

How Supplied: Ophthalmic solution containing 0.002% (0.02mg/mL) of omidenepag isopropyl

Dosing and Administration: The recommended dosage is 1 drop in the affected eye(s) once daily in the evening.

- The bottle should be gently shaken prior to administration.
- If more than 1 topical ophthalmic drug is being used, the drugs should be administered at least 5 minutes apart.
- Contact lenses should be removed prior to the administration of Omlonti® and may be reinserted 15 minutes after administration.

Warnings and Precautions:

- Pigmentation: Pigmentation of the iris is expected to increase as long as Omlonti® is administered and is likely to be permanent even after discontinuation. Patients who receive prostaglandin analogs, including Omlonti®, should be informed of the possibility of increased pigmentation, including permanent changes. Treatment with Omlonti® may be continued in patients who develop noticeably increased iris pigmentation; however, these patients should be examined regularly.

- Eyelash Changes: Treatment with Omlonti® may gradually change eyelashes and vellus hair in the treated eye. These changes include increased length, thickness, and the number of lashes or hairs. Eyelash changes are usually reversible upon discontinuation of treatment.
- Ocular Inflammation: Ocular inflammation has been reported in patients taking Omlonti®. Omlonti® should be used with caution in patients with active ocular inflammation, including iritis/uveitis.
- Macular Edema: Macular edema, including cystoid macular edema, has been reported during clinical trials in patients with pseudophakia receiving Omlonti®. Omlonti® should be used with caution in aphakic patients, in pseudophakia patients, or in patients with known risk factors for macular edema.
- Risk of Contamination and Potential Injury to Eye: Patients should be advised to avoid touching the tip of the bottle to the eye or any surface, as this may contaminate the solution, and to not touch the tip to their eye to avoid the potential for injury to the eye.

Contraindication(s): None

Adverse reactions: The most common adverse reactions (incidence ≥1%) are conjunctival hyperemia, photophobia, blurred vision, dry eye, instillation site pain, eye pain, ocular hyperemia, punctate keratitis, headache, eye irritation, and visual impairment.

Efficacy: The safety and efficacy of Omlonti® were established in (3) Phase 3, randomized controlled, double-masked, active-controlled, parallel group, clinical trials with patients diagnosed with OAG or OHT with average baseline IOP of 24-26mmHg.

- The PEONY trial compared Omlonti® to latanoprost, and the SPECTRUM 3 and SPECTRUM 4 trials compared Omlonti® to timolol.
- The double-masked treatment duration was 3 months in all 3 studies. The SPECTRUM 3 trial included a 9-month open-label treatment period following the 3-month double-masked treatment period.
- In the 3 studies, IOP reductions were observed for all treatment arms. In the Omlonti® arm, the reduction in IOP ranged from 5-7mmHg across all 3 studies. The corresponding reductions for the timolol and latanoprost arms were 5-7mmHg and 6-8mmHg, respectively.
- Omlonti® was determined to be noninferior to timolol and latanoprost in the SPECTRUM 4 and the PEONY trials, but not in the SPECTRUM 3 trial. However, in its review, the FDA noted that the SPECTRUM 4 trial results were “trending in the right direction” and added supportive data to recommend FDA approval.

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

Recommendations

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

1. Adding Omlonti® (omidenepag isopropyl 0.002%) to the Special PA Tier; and
2. Making Combigan® (brimonidine/timolol 0.2%/0.5%) brand preferred; and
3. Moving pilocarpine (Isopto® Carpine 1%, 2%, 4%) from Tier-2 to Tier-1.

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
Alpha-2 Adrenergic Agonists		
brimonidine (Alphagan® 0.2%)	apraclonidine (Iopidine® 0.5%, 1%)	brimonidine (Alphagan-P® 0.15%)
brimonidine (Alphagan® P 0.1%)		
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
Beta-Blockers		
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**	betaxolol (Betoptic® 0.5%, Betoptic-S® 0.25%)	timolol maleate (Istalol® 0.5%)
carteolol (Ocupress® 1%)	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	timolol maleate (Timoptic® in Ocudose® 0.25%, 0.5%)
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)	timolol (Betimol® 0.25%, 0.5%	
levobunolol (Betagan® 0.25%, 0.5%)	timolol maleate (Timoptic-XE® 0.25%, 0.5%)	
timolol maleate (Timoptic® 0.25%, 0.5%)		
Carbonic Anhydrase Inhibitors		
acetazolamide (Diamox® 500mg caps; 125mg, 250mg tabs)+	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	methazolamide (Neptazane® 25mg, 50mg tabs)+
brinzolamide (Azopt® 1%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
dorzolamide (Trusopt® 2%)		
dorzolamide/timolol		

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
(Cosopt® 22.3/6.8mg/mL)		
Cholinergic Agonists/Cholinesterase Inhibitors		
echothiophate iodide (Phospholine Iodide® 0.125%)	~~**pilocarpine (Isopto® Carpine 1%, 2%, 4%)**~~	
pilocarpine (Isopto® Carpine 1%, 2%, 4%)		
Prostaglandin Analogs		
bimatoprost (Lumigan® 0.01%)	bimatoprost (Lumigan® 0.03%)	latanoprost (Xelpros™ 0.005%)
latanoprost (Xalatan® 0.005%)		latanoprostene bunod (Vyzulta® 0.024%)
netarsudil/latanoprost (Rocklatan®)		**omidenepag isopropyl (Omlonti® 0.002%)**
tafluprost (Zioptan® 0.0015%)		
travoprost (Travatan-Z® 0.004%) – **Brand Preferred**		
Rho Kinase Inhibitors		
netarsudil (Rhopressa® 0.02%)		
netarsudil/latanoprost (Rocklatan®)		

*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).
†Indicates available oral medications.
Please note: Combination products are included in both applicable pharmaceutical classes; therefore, combination products are listed twice in the tier chart.
caps = capsules; PA = prior authorization; tabs = tablets

Glaucoma Medications Special Prior Authorization (PA) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why a special formulation is needed over a Tier-1 or Tier-2 medication must be provided; or
3. Approvals may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier-1 and Tier-2 medications; or
4. Approvals may be granted if there is a unique FDA approved indication not covered by all Tier-1 and Tier-2 medications; and
5. Member must have had a comprehensive, dilated eye exam within the last 365-day period as recommended by the National Institutes of Health; and
6. Approvals will be for the duration of 1 year.

[1] Santen Pharmaceuticals Co., Ltd. Santen and Ube Received FDA Approval for Omlonti® (Omidenepag Isopropyl Ophthalmic Solution) 0.002% for the Reduction of Elevated Intraocular Pressure in Patients with Primary Open-Angle Glaucoma or Ocular Hypertension. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20220926005533/en/Santen-and-UBE-Received-FDA-Approval-for-OMLONTI%C2%AE-Omidenepag-Isopropyl-Ophthalmic-Solution-0.002-for-the-Reduction-of-Elevated-Intraocular-Pressure-in-Patients-with-Primary-Open-Angle-Glaucoma-or-Ocular-Hypertension. Issued 09/26/2022. Last accessed 01/11/2023.

[2] U.S. Food and Drug Administration (FDA). Omlonti® Clinical Review Documents. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/215092Orig1s000MedR.pdf. Last accessed 01/11/2023.

[3] Omlonti® (Omidenepag Isopropyl) Prescribing Information. Santen Pharmaceuticals Co., Ltd. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215092s000lbl.pdf. Last revised 09/2022. Last accessed 01/11/2023.

Appendix I

Vote to Prior Authorize Vabysmo™ (Faricimab-svoa) and Update the Approval Criteria for the Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitor Medications

Oklahoma Health Care Authority
February 2023

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

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

- **January 2022:** The FDA approved Vabysmo™ (faricimab-svoa) for the treatment of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME). Vabysmo™ is the first and only FDA approved injectable eye medication for nAMD and DME that improves and maintains vision with treatments from 1 to 4 months apart in the first year following initial monthly doses. The standard of care for nAMD and DME typically requires eye injections every 1 to 2 months. The approval is based on positive results across 4 Phase 3 studies in patients with nAMD or DME.
- **August 2022:** The FDA approved Cimerli™ (ranibizumab-eqrn) as a biosimilar product interchangeable with Lucentis® (ranibizumab) for the treatment of patients with nAMD, macular edema following retinal vein occlusion (RVO), DME, diabetic retinopathy (DR), or myopic choroidal neovascularization (mCNV). The FDA approval is based on data from the COLUMBUS-AMD study which confirmed equivalent safety and efficacy to Lucentis®; therefore, clinical outcomes with Cimerli™ are expected to be the same as Lucentis® for any given patient across all indications.

Vabysmo™ (Faricimab-svoa) Product Summary[5]

Indication(s): Faricimab-svoa is a VEGF and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of adults with nAMD or DME.

How Supplied: 120mg/mL solution in a 0.05mL single-dose vial (SDV)

Dosing and Administration:

- nAMD: Recommended dose is 6mg administered by intravitreal injection every 4 weeks for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6mg dose via intravitreal injections on 1 of the following 3 regimens:

- Weeks 28 and 44; or
- Weeks 24, 36, and 48; or
- Weeks 20, 28, 36, and 44
- Some patients may need every 4 week dosing

- DME: Vabysmo™ is recommended to be dosed by 1 of the following regimens:
  - 6mg administered by intravitreal injection every 4 weeks for at least 4 doses, and if signs of improvement are noted, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on central subfield thickness (CST) and visual acuity evaluations through week 52; or
  - 6mg every 4 weeks for the first 6 doses, followed by 6mg dose via intravitreal injection at 8 week intervals over the next 28 weeks
  - Some patients may need every 4 week dosing

Mechanism of Action:

- Faricimab is a humanized bispecific antibody that acts through inhibition of 2 pathways by binding to VEGF-A and Ang-2. By inhibiting VEGF-A, faricimab suppresses endothelial cell proliferation, neovascularization, and vascular permeability. By inhibiting Ang-2, faricimab is thought to promote vascular stability and desensitize blood vessels to the effects of VEGF-A.

Contraindication(s):

- Ocular or periocular infection
- Active intraocular inflammation
- Hypersensitivity

Safety:

- Endophthalmitis and Retinal Detachments: Intravitreal injections have been associated with endophthalmitis and retinal detachments. Proper aseptic injection techniques must always be used when administering Vabysmo™. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management.
- Increase in Intraocular Pressure (IOP): Transient increases in IOP have been seen within 60 minutes of intravitreal injection, including with Vabysmo™. IOP and the perfusion of the optic nerve head should be monitored and managed appropriately.
- Thromboembolic Events: Although there was a low rate of arterial thromboembolic events (ATEs) observed in the Vabysmo™ clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The

incidence of reported ATEs during the first year was 1% (7 out of 664) and 2% (25 out of 1,262) in patients treated with Vabysmo™ compared with 1% (6 out of 662) and 2% (14 out of 625) in patients treated with aflibercept in the nAMD and DME studies, respectively.

Adverse Reactions:

- Most common adverse reaction (incidence ≥5%) in patients treated with Vabysmo™ was conjunctival hemorrhage

Efficacy:

- nAMD: The safety and efficacy of Vabysmo™ in patients with nAMD were assessed in the Phase 3 TENAYA and LUCERNE studies which were identical randomized, multicenter, double-masked, active comparator-controlled 2-year studies evaluating Vabysmo™ compared to aflibercept in patients with nAMD. The studies had 2 treatment arms: 1) Vabysmo™ 6mg administered at intervals of 8, 12, or 16 weeks, following 4 initial monthly doses, selected based on objective assessment of disease activity at weeks 20 and 24 and 2) aflibercept 2mg administered at fixed 8 week intervals after 3 initial monthly doses. The primary endpoint was defined as the mean change from baseline in best corrected visual acuity (BCVA) when averaged over the week 40, 44, and 48 visits and measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter chart. In the TENAYA Study, the least squares (LS) mean difference between Vabysmo™ and aflibercept was 0.7 [95% confidence interval (CI): -1.1, 2.5]. In the Lucerne Study, the LS mean difference between Vabysmo™ and aflibercept was 0.0 (95% CI: -1.7, 1.8). Both studies demonstrated non-inferiority of Vabysmo™ to aflibercept.
- DME: The safety and efficacy of Vabysmo™ in patients with DME were assessed in the Phase 3 YOSEMITE and RHINE studies which were identical, randomized, multicenter, double-masked, active comparator-controlled 2-year studies. Patients were randomized to receive 1 of 3 regimens: 1) aflibercept 2mg every 8 weeks after the first 5 monthly doses, 2) Vabysmo™ 6mg every 8 weeks after the first 6 monthly doses (Vabysmo™ Q8W group), or 3) Vabysmo™ 6mg every 4 weeks for at least 4 doses and until the CST of the macula measured by optical coherence tomography was <325 microns, then the interval of the dosing was modified by up to 4 weeks interval extensions or up to 8 week interval reductions (Vabysmo™ Variable group). The primary endpoint was defined as the mean change from baseline in BCVA when averaged over the week 48, 52, and 56 visits and measured by the ETDRS letter chart. In the YOSEMITE study, the LS mean difference between the Vabysmo™ Q8W group and aflibercept was -0.2 (97.5% CI: -2.0, 1.6) and the LS mean difference between the Vabysmo™ Variable

group and aflibercept was 0.7 (97.5% CI: -1.1, 2.5). In the RHINE study, the LS mean difference between the Vabysmo™ Q8W group and aflibercept was 1.5 (97.5% CI: -0.1, 3.2) and the LS mean difference between the Vabysmo™ Variable group and aflibercept was 0.5 (97.5% CI: -1.1, 2.1). Both studies demonstrated non-inferiority of Vabysmo™ to aflibercept.

Cost Comparison: Ophthalmic VEGF Inhibitor Medications

Product	Cost Per Dose	Cost Per Year
Vabysmo™ (faricimab-svoa inj) 6mg/0.05mL*	**$2,190 per 0.05mL**	**$28,470**
Cimerli™ (ranibizumab-eqrn inj) 0.5mg/0.05mL±	**$1,360 per 0.05mL**	**$17,680**
Byooviz™ (ranibizumab-nuna inj) 0.5mg/0.05mL±	$1,130 per 0.05mL	$14,690
Lucentis® (ranibizumab inj) 0.5mg/0.05mL±	$1,950 per 0.05mL	$25,350
Eylea® (aflibercept inj) 2mg/0.05mL+	$1,850 per 0.05mL	$14,800
Beovu® (brolucizumab-dbll inj) 6mg/0.05mL≠	$1,850 per 0.05mL	$14,800

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).
Please note: The cost per dose is based on treatment of one eye, and the cost per year is based on the maximum number of doses needed for the treatment of one eye.
*Vabysmo™ cost is based on 6mg every 4 weeks.
±Cimerli™, Byooviz™, and Lucentis® cost is based on 0.5mg every 4 weeks.
+Eylea® cost is based on 2mg every 4 weeks.
≠Beovu® cost is based on 6mg monthly for 3 doses, followed by 6mg every 8 weeks.
inj = injection

Recommendations

The College of Pharmacy recommends the prior authorization of Vabysmo™ (faricimab-svoa) with the following criteria (shown in red):

Vabysmo™ (Faricimab-svoa Intravitreal Injection) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Neovascular (wet) age-related macular degeneration (AMD); or
   b. Diabetic macular edema (DME); and
2. Member must be 18 years of age or older; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Vabysmo™ must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal injections; and
5. Prescriber must verify the member will be monitored for endophthalmitis, retinal detachment, increase in intraocular pressure, and arterial thromboembolic events, and
6. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use

effective contraception during treatment and for 3 months after the final dose of Vabysmo™; and
7. A patient-specific, clinically significant reason why the member cannot use VEGF inhibitor injection products (appropriate to the disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli™ (ranibizumab-eqrn), Eylea® (aflibercept)] must be provided; and
8. A quantity limit of 0.05mL per 28 days will apply.

Additionally, the College of Pharmacy recommends updating the ranibizumab approval criteria based on the FDA approval of Cimerli™ and the low net cost of the biosimilar products relative to Lucentis® (changes shown in red):

Lucentis® (Ranibizumab Intravitreal Injection) ~~Byooviz™ (Ranibizumab-nuna Intravitreal Injection)~~ Approval Criteria:

1. An FDA approved diagnosis ~~of 1 of the following~~:
   ~~a. Neovascular (wet) age-related macular degeneration (AMD); or~~
   ~~b. Macular edema following retinal vein occlusion (RVO); or~~
   ~~c. Myopic choroidal neovascularization (mCNV);~~ and
2. A patient-specific, clinically significant reason why the member cannot use ~~Lucentis® (ranibizumab intravitreal injection)~~ Byooviz™ (ranibizumab-nuna intravitreal injection) or Cimerli™ (ranibizumab-eqrn intravitreal injection) 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.

Lastly, the College of Pharmacy recommends updating the Susvimo™ (ranibizumab intravitreal implant) approval criteria based on the FDA approval of Cimerli™ and approval criteria changes for the ranibizumab injection products (changes shown in red):

Susvimo™ (Ranibizumab Intravitreal Implant) Approval Criteria:

1. An FDA approved diagnosis of neovascular (wet) age-related macular degeneration (AMD) in adults; and
2. Member must have previously responded to ≥2 intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor; and
3. Member must not have ocular or periocular infections or active intraocular inflammation; and
4. Susvimo™ must be prescribed and administered by an ophthalmologist or a physician experienced in vitreoretinal surgery; and

5. Prescriber must verify the member will be monitored for endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion, conjunctival retraction, and conjunctival blebs; and
6. A patient-specific, clinically significant reason why the member cannot use ~~Lucentis® (~~ranibizumab intravitreal injection~~)~~ or other VEGF inhibitor injection products (appropriate to disease state) available without prior authorization [i.e., Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna), Cimerli™ (ranibizumab-eqrn), Eylea® (aflibercept)] must be provided; and
7. A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.

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[1] Roche. FDA approves Roche's Vabysmo™, the First Bispecific Antibody for the Eye, to Treat Two Leading Causes of Vision Loss. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2022/01/31/2375370/0/en/FDA-approves-Roche-s-Vabysmo-the-first-bispecific-antibody-for-the-eye-to-treat-two-leading-causes-of-vision-loss.html. Issued 01/31/2022. Last accessed 01/17/2023.

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Appendix J

Vote to Prior Authorize Auvelity™ (Dextromethorphan/ Bupropion) and Venlafaxine 112.5mg Extended-Release (ER) Tablet

Oklahoma Health Care Authority
February 2023

Market News and Updates[1,2]

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

- **June 2022:** The FDA approved a New Drug Application (NDA) for a new tablet formulation of ER venlafaxine for the indications of major depressive disorder (MDD) or generalized anxiety disorder (GAD) in adults. The new formulation is available as venlafaxine besylate 112.5mg ER tablets. Venlafaxine besylate ER tablets are not recommended for initial dosage, titration, or doses below 112.5mg once daily; however, venlafaxine besylate ER tablets can be initiated at a dose of 112.5mg once daily in patients who have received at least 75mg of another venlafaxine ER product for at least 4 days. The maximum recommended dose of venlafaxine besylate ER is 225mg once daily. The efficacy of venlafaxine besylate ER tablets for the treatment of MDD and GAD in adults was based upon adequate and well-controlled studies of venlafaxine ER capsules. Effexor XR® (venlafaxine hydrochloride ER) is available generically and is supplied as ER tablets in 4 strengths, 37.5mg, 75mg, 150mg, and 225mg and as ER capsules in 3 strengths, 37.5mg, 75mg, and 150mg.
- **August 2022:** The FDA approved Auvelity™ (dextromethorphan hydrobromide/bupropion hydrochloride) ER tablets for the treatment of MDD in adults. It is the first and only N-methyl D-aspartate (NMDA) receptor antagonist approved for the treatment of MDD. The efficacy of Auvelity™ in the treatment of MDD was demonstrated in the GEMINI placebo-controlled study and confirmatory evidence which included the ASCEND study comparing Auvelity™ to bupropion sustained-release (SR) tablets.

Auvelity™ (Dextromethorphan/Bupropion) Product Summary[3]

Indication(s): Auvelity™ is a combination of dextromethorphan, an NMDA receptor antagonist and sigma-1 receptor agonist, and bupropion, an

aminoketone and CYP450 2D6 inhibitor, indicated for the treatment of MDD in adults.

Boxed Warning: Risk for Suicidal Thoughts and Behaviors

- Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. All antidepressant-treated patients should be closely monitored for clinical worsening and emergence of suicidal thoughts and behaviors.
- Auvelity™ is not approved for use in pediatric patients.

How Supplied: 45mg/105mg dextromethorphan/bupropion ER tablets

Dosing and Administration:

- Prior to initiating treatment and during treatment with Auvelity™:
  - Blood pressure should be assessed and monitored periodically during treatment.
  - Patients should be screened for a personal or family history of bipolar disorder, mania, or hypomania.
  - Patients should be screened to determine if they are receiving any other medications that contain bupropion or dextromethorphan.
- The recommended starting dose is 1 tablet once daily in the morning. After 3 days, the dose should be increased to the maximum recommended dosage of 1 tablet twice daily, separated by at least 9 hours. Patients should not exceed 2 doses within the same day.
- Tablets should be swallowed whole and should not be crushed, divided, or chewed.
- For moderate renal impairment or CYP2D6 poor metabolizers, the recommended dose is 1 tablet by mouth once daily in the morning.

Mechanism of Action:

- Dextromethorphan is a noncompetitive antagonist of the NMDA receptor and a sigma-1 receptor agonist.
- Bupropion increases plasma levels of dextromethorphan by competitively inhibiting cytochrome P450 2D6, which catalyzes a major biotransformation pathway for dextromethorphan.

Contraindication(s):

- Seizure disorder
- Current or prior diagnosis of bulimia or anorexia nervosa
- Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs
- Concomitant use of monoamine oxidase inhibitors (MAOIs) or within 14 days of discontinuing an MAOI

- Known hypersensitivity to bupropion, dextromethorphan, or other components of Auvelity™

Safety:

- Seizures: Bupropion, a component of Auvelity™, can cause seizures. The risk of seizures with bupropion is dose-related. Because the risk of seizures with bupropion is dose-related, patients should be screened for other bupropion-containing products prior to initiating Auvelity™. If concomitant use of Auvelity™ with other bupropion-containing products is clinically warranted, patients should be informed of the risk of seizures. Auvelity™ should be discontinued and treatment with Auvelity™ should not be restarted if a patient experiences a seizure.
- Increased Blood Pressure and Hypertension: Bupropion can cause elevated blood pressure and hypertension. The risk of hypertension is increased if Auvelity™ is used concomitantly with MAOIs or other drugs that increase the dopaminergic or noradrenergic activity. Blood pressure should be assessed prior to initiating treatment and should be periodically monitored during treatment with Auvelity™.
- Activation of Mania or Hypomania: Antidepressant treatment can precipitate a manic, mixed, or hypomanic manic episode. The risk appears to be increased in patients with bipolar disorder or who have risk factors for bipolar disorder. Prior to initiating Auvelity™, patients should be screened for a history of bipolar disorder and the presence of risk factors for bipolar disorder.
- Psychosis and Other Neuropsychiatric Reactions: Depressed patients treated with bupropion have had a variety of neuropsychiatric signs and symptoms, including delusions, hallucinations, psychosis, concentration disturbance, paranoia, and confusion. Dextromethorphan overdose can cause toxic psychosis, stupor, coma, and hyperexcitability. The risks of neuropsychiatric reactions are dose-related. Patients should be screened for use of other bupropion- or dextromethorphan-containing products prior to initiating Auvelity™. If concomitant use of Auvelity™ with other bupropion- or dextromethorphan-containing products is clinically warranted, patients should be monitored for neuropsychiatric reactions and should be instructed to contact a health care provider if such reactions occur.
- Angle-Closure Glaucoma: The pupillary dilation that occurs following the use of many antidepressant drugs including bupropion may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Use of antidepressants, including Auvelity™, should be avoided in patients with untreated anatomically narrow angles.
- Dizziness: Auvelity™ may cause dizziness. Precautions should be taken to reduce the risk of falls, particularly in patients with motor

impairment affecting gait or those with a history of falls. Patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that Auvelity™ therapy does not affect them adversely.

- Serotonin Syndrome: Concomitant use of Auvelity™ with selective serotonin reuptake inhibitors (SSRIs) or tricyclic antidepressants may cause serotonin syndrome, a potentially life-threatening condition with changes including altered mental status, hypertension, restlessness, myoclonus, hyperthermia, hyperreflexia, diaphoresis, shivering, and tremor. Patients should be screened for use of other dextromethorphan-containing products prior to initiating Auvelity™. If concomitant use of Auvelity™ with other serotonergic drugs is clinically warranted, patients should be informed of the increased risk of serotonin syndrome and should be monitored for symptoms. If symptoms of serotonin syndrome occur, Auvelity™ and/or concomitant serotonergic drugs should be discontinued immediately and supportive symptomatic treatment should be initiated.
- Embryo-fetal Toxicity: Based on animal studies, Auvelity™ may cause fetal harm when administered during pregnancy. In developmental toxicity studies in rats and rabbits, when a combination of dextromethorphan/quinidine was given to pregnant animals, fetal malformations (rabbits) and embryo lethality were demonstrated in offspring. The separate effect of dextromethorphan on developmental toxicity at the recommended clinical dose is unclear. Treatment with Auvelity™ should be discontinued in pregnant females, and the patient should be advised about the potential risk to the fetus. Alternative treatment should be used for females who are planning to become pregnant.

Adverse Reactions:

- Most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) in clinical studies were dizziness, headache, diarrhea, somnolence, dry mouth, sexual dysfunction, and hyperhidrosis.

Efficacy: The efficacy of Auvelity™ for treatment of MDD in adults was demonstrated in a placebo-controlled clinical study known as GEMINI and confirmatory evidence from the ASCEND study which compared Auvelity™ to bupropion SR tablets.

- In the **GEMINI study**, adult patients who met the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for MDD were randomized to receive Auvelity™ (N=156) or placebo (N=162) twice daily for 6 weeks. The primary outcome was the change from baseline to week 6 in the total score of the Montgomery-Asberg Depression Rating Scale (MADRS). MADRS is a clinician-rated scale used to assess the

severity of depressive symptoms. Scores range from 0 to 60, with higher scores indicating more severe depression. Auvelity™ was statistically significantly superior to placebo in improvements of depressive symptoms. The mean baseline MADRS total score was 33.6 [standard deviation (SD): 4.4] in the Auvelity™ group and 33.2 (SD: 4.4) in the placebo group. At week 6, the least-squares (LS) mean change from baseline in the MADRS total score was -15.9 [standard error (SE): 0.9] in the Auvelity™ group compared to -12.1 (0.9) in the placebo group [LS mean difference: -3.9; 95% confidence interval (CI): -6.4, -1.4].

- In the **ASCEND study**, patients with MDD were randomized to receive Auvelity™ or bupropion SR 105mg tablets twice daily for 6 weeks. The primary outcome calculated by assessing the change from baseline in the total MADRS score at each on-site visit from week 1 to 6 and then taking the average of those scores. The results showed treatment with Auvelity™ compared to bupropion demonstrated an average decrease of MADRS points of 13.7 versus 8.8 with bupropion, which showed that dextromethorphan contributes to the antidepressant properties of Auvelity™.

Cost: The Wholesale Acquisition Cost (WAC) of Auvelity™ is $17.47 per tablet, resulting in an estimated monthly cost of $1,048.20 and annual cost of $12,578.40 based on the recommended dose of 1 tablet twice a day.

Cost Comparison: Venlafaxine ER Products

Product	Cost Per Unit	Cost Per 30 Days
Venlafaxine besylate ER tab 112.5mg	**$6.17**	**$185.10**
Venlafaxine HCl ER cap 75mg	$0.11	$3.30
Venlafaxine HCl ER tab 75mg	$3.17	$95.10
Venlafaxine HCl ER cap 150mg	$0.14	$4.20
Venlafaxine HCl ER tab 150mg	$3.45	$103.50
Venlafaxine HCl ER tab 225mg	$13.24	$397.20

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 30 days based once daily dosing of each strength.
Unit = capsule or tablet
cap = capsule; ER = extended release; HCl = hydrochloride; tab = tablet

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 Auvelity™ (dextromethorphan/bupropion) and placement in the Special PA Tier (changes based on discussion at the December DUR Board meeting are shown in red); and
2. Prior authorization of venlafaxine 112.5mg ER tablet and placement in the Special PA Tier.

Antidepressants*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Selective Serotonin Reuptake Inhibitors (SSRIs)			
citalopram (Celexa®)			citalopram 30mg caps
escitalopram (Lexapro®)			citalopram 20mg/10mL soln (UDC)
fluoxetine caps (Prozac®)			escitalopram 10mg/10mL soln (UDC)
fluvoxamine (Luvox®)			fluoxetine 20mg/5mL soln (UDC)
paroxetine (Paxil®)			fluoxetine tabs
sertraline (Zoloft®)			fluoxetine DR (Prozac® Weekly™)
			fluvoxamine CR (Luvox CR®)
			paroxetine CR (Paxil CR®)
			paroxetine (Pexeva®)
			sertraline 150mg & 200mg
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 (Effexor®, Effexor XR® caps)			trazodone 300mg tabs (Desyrel®)
			venlafaxine 112.5mg ER tabs
			venlafaxine ER tabs (Effexor XR® tabs)
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).
caps = capsules; CR = controlled-release; DR = delayed-release; ER = extended-release; PA = prior authorization; soln = solution; tabs = tablets; UDC = unit dose cups

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.
4. **Auvelity™ (Dextromethorphan/Bupropion) Approval Criteria:**
    a. An FDA approved diagnosis of major depressive disorder; and
    b. Member must be 18 years of age or older; and
    c. Prescriber must agree that member's blood pressure will be assessed prior to treatment initiation and monitored periodically during treatment; and
    d. Prescriber must agree to screen members for history of bipolar disorder, mania, or hypomania; and
    e. Member must not be taking any other medications containing bupropion or dextromethorphan; and

f. 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
g. Member must not have severe hepatic or renal impairment; and
h. 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, ~~bupropion~~), or is a known poor CYP2D6 metabolizer; and
i. Prescribers must verify that female members are not currently pregnant and will use effective contraception while receiving treatment with Auvelity™; and
j. 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
k. 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
l. A quantity limit of 60 tablets per 30 days will apply.

5. **Citalopram Capsule Approval Criteria:**
   a. An FDA approved diagnosis of major depressive disorder (MDD) in adults; and
   b. Member must have initiated treatment with citalopram tablets for dose titration up to the 30mg dose; and
   c. 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
   d. Citalopram capsules will not be approved for members 60 years of age or older; and
   e. A quantity limit of 30 capsules per 30 days will apply.
6. **Citalopram 20mg/10mL Solution, Escitalopram 10mg/10mL Solution, and Fluoxetine 20mg/5mL Solution Unit Dose Cup (UDC) Approval Criteria:**
   a. An FDA approved indication; and
   b. A patient-specific, clinically significant reason why the member cannot use the bulk medication must be provided.
7. **Desyrel® (Trazodone 300mg Tablet) Approval Criteria:**

a. 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.

8. **Drizalma Sprinkle™ (Duloxetine Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:**
   a. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
   b. 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
   c. A quantity limit of 30 capsules per 30 days will apply.
9. **Fluoxetine Tablet Approval Criteria:**
   a. 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.
10. **Irenka™ (Duloxetine 40mg Capsule) Approval Criteria [Diabetic Peripheral Neuropathic Pain/Chronic Musculoskeletal Pain Diagnosis]:**
    a. An FDA approved diagnosis of diabetic peripheral neuropathy or chronic musculoskeletal pain; and
    b. 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
    c. A quantity limit of 30 capsules per 30 days will apply; and
11. **Marplan® (Isocarboxazid) Approval Criteria:**
    a. 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.
12. **Sertraline Capsule Approval Criteria:**
    a. An FDA approved diagnosis of major depressive disorder (MDD) in adults or obsessive-compulsive disorder (OCD) in adults and pediatric patients 6 years of age and older; and
    b. Member must have initiated treatment with sertraline tablets for dose titration up to the 150mg or 200mg dose; and
    c. 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
    d. A quantity limit of 30 capsules per 30 days will apply.

13. **Venlafaxine 112.5mg Extended-Release (ER) Tablet Approval Criteria:**
    a. An FDA approved diagnosis of major depressive disorder (MDD) or generalized anxiety disorder (GAD); and
    b. Member must be 18 years of age or older; and
    c. Member must have received at least 75mg of venlafaxine ER capsules for at least 4 days; and
    d. A patient-specific, clinically significant reason why the member cannot use venlafaxine ER capsules must be provided; and
    e. A quantity limit of 30 tablets per 30 days will apply.

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[1] Venlafaxine Extended-Release Tablets Prescribing Information. Norwich Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215429s000lbl.pdf. Last revised 06/2022. Last accessed 01/17/2023.

[2] Axsome Therapeutics, Inc. Axsome Therapeutics Announces FDA Approval of Auvelity™, the First and Only Oral NMDA Receptor Antagonist for the Treatment of Major Depressive Disorder in Adults. Available online at: https://www.globenewswire.com/news-release/2022/08/19/2501453/33090/en/Axsome-Therapeutics-Announces-FDA-Approval-of-AUVELITY-the-First-and-Only-Oral-NMDA-Receptor-Antagonist-for-the-Treatment-of-Major-Depressive-Disorder-in-Adults.html. Issued 08/19/2022. Last accessed 01/17/2023.

[3] Auvelity™ (Dextromethorphan/Bupropion) Extended-Release Tablets Prescribing Information. Axsome Therapeutics, Inc. Available online at: https://www.axsome.com/auvelity-prescribing-information.pdf. Last revised 10/2022. Last accessed 01/17/2023.

Appendix K

Vote to Prior Authorize Kimmtrak® (Tebentafusp-tebn) and Opdualag™ (Nivolumab/Relatlimab-rmbw) and Update the Approval Criteria for the Skin Cancer Medications

Oklahoma Health Care Authority
February 2023

Market News and Updates[1]

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

- **December 2021:** The FDA approved Keytruda® (pembrolizumab) for the adjuvant treatment of adult and pediatric patients 12 years of age and older with stage 2B or 2C melanoma following complete resection.
- **January 2022:** The FDA approved Kimmtrak® (tebentafusp-tebn), a bispecific gp100 peptide-human leukocyte antigen (HLA)-directed cluster of differentiation 3 (CD3) T cell engager, for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.
- **March 2022:** The FDA approved Opdualag™ (nivolumab/relatlimab-rmbw) for adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. Opdualag™ is a fixed-dose combination of a lymphocyte activation gene-3 (LAG-3)-blocking antibody (relatlimab-rmbw) and a programmed death 1 (PD-1) blocking antibody (nivolumab).
- **June 2022:** The FDA granted accelerated approval to Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib) for the treatment of adult and pediatric patients 6 years 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.
- **November 2022:** The FDA approved Libtayo® (cemiplimab-rwlc) in combination with platinum-based chemotherapy for adult patients with advanced non-small cell lung cancer (NSCLC) with no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 aberrations.

Kimmtrak® (Tebentafusp-tebn) Product Summary[2]

- **Therapeutic Class:** Bispecific gp100 peptide-HLA-directed CD3 T cell engager
- **Indication(s):** Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma

- **How Supplied:** 100mcg/0.5mL solution in a single-dose vial (SDV) for intravenous (IV) infusion
- **Dose:** 20mcg on day 1, 30mcg on day 8, 68mcg on day 15, and 68mcg once every week thereafter
- **Cost:** The Wholesale Acquisition Cost (WAC) is $37,520 per mL, resulting in a cost per dose of $18,760 and an annual cost of $994,280 based on the recommended dosing.

Opdualag™ (Nivolumab/Relatlimab-rmbw) Product Summary[3]

- **Therapeutic Class:** Combination of a PD-1 blocking antibody and a LAG-3 blocking antibody
- **Indication(s):** Treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma
- **How Supplied:** 240mg of nivolumab and 80mg of relatlimab-rmbw per 20mL (12mg/4mg/mL) in a SDV for IV infusion
- **Dose:**
  - Adult patients and pediatric patients 12 years of age or older who weigh at least 40kg: 480mg nivolumab/160mg relatlimab-rmbw every 4 weeks
- **Cost:** The WAC is $684.71 per mL, resulting in a cost per dose of $27,388.40 and an annual cost of $356,049.20 based on the recommended dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Kimmtrak® (tebentafusp-tebn) and Opdualag™ (nivolumab/relatlimab-rmbw) with the following criteria (shown in red):

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.

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)].

The College of Pharmacy also recommends updating the approval criteria for Keytruda® (pembrolizumab), Libtayo® (cemiplimab-rwlc), Mekinist® (trametinib), and Tafinlar® (dabrafenib) based on recent FDA approvals (updates shown in red):

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

1. Member meets 1 of the following:
    a. ~~Adjuvant treatment of members with melanoma with involvement of lymph node(s) following complete resection; or~~
    b. Adjuvant treatment of adult and pediatric members 12 years or older with stage 2B, 2C, or 3 melanoma following complete resection; or
    c. 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.

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 [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.

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.

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[1] U.S. Food and Drug Administration (FDA). Hematology/Oncology (Cancer) Approvals & Safety Notifications. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications. Last revised 11/18/2022. Last accessed 01/18/2023.

[2] Kimmtrak® (Tebentafusp-tebn) Prescribing Information. Immunocore Limited. Available online at: https://www.immunocore.com/application/files/1816/4422/3424/Approved_USPI_02_04_22_for_commercial_printing_and_website.pdf. Last revised 01/2022. Last accessed 01/18/2023.

[3] Opdualag™ (Nivolumab/Relatlimab-rmbw) Prescribing Information. Bristol-Myers Squibb. Available online at: https://packageinserts.bms.com/pi/pi_opdualag.pdf. Last revised 03/2022. Last accessed 01/18/2023.

Appendix L

Vote to Prior Authorize Lytgobi® (Futibatinib) and Update the Approval Criteria for the Gastrointestinal (GI) Cancer Medications and

Oklahoma Health Care Authority
February 2023

Market News and Updates[1,2,3]

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

- **August 2022:** The FDA approved Pemazyre® (pemigatinib) for adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement.
- **September 2022:** The FDA granted accelerated approval to Lytgobi® (futibatinib) for adults with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements.

Lytgobi® (Futibatinib) Product Summary[4]

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Treatment of adult patients with previously treated unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring FGFR2 gene fusions or other rearrangements
- **How Supplied:** 4mg oral tablets
- **Dose:** 20mg [(5) 4mg tablets] once daily until disease progression or unacceptable toxicity occurs
- **Cost:** The Wholesale Acquisition Cost (WAC) of Lytgobi® is $208.39 per 4mg tablet, resulting in a cost of $31,258.50 per 30 days based on the recommended dosing.

Recommendations

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

Lytgobi® (Futibatinib) Approval Criteria [Intrahepatic Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma; and
2. Member was previously treated with at least 1 prior therapy; and

3. Tumor is positive for fibroblast growth factor receptor 2 (FGFR2) gene fusion or rearrangement.

The College of Pharmacy also recommends updating the approval criteria for Pemazyre® (pemigatinib) based on recent FDA approval (updates shown in red):

Pemazyre® (Pemigatinib) Approval Criteria [Myeloid/Lymphoid Neoplasms (MLNs) Diagnosis]:

1. Diagnosis of relapsed or refractory MLNs; and
2. Disease is positive for a fibroblast growth factor receptor 1 (FGFR1) rearrangement.

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[1] U.S. Food and Drug Administration (FDA). FDA Approves Pemigatinib for Relapsed or Refractory Myeloid/Lymphoid Neoplasms with FGFR1 Rearrangement. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pemigatinib-relapsed-or-refractory-myeloidlymphoid-neoplasms-fgfr1-rearrangement. Issued 08/26/2022. Last accessed 01/18/2023.

[2] Pemazyre® (Pemigatinib) Prescribing Information. Incyte Corporation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213736s002lbl.pdf. Last revised 08/2022. Last accessed 01/18/2023.

[3] U.S. FDA. FDA Grants Accelerated Approval to Futibatinib for Cholangiocarcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-futibatinib-cholangiocarcinoma. Issued 09/30/2022. Last accessed 01/18/2023.

[4] Lytgobi® (Futibatinib) Prescribing Information. Taiho Oncology. Available online at: https://taihocorp-media-release.s3.us-west-2.amazonaws.com/documents/LYTGOBI_Prescribing_Information.pdf. Last revised 09/2022. Last accessed 01/18/2023.

Appendix M

Vote to Prior Authorize Pedmark® (Sodium Thiosulfate) and Vijoice® (Alpelisib)

Oklahoma Health Care Authority
February 2023

Market News and Updates[1,2]

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

- **April 2022:** The FDA granted accelerated approval to Vijoice® (alpelisib) for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.
- **September 2022:** The FDA approved Pedmark® (sodium thiosulfate injection) to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

Pedmark® (Sodium Thiosulfate) Product Summary[3]

- **Therapeutic Class:** Cisplatin binding agent
- **Indication(s):** Reduction of the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors
- **How Supplied:** 12.5g/100mL (125mg/mL) solution in a single-dose vial (SDV) for intravenous (IV) infusion
- **Dose:**
  - The recommended dose is based on body surface area (BSA) according to actual body weight:

Actual Body Weight	Recommended Dose
<5kg	10g/m^2
5 to 10kg	15g/m^2
>10kg	20g/m^2

  - Pedmark® should be administered as an IV infusion over 15 minutes following cisplatin infusions that are 1 to 6 hours in duration.
    - The safety and efficacy of Pedmark® have not been established when administered following cisplatin infusions longer than 6 hours; Pedmark® may not reduce the risk of ototoxicity when administered following longer cisplatin infusions as irreversible ototoxicity may have already occurred.

- Pedmark® should be administered 6 hours after completion of a cisplatin infusion.
- For multi-day cisplatin regimens, Pedmark® should be administered 6 hours after completion of each cisplatin infusion and at least 10 hours before the next cisplatin infusion.

- **Cost:** The Wholesale Acquisition Cost (WAC) of Pedmark® is $114.17 per milliliter, resulting in a cost of $11,417 per SDV and an estimated cost of $11,417 per treatment (per cisplatin infusion) for a pediatric patient with a BSA of 0.5m^2, based on the recommended dose of 20g/m^2.

Vijoice® (Alpelisib) Product Summary[4]

- **Therapeutic Class:** Kinase inhibitor
- **Indication(s):** Treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PROS who require systemic therapy
- **How Supplied:** 50mg oral tablets, 125mg oral tablets, and 250mg daily dose blister pack containing 50mg and 200mg oral tablets
- **Dose:**
  - Pediatric patients (2 years to younger than 18 years of age): 50mg once daily with food
  - Adult patients: 250mg once daily with food
- **Cost:** The WAC is $1,160.71 per dose, resulting in a cost of $34,821.30 per 30 days based on the recommended once daily dosing.

Recommendations

The College of Pharmacy recommends the prior authorization of Pedmark® (sodium thiosulfate) and Vijoice® (alpelisib) with the following criteria (shown in red):

Pedmark® (Sodium Thiosulfate) Approval Criteria [Reduction in Ototoxicity Risk Associated with Cisplatin for Solid Tumor Diagnosis]:

1. Pediatric members 1 month to 18 years of age with a diagnosis of localized, non-metastatic solid tumor; and
2. An FDA approved indication to reduce the risk of ototoxicity associated with cisplatin; and
   a. Member's cisplatin regimen must be provided (i.e., frequency of chemotherapy cycles, number of treatment days per cycle, number of chemotherapy cycles remaining); and
3. Pedmark® will be administered as follows:
   a. Starting 6 hours after completion of cisplatin infusion; or
   b. For multi-day cisplatin regimens, Pedmark® will be administered 6 hours after each cisplatin infusion but at least 10 hours before the next cisplatin infusion; and

4. Member has a baseline serum sodium <145mmol/L.

Vijoice® (Alpelisib) Approval Criteria [PIK3CA-Related Overgrowth Spectrum (PROS) Diagnosis]:

1. Adult and pediatric members 2 years of age and older; and
2. Documented PIK3CA gene mutation; and
3. Severe or life-threatening clinical manifestations of PROS.

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[1] Novartis. FDA Approves Novartis Vijoice® (Alpelisib) as Frist and Only Treatment for Select Patients with PIK3CA-Related Overgrowth Spectrum (PROS). Available online at: https://www.novartis.com/news/media-releases/fda-approves-novartis-vijoice-alpelisib-first-and-only-treatment-select-patients-pik3ca-related-overgrowth-spectrum-pros. Issued 04/06/2022. Last accessed 01/18/2023.

[2] Fennec Pharmaceuticals, Inc. Fennec Pharmaceuticals Announces FDA Approval of Pedmark® (Sodium Thiosulfate Injection). Available online at: https://investors.fennecpharma.com/news-releases/news-release-details/fennec-pharmaceuticals-announces-fda-approval-pedmarkr-sodium. Issued 09/21/2022. Last accessed 01/18/2023.

[3] Pedmark® (Sodium Thiosulfate) Prescribing Information. Fennec Pharmaceuticals, Inc. Available online at: https://pedmark.com/wp-content/uploads/2022/09/pedmark-pi.pdf. Last revised 09/2022. Last accessed 01/18/2023.

[4] Vijoice® (Alpelisib) Prescribing Information. Novartis. Available online at: https://www.novartis.com/us-en/sites/novartis_us/files/vijoice.pdf. Last revised 11/2022. Last accessed 01/18/2023.

Appendix N

Vote to Prior Authorize Hyftor™ (Sirolimus Topical Gel)

Oklahoma Health Care Authority
February 2023

Market News and Updates[1]

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

- **March 2022:** The FDA approved Hyftor™ (sirolimus topical gel), a mechanistic target of rapamycin (mTOR) inhibitor immunosuppressant, for the treatment of facial angiofibromas associated with tuberous sclerosis complex (TSC) in adults and children 6 years of age or older.

Hyftor™ (Sirolimus Topical Gel) Product Summary[2]

- **Therapeutic Class:** mTOR inhibitor immunosuppressant
- **Indication(s):** Treatment of facial angiofibroma associated with TSC in adults and pediatric patients 6 years of age and older
- **How Supplied:** 0.2% topical gel in a 10g tube
- **Dose:**
  - Maximum recommended daily dosage, as follows:
    - 600mg (2cm) for pediatric patients 6 to 11 years of age
    - 800mg (2.5cm) for adults and pediatric patients 12 years of age and older
  - Hyftor™ should be applied to the skin of the face affected with angiofibroma twice daily in the morning and at bedtime.
  - If symptoms do not improve within 12 weeks of treatment, the need for continuing Hyftor™ should be reevaluated.
- **Cost:** The Wholesale Acquisition Cost (WAC) of Hyftor™ is $175 per gram, resulting in a cost of $1,750 per 10g tube and an approximate cost per 30 days of $3,500 for a pediatric member 6 to 11 years of age.

Recommendations

The College of Pharmacy recommends the prior authorization of Hyftor™ (sirolimus topical gel) with the following criteria (shown in red):

Hyftor™ (Sirolimus Topical Gel) Approval Criteria [Facial Angiofibromas Associated with Tuberous Sclerosis Complex (TSC) Diagnosis]:

1. Documented diagnosis of TSC; and
2. Member has facial angiofibromas that are at least 2mm in diameter with redness in each; and
3. Member must be 6 to 20 years of age; or

   a. For members older than 20 years of age, a clinical exception may apply for medical issues caused by facial angiofibromas (specific documentation of clinically significant medical issues must be provided; Hyftor™ is not covered for cosmetic use); and
4. Initial approvals will be for a duration of 12 weeks, as the need for continuing Hyftor™ should be reevaluated if symptoms do not improve within 12 weeks of treatment. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and documents the anticipated duration of treatment.

[1] U.S. Food and Drug Administration (FDA). Hyftor™ (Sirolimus Topical Gel) New Drug Application (NDA) Approval. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/213478Orig1s000ltr.pdf. Issued 03/22/2022. Last accessed 01/18/2023.
[2] Hyftor™ (Sirolimus Topical Gel) Prescribing Information. Nobelpharma America, LLC. Available online at: https://hcp.hyftor.com/wp-content/uploads/2022/04/Approved-PI.pdf. Last revised 03/2022. Last accessed 01/18/2023.

Appendix O

Fiscal Year 2022 Annual Review of Anti-Migraine Medications

Oklahoma Health Care Authority
February 2023

Current Prior Authorization Criteria

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

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			ubrogepant tablet (Ubrelvy®)

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

Anti-Migraine Medications Tier-2 Approval Criteria:

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

Anti-Migraine Medications Tier-3 Approval Criteria:

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

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of brand D.H.E. 45® (dihydroergotamine injection) or brand Migranal® (dihydroergotamine nasal spray) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications. Brand formulation is preferred for D.H.E. 45® and Migranal®; use of the generic formulations will require a patient-specific, clinically significant reason why the member cannot use the brand formulation and lower-tiered triptan medications.
2. Use of Trudhesa® (dihydroergotamine nasal spray) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation of D.H.E. 45®, Migranal®, and lower-tiered triptan medications.
3. Use of generic eletriptan will require a patient-specific, clinically significant reason why the member cannot use the brand formulation of Relpax® (brand formulation is preferred).
4. Use of Ergomar® (ergotamine sublingual tablets) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
    a. Member must not have any of the contraindications for use of Ergomar® (e.g., coadministration with a potent CYP3A4 inhibitor,

women who are or may become pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and
   b. A quantity limit of 20 tablets per 28 days will apply.
5. Use of Reyvow® (lasmiditan) or Ubrelvy® (ubrogepant) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
   a. Reyvow® and Ubrelvy® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor.
6. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]+:
   a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
   b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
   c. A quantity limit of 8 ODTs per 30 days will apply.

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

   +Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta™ and Vyepti® approval criteria.
7. Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.
8. Use of Zembrace® SymTouch® (sumatriptan injection) or Tosymra® (sumatriptan nasal spray) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.

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

1. An FDA approved indication for the preventive treatment of migraine in adults; and
2. Member must be 18 years of age or older; and
3. Member has documented chronic migraine or episodic migraine headaches:

    a. Chronic migraine: 15 or more headache days per month with 8 or more migraine days per month; or
    b. Episodic migraine: 4 to 14 migraine days per month on average for the past 3 months; and
        i. For episodic migraine, member must have had a history of migraines for a duration of 12 months or longer; and
4. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:
    a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); or
    b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and
5. Migraine headache exacerbation secondary to other medication therapies or conditions have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
6. The member has failed medical migraine preventive therapy with at least 2¥ agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. [¥The manufacturers of Aimovig®, Ajovy® and Emgality® have currently provided a supplemental rebate to be the preferred calcitonin gene-related peptide (CGRP) inhibitor(s) and require a trial with 2 other migraine preventative therapies; however, Aimovig®, Ajovy® and Emgality® will follow the original criteria and require trials with 3 other migraine preventative therapies if the manufacturers choose not to participate in supplemental rebates.] This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta-blocker therapy); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
7. Member is not frequently taking medications that are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
    b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and

    c. Opioids (≥10 days/month for >3 months); and
    d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
    e. Ergotamine-containing medications (≥10 days/month for >3 months); and
    f. Triptans (≥10 days/month for >3 months); and
8. Member is not taking any medications that are likely to be the cause of the headaches; and
9. Member must have been evaluated within the last 6 months by a neurologist for migraine headaches and the requested medication (e.g., Aimovig®, Ajovy®, Emgality®) recommended as treatment (not necessarily prescribed by a neurologist); and
10. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative CGRP inhibitor; and
11. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
12. Prescriber must verify member has been counseled on appropriate use, storage of the medication, and administration technique; and
13. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
14. Quantity limits will apply based on FDA-approved dosing:
    a. For Aimovig®, a quantity limit of 1 syringe or autoinjector per 30 days will apply; and
    b. For Ajovy® prefilled syringe and autoinjector, a quantity limit of 1 syringe or 1 autoinjector per 30 days will apply. Requests for quarterly dosing (675mg every 3 months) will be approved for a quantity limit override upon meeting Ajovy® approval criteria; and
    c. For Emgality®, a quantity limit of 1 syringe or pen per 30 days will apply. Requests for an initial loading dose (240mg administered as 2 consecutive 120mg injections) will be approved for a quantity limit override upon meeting Emgality® approval criteria.

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

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

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

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

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

   b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
   c. Opioids (≥10 days/month for >3 months); and
   d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
   e. Ergotamine-containing medications (≥10 days/month for >3 months); and
   d. Triptans (≥10 days/month for >3 months); and
8. Member is not taking any medications that are likely to be the cause of the headaches; and
9. Member must have been evaluated within the last 6 months by a neurologist for migraine headaches and the requested medication (e.g., Nurtec® ODT, Qulipta™, Vyepti®) recommended as treatment (not necessarily prescribed by a neurologist); and
10. Member will not use requested medication concurrently with botulinum toxin for the prevention of migraine or with an alternative calcitonin gene-related peptide (CGRP) inhibitor; and
11. Other aggravating factors that are contributing to the development of episodic/chronic migraine headaches are being treated when applicable (e.g., smoking); and
12. For Vyepti®, prescriber must verify the medication will be prepared and administered according the Vyepti® *Prescribing Information*; and
13. A patient-specific, clinically significant reason why member cannot use Aimovig® (erenumab-aooe), Ajovy® (fremanezumab-vfrm), or Emgality® (galcanezumab-gnlm) must be provided (members currently taking Nurtec® ODT for acute migraine treatment are not exempt from this criteria requirement); and
14. For consideration of Vyepti® at the maximum recommended dosing (300mg every 3 months), a patient-specific, clinically significant reason why other available CGRP inhibitors for migraine prophylaxis are not appropriate for the member must be provided; and
15. Initial approvals will be for the duration of 3 months. Compliance and information regarding efficacy, such as a reduction in monthly migraine days, will be required for continued approval. Continuation approvals will be granted for the duration of 1 year; and
16. Quantity limits will apply based on FDA-approved dosing:
   a. For Nurtec® ODT, a quantity limit of 16 orally disintegrating tablets (ODTs) per 30 days will apply; and
   b. For Qulipta™, a quantity limit of 30 tablets per 30 days will apply; and
   c. For Vyepti®, a quantity limit of 3 vials per 90 days will apply.

Utilization of Anti-Migraine Medications: Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	5,561	13,200	$1,189,809.38	$90.14	$4.73	134,924	251,405
2022	8,763	20,192	$2,256,656.92	$111.76	$5.67	206,076	397,996
% Change	**57.60%**	**53.00%**	**89.70%**	**24.00%**	**19.90%**	**52.70%**	**58.30%**
Change	**3,202**	**6,992**	**$1,066,847.54**	**$21.62**	**$0.94**	**71,152**	**146,591**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

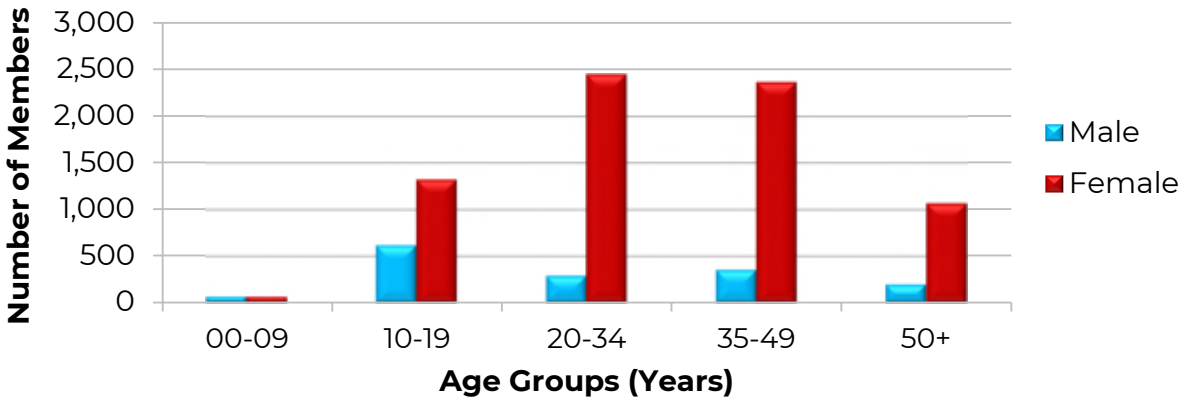
Fiscal Year 2022 Utilization: Medical Claims

Fiscal Year	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	1	1	$1,601.00	$1,601.00	1

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
Please note: There were no paid medical claims during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

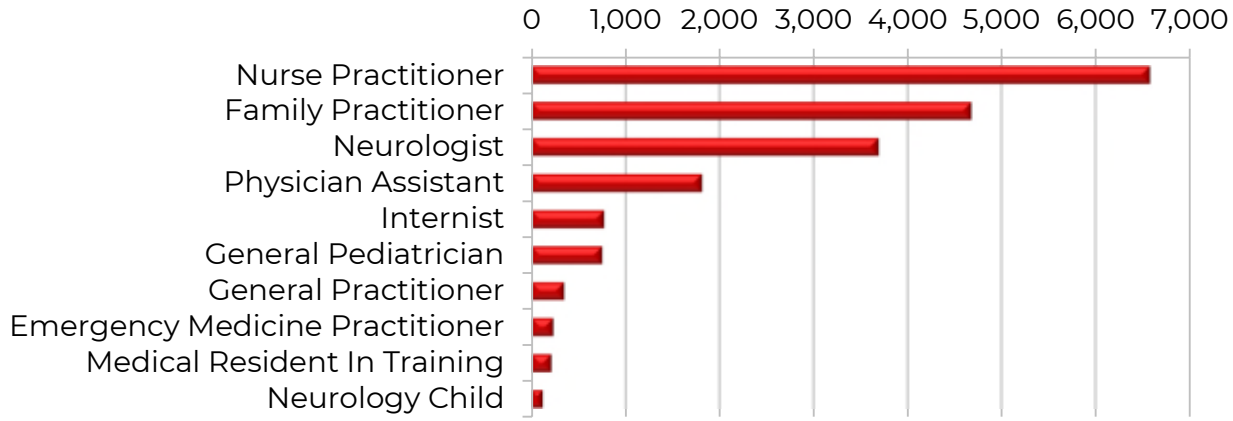
- The anti-migraine medications are influenced by federal and supplemental rebates. These rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.
  - Aggregate drug rebates collected during fiscal year 2022 for the anti-migraine medications: $1,537,302.15[Δ]

Demographics of Members Utilizing Anti-Migraine 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.

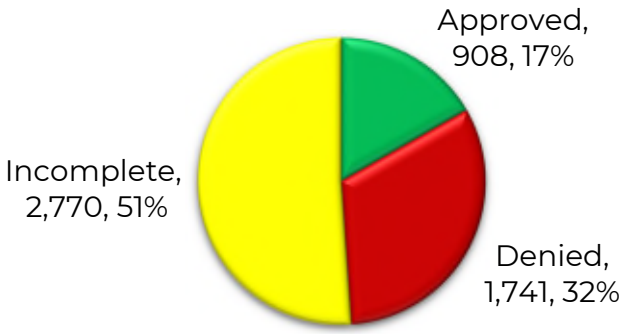
Top Prescriber Specialties of Anti-Migraine Medications by Number of Claims



Prior Authorization of Anti-Migraine Medications

There were 5,419 prior authorization requests submitted for anti-migraine medications during fiscal year 2022. Computer edits are in place to detect lower tiered medications in the member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Tosymra® (sumatriptan nasal spray): July 2031
- Onzetra® Xsail® (sumatriptan nasal powder): October 2034
- Qulipta™ (atogepant tablet): January 2035
- Ubrelvy® (ubrogepant tablet): January 2035
- Zembrace® SymTouch® [sumatriptan subcutaneous (sub-Q) injection]: January 2036
- Reyvow® (lasmiditan tablet): December 2037

- Trudhesa® [dihydroergotamine (DHE) nasal spray]: January 2039
- Nurtec® ODT [rimegepant orally disintegrating tablet (ODT)]: March 2039

News:

- **January 2022:** The safety and efficacy of intranasal ketamine used to treat acute cluster headache attacks were assessed in a single-center, open-label, proof-of-concept study of 23 Danish patients with chronic cluster headaches. The average age was 51 years, 70% of patients were male, and their mean disease duration was 18 years. Under in-hospital observation, patients received 15mg of intranasal ketamine every 6 minutes up to a maximum of 5 times. Of the 23 participants, only 20 received the study drug, as 3 participants did not have a cluster headache attack during their admission. On average, patients received 3.7 doses of intranasal ketamine. The primary endpoint was a 50% reduction in pain intensity within 15 minutes after treatment initiation. The results showed, after 15 minutes, the mean pain intensity was reduced from 7.2 (±1.3) to 6.1 (±3.1) on an 11-point numeric rating scale, equivalent to a 15% reduction and well below the primary endpoint of a 50% or greater reduction. Only 4 of the 20 patients had a reduction of 50% or more, and 4 patients chose rescue medication at 15 minutes. However, at 30 minutes, pain intensity was reduced by 59% (mean difference: 4.3; 95% confidence interval: 2.4, 6.2; P>0.001), with 11 out of 16 patients scoring a 4 or below. Complete relief provided by the ketamine nasal spray was reported by 8 of the 20 patients, while 6 participants reported feeling no effects. Half of the patients said they preferred ketamine to oxygen and/or sumatriptan injection. A total of 17 patients reported side effects, but 12 of them classified their side effects as few. No serious adverse events were identified, with the most common adverse events being dizziness, lightheadedness, nausea/ vomiting, and paresthesia.
- **February 2022:** Anti-calcitonin gene-related peptide (anti-CGRP) monoclonal antibodies are effective for patients with chronic migraine and medication overuse headache (MOH) regardless of detoxification strategy, according to investigators in a recent study that evaluated use of anti-CGRP monoclonal antibodies in patients with MOH. The study compared treatment with galcanezumab or erenumab on an inpatient vs. outpatient basis. Out of 401 patients enrolled, 111 satisfied inclusion criteria, including diagnosis of chronic migraine and MOH. Of these 111 patients, 83 underwent in-hospital detox, while the remaining 28 patients, who declined detox based on personal reasons or COVID-19-related bed shortage, were advised to discontinue overused medication on an outpatient basis (without oversight). The primary endpoint was MOH responder rate after 3 months, as defined by International

Classification of Headache Disorders, 3rd edition (ICHD-3) diagnostic criteria. Secondary endpoints included 6-item headache impact test (HIT-6), monthly headache days (MHD), migraine disability assessment score (MIDAS), mean pain intensity (MPI), monthly pain medication intake (MPMI), baseline predictors of response/refractoriness, and safety. Three months after starting anti-CGRP therapy, 59% of patients had resolution of MOH, including 57% in the inpatient detox group and 64% in the outpatient group, a difference that was not statistically significant (P=0.4788). Approximately half of the patients (51%) had at least 50% reduction in monthly headache days, and although the rate was numerically lower in the inpatient group compared with the outpatient group, the difference was again not statistically significant (51% vs. 54%; P=0.8393).

- **June 2022:** AbbVie submitted a Supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for Qulipta™ (atogepant) to support the preventive treatment of chronic migraines in adults. The submission includes data from the pivotal Phase 3 PROGRESS trial in patients with chronic migraine, which supplements the existing data in episodic migraines. If approved, Qulipta™ (atogepant) would be the first gepant, an oral CGRP receptor antagonist, approved for the preventive treatment of both chronic and episodic migraines. The pivotal Phase 3 PROGRESS trial met its primary endpoint of statistically significant reduction from baseline in mean monthly migraine days compared to placebo across the 12-week treatment period in adults with chronic migraine. The trial also demonstrated that treatment with Qulipta™ (atogepant) 60mg once daily and 30mg twice daily resulted in statistically significant improvements in all 6 secondary endpoints. This included a key secondary endpoint that measured the proportion of patients that achieved at least a 50% reduction in mean monthly migraine days across the 12-week treatment period. The overall safety profile of the Phase 3 PROGRESS study was consistent with safety findings observed in previous studies in an episodic migraine population. The most common adverse events were constipation and nausea.

Pipeline:

- **AXS-07 (Rizatriptan/Meloxicam):** Axsome Therapeutics announced that they received a Complete Response Letter (CRL) from the FDA regarding their New Drug Application (NDA) for AXS-07 for the acute treatment of migraine. The CRL did not identify or raise any concerns about the clinical efficacy or safety data in the NDA, and the FDA did not request any new clinical trials to support the approval of AXS-07. The principal reasons given in the CRL relate to chemistry, manufacturing, and controls (CMC) considerations. The CRL identified

the need for additional CMC data pertaining to the drug product and manufacturing process. Axsome believes that the issues raised in the CRL are addressable and intends to provide potential timing for a resubmission following consultation with the FDA. AXS-07 is a novel, oral, rapidly absorbed, multi-mechanistic investigational medicine for the acute treatment of migraine, consisting of Molecular Solubility Enhanced Inclusion Complex (MoSEIC™) meloxicam and rizatriptan. Meloxicam is a new molecular entity for migraine enabled by Axsome's MoSEIC™ technology, which results in rapid absorption of meloxicam while maintaining a long plasma half-life. Meloxicam is a COX-2 preferential non-steroidal anti-inflammatory drug (NSAID) and rizatriptan is a 5-$HT_{1B/1D}$ agonist (triptan). AXS-07 is designed to provide rapid, enhanced, and consistent relief of migraine, with reduced symptom recurrence. The NDA is supported by results from 2 Phase 3 randomized, double blind, controlled trials of AXS-07 in the acute treatment of migraine, the MOMENTUM and INTERCEPT trials, which demonstrated statistically significant elimination of migraine pain with AXS-07 compared to placebo and active controls.

- **STS101 (DHE Nasal Powder):** Satsuma Pharmaceuticals announced an update to the development program for STS101, an investigational acute treatment for migraine. STS101 is a unique and proprietary nasal powder formulation of the well-established anti-migraine drug, DHE, administered via Satsuma's proprietary nasal delivery device. The update included a recap of the SUMMIT Phase 3 efficacy trial. STS101 demonstrated numerical but not statistically significant differences versus placebo on the study co-primary endpoints [% of subjects free from pain and % of subjects free from most-bothersome-symptom (MBS) at 2 hours post-dose]. However, STS101 demonstrated robust and sustained effects ($P<0.001$) on the key study endpoints at all post-dose timepoints after 2 hours (3, 4, 6, 12, 24 and 48 hours). In addition, STS101 was statistically superior to placebo on multiple key secondary endpoints considered clinically relevant and recommended for assessment in acute treatment of migraine efficacy trials by the FDA in its current industry guidance document and/or the International Headache Society's guidelines for controlled trials. Based on its communications with the FDA in multiple Type C meetings and the May 2022 Type B clinical pre-NDA meeting, Satsuma believes the results of its STS101 clinical trial program, and in particular, results from the Phase 1 comparative pharmacokinetics study completed in 2021 and the on-going ASCEND long-term, open-label safety trial, support a planned NDA filing in the first quarter of 2023 and potential approval.
- **Zavegepant:** Biohaven Pharmaceutical Holding Company announced that they have filed and the FDA has accepted an NDA for zavegepant nasal spray, the only small molecule CGRP receptor antagonist in an

intranasal formulation, for the acute treatment of migraine in adults. The NDA for zavegepant was based on 2 pivotal double-blind, placebo-controlled trials that established the efficacy, tolerability, and safety profile of zavegepant for the acute treatment of migraine. The Prescription Drug User Fee Act (PDUFA) goal date for completion of the FDA review of the NDA is set for the first quarter of 2023.

Recommendations

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

1. Removing the brand preferred status for eletriptan tablet (Relpax®); and
2. Moving brand name Zomig® nasal spray to Tier-1 and making it brand preferred; and
3. Moving generic zolmitriptan nasal spray to the Special PA Tier.

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

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
			sumatriptan nasal powder (Onzetra® Xsail®)
			sumatriptan nasal spray (Imitrex®)
			sumatriptan nasal spray (Tosymra®)
			zolmitriptan nasal spray (generic Zomig® nasal spray)
			ubrogepant tablet (Ubrelvy®)

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

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

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

5. Use of Reyvow® (lasmiditan) or Ubrelvy® (ubrogepant) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
    a. Reyvow® and Ubrelvy® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor.
6. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]+:
    a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
    b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
    c. A quantity limit of 8 ODTs per 30 days will apply.

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

    +Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta™ and Vyepti® approval criteria.
7. Use of any non-oral sumatriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.
8. Use of Zembrace® SymTouch® (sumatriptan injection) or Tosymra® (sumatriptan nasal spray) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
9. Use of generic zolmitriptan nasal spray will require a patient-specific, clinically significant reason why the member cannot use the brand formulation of Zomig® nasal spray (brand formulation is preferred) and lower-tiered triptan medications.

Utilization Details of Anti-Migraine Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 MEDICATIONS						
SUMATRIPTAN PRODUCTS						
SUMATRIPTAN TAB 50MG	4,889	2,760	$74,546.89	$15.25	1.77	3.30%
SUMATRIPTAN TAB 100MG	4,188	1,746	$64,671.49	$15.44	2.4	2.87%
SUMATRIPTAN TAB 25MG	2,782	1,695	$46,927.56	$16.87	1.64	2.08%
SUBTOTAL	**11,859**	**6,201**	**$186,145.94**	**$15.70**	**1.91**	**8.25%**
RIZATRIPTAN PRODUCTS						
RIZATRIPTAN TAB 10MG	2,497	1,218	$41,080.97	$16.45	2.05	1.82%
RIZATRIPTAN ODT 10MG	1,481	754	$27,802.40	$18.77	1.96	1.23%
RIZATRIPTAN TAB 5MG	759	420	$13,385.50	$17.64	1.81	0.59%
RIZATRIPTAN ODT 5MG	597	323	$11,584.50	$19.40	1.85	0.51%
SUBTOTAL	**5,334**	**2,715**	**$93,853.37**	**$17.60**	**1.96**	**4.16%**
ELETRIPTAN PRODUCTS						
RELPAX TAB 40MG	283	127	$176,848.78	$624.91	2.23	7.84%
RELPAX TAB 20MG	114	53	$77,292.81	$678.01	2.15	3.43%
SUBTOTAL	**397**	**180**	**$254,141.59**	**$640.16**	**2.21**	**11.27%**
SUMATRIPTAN/NAPROXEN COMBINATION PRODUCTS						
SUMAT-NAPROX TAB 85-500MG	98	44	$23,652.62	$241.35	2.23	1.05%
SUBTOTAL	**98**	**44**	**$23,652.62**	**$241.35**	**2.23**	**1.05%**
TIER-1 SUBTOTAL	**17,688**	**8,491***	**$557,793.52**	**$31.54**	**2.08**	**24.72%**
TIER-2 MEDICATIONS						
ZOLMITRIPTAN PRODUCTS						
ZOLMITRIPTAN SPR 5MG	39	11	$17,388.84	$445.87	3.55	0.77%
ZOLMITRIPTAN TAB 5MG	31	13	$624.27	$20.14	2.38	0.03%
ZOMIG SPR 5MG	12	2	$6,872.59	$572.72	6	0.30%
ZOLMITRIPTAN ODT 5MG	8	5	$236.37	$29.55	1.6	0.01%
ZOMIG SPR 2.5MG	5	4	$2,668.82	$533.76	1.25	0.12%
ZOLMITRIPTAN SPR 2.5MG	3	2	$1,588.92	$529.64	1.5	0.07%
ZOLMITRIPTAN ODT 2.5MG	2	1	$55.80	$27.90	2	0.00%
ZOLMITRIPTAN TAB 2.5MG	1	1	$16.80	$16.80	1	0.00%
SUBTOTAL	**101**	**39**	**$29,452.41**	**$291.61**	**2.59**	**1.30%**
NARATRIPTAN PRODUCTS						
NARATRIPTAN TAB 2.5MG	30	13	$704.47	$23.48	2.31	0.03%
NARATRIPTAN TAB 1MG	1	1	$21.43	$21.43	1	0.00%
SUBTOTAL	**31**	**14**	**$725.90**	**$23.42**	**2.21**	**0.03%**
TIER-2 SUBTOTAL	**132**	**50***	**$30,178.31**	**$228.62**	**2.64**	**1.33%**
TIER-3 MEDICATIONS						
ALMOTRIPTAN PRODUCTS						
ALMOTRIPTAN TAB 12.5MG	3	1	$695.79	$231.93	3	0.03%
ALMOTRIPTAN TAB 6.25MG	1	1	$403.41	$403.41	1	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**4**	**2**	**$1,099.20**	**$274.80**	**2**	**0.05%**
FROVATRIPTAN PRODUCTS						
FROVATRIPTAN TAB 2.5MG	1	1	$64.19	$64.19	1	0.00%
SUBTOTAL	**1**	**1**	**$64.19**	**$64.19**	**1**	**0.00%**
TIER-3 SUBTOTAL	**5**	**3***	**$1,163.39**	**$232.68**	**1.67**	**0.05%**
SPECIAL PRIOR AUTHORIZATION (PA) MEDICATIONS						
SUMATRIPTAN PRODUCTS						
SUMATRIPTAN INJ 6MG/0.5ML	26	7	$5,655.78	$217.53	3.71	0.25%
SUMATRIPTAN SPR 5MG/ACT	4	2	$822.54	$205.64	2	0.04%
SUMATRIPTAN INJ 4MG/0.5ML	4	1	$660.45	$165.11	4	0.03%
SUMATRIPTAN SPR 20MG/ACT	3	3	$586.48	$586.48	1	0.03%
SUBTOTAL	**37**	**13**	**$7,725.25**	**$208.79**	**2.85**	**0.34%**
LASMIDITAN PRODUCTS						
REYVOW TAB 50MG	3	1	$2,058.43	$686.14	3	0.09%
REYVOW TAB 100MG	1	1	$686.46	$686.46	1	0.03%
SUBTOTAL	**4**	**2**	**$2,744.89**	**$686.22**	**2**	**0.12%**
ELETRIPTAN PRODUCTS						
ELETRIPTAN TAB 20MG	1	1	$33.15	$33.15	1	0.00%
SUBTOTAL	**1**	**1**	**$33.15**	**$33.15**	**1**	**0.00%**
DIHYDROERGOTAMINE PRODUCTS						
DIHYDROERGOT SPR 4MG/ML	**1**	**1**	**$961.54**	**$961.54**	**1**	**0.04%**
SUBTOTAL	**1**	**1**	**$961.54**	**$961.54**	**1**	**0.04%**
SPECIAL PA SUBTOTAL	**43**	**16***	**$11,464.83**	**$266.62**	**2.53**	**0.51%**
CALCITONIN GENE-RELATED PEPTIDE (CGRP) PRODUCTS⁺						
GALCANEZUMAB PRODUCTS						
EMGALITY INJ 120MG/ML	1,168	232	$742,975.11	$635.25	5.03	32.88%
EMGALITY SYR 120MG/ML	123	25	$80,577.91	$655.10	4.92	3.57%
EMGALITY SYR 100MG/ML	1	1	$1,582.27	$1,582.27	1	0.07%
SUBTOTAL	**1,292**	**258**	**$824,135.29**	**$637.88**	**5.01**	**36.52%**
RIMEGEPANT PRODUCTS						
NURTEC ODT 75MG	406	136	$400,118.05	$985.51	2.99	17.73%
SUBTOTAL	**406**	**136**	**$400,118.05**	**$985.51**	**2.99**	**17.73%**
FREMANEZUMAB PRODUCTS						
AJOVY INJ 225MG/1.5ML	270	63	$172,871.87	$640.27	4.29	7.66%
AJOVY SYR 225MG/1.5ML	82	24	$52,787.32	$643.75	3.42	2.34%
SUBTOTAL	**352**	**87**	**$225,659.19**	**$641.08**	**4.05**	**10.00%**
ERENUMAB PRODUCTS						
AIMOVIG INJ 140MG/ML	121	20	$83,099.27	$686.77	6.05	3.68%
AIMOVIG INJ 70MG/ML	48	12	$29,862.15	$622.13	4	1.32%
SUBTOTAL	**169**	**32**	**$112,961.42**	**$668.41**	**5.28**	**5.01%**
UBROGEPANT PRODUCTS						
UBRELVY TAB 100 MG	71	22	$62,689.44	$882.95	3.23	2.78%
UBRELVY TAB 50 MG	23	10	$19,786.73	$860.29	2.3	0.88%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**94**	**32**	**$82,476.17**	**$877.41**	**2.94**	**3.66%**
ATOGEPANT PRODUCTS						
QULIPTA TAB 60MG	11	4	$10,706.75	$973.34	2.75	0.47%
SUBTOTAL	**11**	**4**	**$10,706.75**	**$973.34**	**2.75**	**0.47%**
CGRP SUBTOTAL	**2,324**	**498***	**$1,656,056.87**	**$712.59**	**4.67**	**73.39%**
TOTAL	**20,192**	**8,763***	**$2,256,656.92**	**$111.76**	**2.3**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Please note: Nurtec® ODT and Ubrelvy® are CGRP products but are included in the Anti-Migraine Medications Special PA Tier for acute migraine treatment. Nurtec® ODT is also FDA approved for the preventive treatment of episodic migraine and has separate criteria for preventive treatment.
ACT = actuation; DIHYDROERGOT= dihydroergotamine; INJ = injection; NAPROX = naproxen; ODT = orally disintegrating tablet; SPR = nasal spray; SUMAT = sumatriptan; SYR = prefilled syringe; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
EPTINEZUMAB-JJMR INJ 1MG (J3032)	1⁺	1*	$1,601.00	$1,601.00	1
TOTAL	**1⁺**	**1***	**$1,601.00**	**$1,601.00**	**1**

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

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Appendix P

Fiscal Year 2022 Annual Review of Leukemia Medications and 30-Day Notice to Prior Authorize Rezlidhia™ (Olutasidenib)

Oklahoma Health Care Authority
February 2023

Current Prior Authorization Criteria

Approval criteria for Adcetris® (brentuximab vedotin), Beleodaq® (belinostat), Calquence® (acalabrutinib), Copiktra® (duvelisib), Folotyn® (pralatrexate), Poteligeo® (mogamulizumab-kpkc), and Tecartus® (brexucabtagene autoleucel) for indications other than leukemia diagnoses can be found in the April 2022 Drug Utilization Review (DUR) Board packet. These medications are reviewed annually with the lymphoma medications. Approval criteria for Ayvakit™ (avapritinib) for indications other than leukemia diagnoses can be found in the January 2023 DUR Board packet. Ayvakit™ is reviewed annually with the gastrointestinal cancer medications. Approval criteria for Zelboraf® (vemurafenib) for indications other than leukemia diagnoses can be found in the December 2022 DUR Board packet. Zelboraf® is reviewed annually with the skin cancer medications.

Adcetris® (Brentuximab Vedotin) Approval Criteria [Adult T-Cell Leukemia/Lymphoma Diagnosis]:

1. CD30+ disease; and
2. Member meets 1 of the following:
    a. In combination with cyclophosphamide, doxorubicin, and prednisone (CHP) in nonresponders to first-line therapy for chronic/smoldering subtype; or
    b. In combination with CHP for first-line therapy for acute or lymphoma subtype; or
    c. In combination with CHP for continued treatment in responders to first-line therapy for acute or lymphoma subtype; or
    d. As a single agent in members who have received ≥1 line of therapy.

Arzerra® (Ofatumumab) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. For first-line treatment of CLL/SLL in combination with chlorambucil or bendamustine; or
2. Relapsed/refractory disease as a single agent or in combination with fludarabine and cyclophosphamide; or

3. Maintenance therapy as second-line extended dosing following complete or partial response to relapsed/refractory therapy (maximum 2 years).

Arzerra® (Ofatumumab) Approval Criteria [Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma Diagnosis]:

1. For previously treated disease that does not respond to primary therapy or for progressive or relapsed disease; and
2. Member is rituximab-intolerant; and
3. As a single agent or combination therapy.

Asparlas® (Calaspargase Pegol-mknl) and Oncaspar® (Pegaspargase) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
2. For Asparlas®, member must be 1 month to 21 years of age; and
3. Diagnosis of ALL; and
4. Used as first line therapy; or
5. May be used to treat members with a hypersensitivity to native forms of L-asparaginase; or
6. Used as systemic central nervous system (CNS)-directed therapy; or
7. Used in relapsed/refractory disease; and
    a. Philadelphia chromosome negative (Ph-); or
    b. Philadelphia chromosome positive (Ph+); and
        i. Refractory to tyrosine kinase inhibitor (TKI) therapy or used in conjunction with a TKI (if not previously used).

Asparlas® (Calaspargase Pegol-mknl) and Oncaspar® (Pegaspargase) Approval Criteria [Extranodal NK/T-Cell Lymphoma Diagnosis]:

1. For Asparlas®, a patient-specific, clinically significant reason why the member cannot use Oncaspar® (pegaspargase) must be provided; and
2. For Asparlas®, member must be 1 month to 21 years of age; and
3. Diagnosis of NK/T-Cell lymphoma; and
4. Member has nasal disease; and
    a. Used as induction therapy; or
    b. Used as additional therapy in members with a positive biopsy following a partial or no response to induction therapy.

Ayvakit™ (Avapritinib) Approval Criteria [Systemic Mastocytosis Diagnosis]:

1. Diagnosis of advanced systemic mastocytosis, including members with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia; and
2. Platelet count ≥50 x 10^9/L.

Beleodaq® (Belinostat) Approval Criteria [Adult T-Cell Leukemia/ Lymphoma Diagnosis]:

1. As a single agent in relapsed/refractory disease.

Besponsa® (Inotuzumab Ozogamicin) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Member must have 1 of the following:
    a. Relapsed/refractory Philadelphia chromosome negative (Ph-) ALL; or
    b. Relapsed/refractory Philadelphia chromosome positive (Ph+) ALL who are intolerant/refractory to ≥2 tyrosine kinase inhibitors (TKIs); and
2. As a single agent only.

Blincyto® (Blinatumomab) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Member must have 1 of the following:
    a. Relapsed/refractory Philadelphia chromosome negative (Ph-) ALL; or
    b. Relapsed/refractory Philadelphia chromosome positive (Ph+) ALL after failure of ≥2 tyrosine kinase inhibitors (TKIs); or
    c. Ph- ALL as consolidation in adolescent/young adults or members younger than 65 years of age without substantial comorbidity with persistent or late clearance minimal residual disease positive (MRD+) following a complete response to induction; and
2. As a single agent.

Bosulif® (Bosutinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Relapsed/refractory Ph+ ALL; and
    a. As a single agent; or
    b. In combination with an induction regimen not previously given; and
2. E255K/V, F317L/VI/C, F359V/C/I, T315A, or Y253H mutations.

Bosulif® (Bosutinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Chronic, accelerated, or blast phase CML; and
2. Newly diagnosed or resistant/intolerant to other tyrosine kinase inhibitors (TKIs).

Calquence® (Acalabrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. As a single agent.

Copiktra® (Duvelisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Relapsed/refractory CLL or SLL; and
2. Progression of disease following ≥2 lines of systemic therapy; and
3. As a single agent.

Daurismo® (Glasdegib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly-diagnosed AML; and
2. Member meets 1 of the following:
    a. Member is 75 years of age or older; or
    b. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
3. In combination with low-dose cytarabine (LDAC).

Erwinase® (Crisantaspase), Erwinaze® (Asparaginase *Erwinia Chrysanthemi*), and Rylaze™ [Asparaginase *Erwinia Chrysanthemi* (Recombinant)-rywn] Approval Criteria [Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma Diagnosis]:

1. Diagnosis of ALL or lymphoblastic lymphoma; and
2. Used as a component of multi-agent chemotherapy; and
3. Member has a documented hypersensitivity to *Escherichia coli*-derived asparaginase.

Folotyn® (Pralatrexate) Approval Criteria [Adult T-Cell Leukemia/ Lymphoma Diagnosis]:

1. As a single agent in relapsed/refractory disease.

Gazyva® (Obinutuzumab) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. As a single agent in relapsed/refractory disease; or
2. In combination with chlorambucil, bendamustine, ibrutinib, or venetoclax for first-line therapy; and
3. When obinutuzumab is used in combination with venetoclax, maximum approval duration of obinutuzumab will be 6 treatment cycles.

Gazyva® (Obinutuzumab) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Grade 1 or 2 members with Stage I (≥7cm), contiguous Stage II (≥7cm), noncontiguous Stage II, Stage III, or Stage IV members (first, second, or subsequent therapy); and
2. In combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), cyclophosphamide, vincristine, and prednisone (CVP), or bendamustine; and

3. When used for maintenance therapy, a total of 12 doses will be approved.

Gazyva® (Obinutuzumab) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:

1. As second-line or subsequent therapy in combination with bendamustine; or
2. Maintenance therapy as second-line consolidation or extended dosing in rituximab-refractory members treated with obinutuzumab and bendamustine for a total of 12 doses.

Iclusig® (Ponatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Used in 1 of the following settings:
    a. Induction/consolidation with hyperfractionated cyclophosphamide, vincristine sulfate, doxorubicin hydrochloride (Adriamycin®), and dexamethasone (HyperCVAD); or
    b. Maintenance therapy in combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
    c. Maintenance therapy post-hematopoietic stem cell transplantation; or
    d. Relapsed/refractory disease either as a single agent, in combination with chemotherapy not previously given, or in patients with T315I mutations.

Iclusig® (Ponatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have 1 of the following:
    a. T315I mutation; or
    b. Intolerant or resistant to ≥2 tyrosine kinase inhibitors (TKIs); or
    c. Post-hematopoietic stem cell transplantation in patients with prior accelerated or blast phase prior to transplant or who have relapsed.

Idhifa® (Enasidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
    a. Member meets 1 of the following:
        i. Member is 75 years of age or older; or
        ii. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
    b. As a single agent; and
    c. Isocitrate dehydrogenase-2 (IDH2) mutation; or
2. Relapsed/refractory AML; and
    a. IDH2 mutation; and

b. As a single agent.

Imbruvica® (Ibrutinib) Approval Criteria [Chronic Graft-Versus-Host Disease (cGVHD) Diagnosis]:

1. Failure of 1 or more lines of therapy.

Imbruvica® (Ibrutinib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. As first-line or subsequent therapy for CLL/SLL; and
2. As a single agent or in combination with bendamustine, rituximab, or obinutuzumab.

Imbruvica® (Ibrutinib) Approval Criteria [Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis or Acquired Immunodeficiency Syndrome (AIDS)-Related B-Cell Lymphoma Diagnosis]:

1. Non-germinal center DLBCL; and
2. As second-line or subsequent therapy; and
3. Member is not a candidate for high-dose therapy.

Imbruvica® (Ibrutinib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Grade 1 or 2 FL; and
2. As subsequent therapy (third-line or greater) for histologic transformation to non-germinal center diffuse large B-cell lymphoma (DLBCL).

Imbruvica® (Ibrutinib) Approval Criteria [Hairy Cell Leukemia (HCL) Diagnosis]:

1. As a single agent in members with indication(s) for treatment for progression.

Imbruvica® (Ibrutinib) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. As second-line or subsequent therapy; and
2. As a single agent or in combination with rituximab or lenalidomide/rituximab.

Imbruvica® (Ibrutinib) Approval Criteria [Histologic Transformation of Marginal Zone Lymphoma (MZL) to Diffuse Large B-Cell Lymphoma (DLBCL) Diagnosis]:

1. As third-line or greater therapy for members who have transformed to non-germinal center DLBCL.

Imbruvica® (Ibrutinib) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:

1. As second-line or subsequent therapy for refractory or progressive disease.

Imbruvica® (Ibrutinib) Approval Criteria [Post-Transplantation Lymphoproliferative Disorders Diagnosis]:

1. As second-line or subsequent therapy in members with partial response, persistent, or progressive disease; and
2. Non-germinal center B-cell type.

Imbruvica® (Ibrutinib) Approval Criteria [Waldenström's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma Diagnosis]:

1. As first-line or subsequent therapy; and
2. As a single agent or in combination with rituximab.

Inqovi® (Decitabine/Cedazuridine) Approval Criteria [Myelodysplastic Syndromes (MDS) Diagnosis]:

1. Diagnosis of MDS (intermediate-1, intermediate-2, or high risk) in adults including previously treated and untreated, de novo, and secondary MDS with the 1 of the following subtypes:
    a. Refractory anemia; or
    b. Refractory anemia with ring sideroblasts; or
    c. Refractory anemia with excess blasts; or
    d. Chronic myelomonocytic leukemia (CMML).

Kymriah® (Tisagenlecleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Members must meet all of the following:
    a. B-cell precursor ALL; and
    b. Member must be 25 years of age or younger; and
    c. Refractory or in second or later relapse:
        i. Philadelphia chromosome negative (Ph-) ALL: Must be refractory or with ≥2 relapses; or
        ii. Philadelphia chromosome positive (Ph+) ALL: Must have failed ≥2 tyrosine kinase inhibitors (TKIs); and
    d. Therapies to consider prior to tisagenlecleucel if appropriate: Clinical trial, multi-agent chemotherapy with or without hematopoietic cell transplantation (HCT), blinatumomab (category 1 recommendation), and inotuzumab (category 1 recommendation); and
2. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells, must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and must

comply with the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) requirements.

Kymriah® (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)]; and
2. Relapsed/refractory disease; and
3. Member must be 18 years of age or older; and
4. Member must not have primary central nervous system lymphoma; and
5. Member must have had ≥2 lines of therapy; and
6. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells, must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and must comply with the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) requirements.

Lumoxiti® (Moxetumomab Pasudotox-tdfk) Approval Criteria [Hairy Cell Leukemia (HCL) Diagnosis]:

1. Treatment of relapsed or refractory HCL in adults; and
2. Member has received ≥2 prior systemic therapies, including treatment with a purine nucleoside analog (PNA); and
3. Creatinine clearance (CrCl) ≥30mL/min/1.73m^2; and
4. As a single agent.

Onureg® (Azacitidine) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Diagnosis of AML; and
2. Used as maintenance therapy in members who have achieved first complete remission (CR) or complete remission with incomplete blood count recover (CRi) following intensive induction chemotherapy; and
3. Member is unable to complete intensive curative therapy.

Poteligeo® (Mogamulizumab-kpkc) Approval Criteria [Adult T-Cell Leukemia/Lymphoma Diagnosis]:

1. As a single agent in relapsed/refractory disease.

Scemblix® (Asciminib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Diagnosis of Philadelphia chromosome-positive (Ph+) CML in chronic phase; and
    a. Previously treated with ≥2 tyrosine kinase inhibitors (TKIs); or
    b. Frontline or subsequent therapy in members with the T315I mutation.

Sprycel® (Dasatinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Member must have 1 of the following:
    a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
    b. Maintenance therapy including:
        i. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
        ii. Post-hematopoietic stem cell transplantation; or
    c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy.

Sprycel® (Dasatinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have 1 of the following:
    a. Chronic, accelerated, or blast phase CML; or
    b. Post-hematopoietic stem cell transplantation.

Sprycel® (Dasatinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Member must have all of the following:
    a. Progressive disease and failed imatinib, sunitinib, or regorafenib; and
    b. PDGFRA D842V mutation.

Synribo® (Omacetaxine) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have 1 of the following:
    a. Primary treatment of advanced phase CML with disease progression to accelerated phase; or
    b. Post-hematopoietic stem cell transplant in members who have relapsed; or
    c. T315I mutation; or
    d. Members who are intolerant or resistant to ≥2 tyrosine kinase inhibitors (TKIs); and
2. As a single agent.

Tasigna® (Nilotinib) Approval Criteria [Philadelphia Chromosome Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Member must have 1 of the following:
    a. Upfront therapy (including induction and consolidation) in combination with multi-agent chemotherapy or as a single agent; or
    b. Maintenance therapy including:

i. In combination with vincristine and prednisone, with or without methotrexate and mercaptopurine; or
ii. Post-hematopoietic stem cell transplant; or

c. Relapsed/refractory disease as a single agent or in combination with multi-agent chemotherapy.

Tasigna® (Nilotinib) Approval Criteria [Chronic Myeloid Leukemia (CML) Diagnosis]:

1. Member must have 1 of the following:
   a. Newly diagnosed chronic, accelerated, or blast phase CML; or
   b. Philadelphia Chromosome Positive (Ph+) CML chronic phase (CP) resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy; or
   c. Post-hematopoietic stem cell transplantation.

Tasigna® (Nilotinib) Approval Criteria [Soft Tissue Sarcoma – Gastrointestinal Stromal Tumors (GIST) Diagnosis]:

1. Member must have progressive disease and failed imatinib, sunitinib, or regorafenib.

Tecartus® (Brexucabtagene Autoleucel) Approval Criteria [Acute Lymphoblastic Leukemia (ALL) Diagnosis]:

1. Diagnosis of ALL; and
2. Relapsed or refractory disease; and
3. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells and must be trained in the management of cytokine release syndrome (CRS), neurologic toxicities, and comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements.

Tibsovo® (Ivosidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
   a. Member meets 1 of the following:
      i. Member is 75 years of age or older; or
      ii. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
   b. As a single agent; and
   c. Isocitrate dehydrogenase-1 (IDH1) mutation; or
2. Relapsed/refractory AML; and
   a. As a single agent; and
   b. IDH1 mutation.

Tibsovo® (Ivosidenib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic cholangiocarcinoma; and
2. An isocitrate dehydrogenase-1 (IDH1) mutation; and

3. Member has received prior treatment for this diagnosis.

Venclexta® (Venetoclax) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Member meets 1 of the following:
   a. Member is 75 years of age or older; or
   b. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
2. As first-line therapy or in relapsed/refractory disease; and
3. In combination with azacitidine, decitabine, or low-dose cytarabine (LDAC).

Venclexta® (Venetoclax) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. As first-line therapy in combination with obinutuzumab for a maximum duration of 12 months; or
2. Relapsed/refractory disease in combination with rituximab or as a single agent.

Venclexta® (Venetoclax) Approval Criteria [Mantle Cell Lymphoma (MCL) Diagnosis]:

1. As second-line or subsequent therapy; and
2. As a single agent.

Xospata® (Gilteritinib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Relapsed/refractory AML; and
2. FMS-related tyrosine kinase 3 (FLT3) mutation; and
3. As a single agent.

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

1. Disease progression following failure of purine analog therapy (i.e., pentostatin, cladribine); and
2. As a single agent.

Zydelig® (Idelalisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Diagnosis]:

1. Relapsed/refractory disease; and
2. In combination with rituximab or rituximab/bendamustine; or
3. As a single agent.

Zydelig® (Idelalisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:

1. Grade 1 to 2 FL; and

2. As second-line or subsequent therapy for refractory or progressive disease; and
3. Refractory to both alkylator and rituximab therapy.

Zydelig® (Idelalisib) Approval Criteria [Gastric or Nongastric Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma, Nodal or Splenic Marginal Zone Lymphoma (MZL) Diagnosis]:

1. As second-line or subsequent therapy for refractory or progressive disease; and
2. Refractory to both alkylator and rituximab therapy.

Utilization of Leukemia Medications: Fiscal Year 2022

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

Fiscal Year Comparison: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	46	320	$4,666,225.69	$14,581.96	$497.57	16,640	9,378
2022	84	563	$8,551,735.27	$15,189.58	$515.91	30,673	16,576
% Change	**82.60%**	**75.90%**	**83.30%**	**4.20%**	**3.70%**	**84.30%**	**76.80%**
Change	**38**	**243**	**$3,885,509.58**	**$607.62**	**$18.34**	**14,033**	**7,198**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Fiscal Year Comparison: Medical Claims

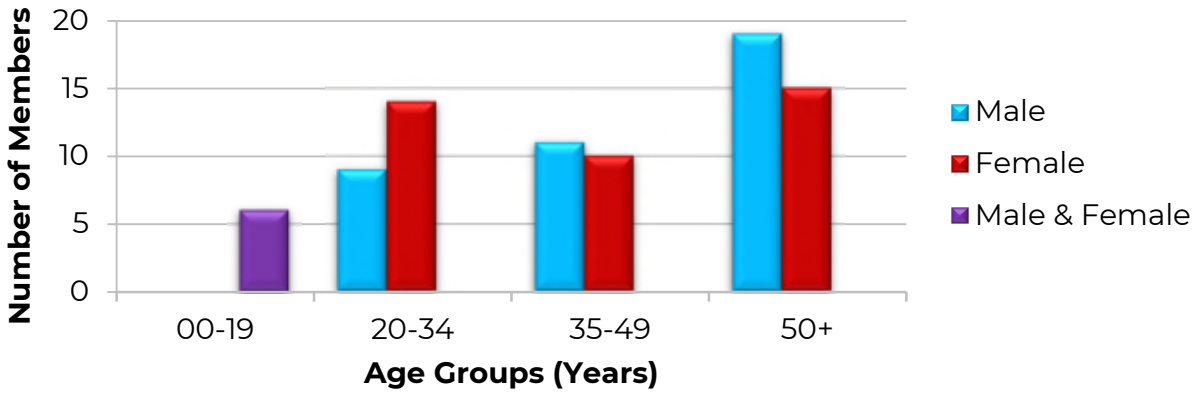
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	7	52	$288,350.39	$5,545.20	7.43
2022	39	119	$2,089,506.59	$17,558.88	3.05
% Change	**457.14%**	**128.85%**	**624.64%**	**216.65%**	**-58.95%**
Change	**32**	**67**	**$1,801,156.20**	**$12,013.68**	**-4.38**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

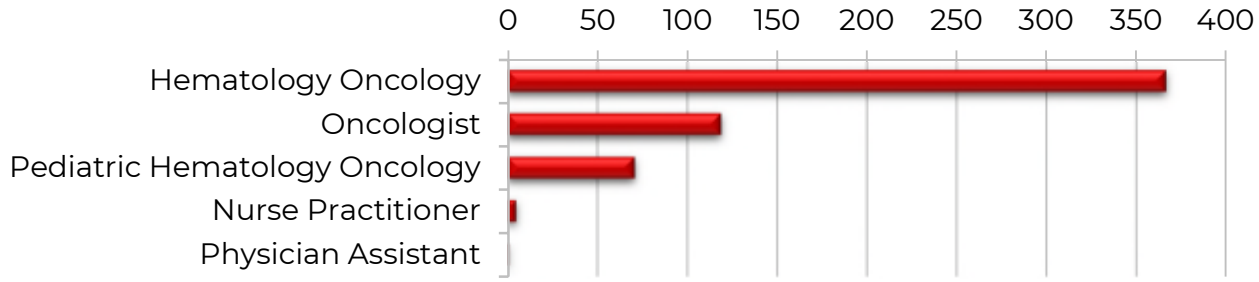
- Aggregate drug rebates collected during fiscal year 2022 for leukemia medications: $4,448,506.47.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[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 Leukemia Medications: Pharmacy Claims



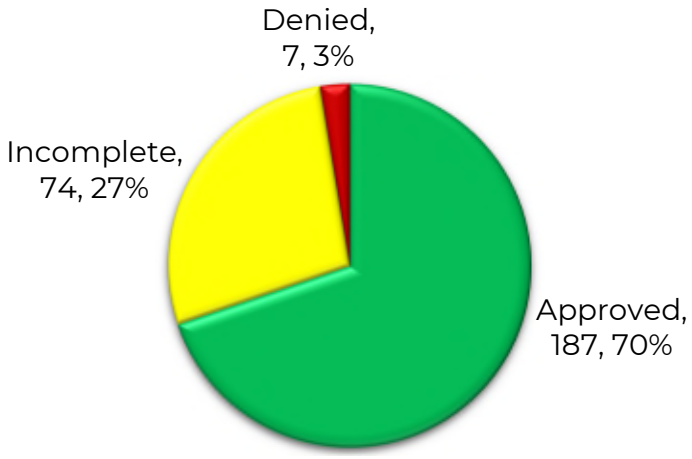
Top Prescriber Specialties of Leukemia Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Leukemia Medications

There were 268 prior authorization requests submitted for leukemia medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Sprycel® (dasatinib): September 2026
- Onureg® (azacitidine): June 2030
- Inqovi® (decitabine): August 2030
- Tasigna® (nilotinib): October 2032
- Venclexta® (venetoclax): September 2033
- Zydelig® (idelalisib): September 2033
- Iclusig® (ponatinib): December 2033
- Bosulif® (bosutinib): February 2034
- Idhifa® (enasidenib): September 2034
- Daurismo® (glasdegib): April 2036
- Xospata® (gilteritinib): July 2036
- Imbruvica® (ibrutinib): September 2036
- Rezlidhia™ (olutasidenib): May 2039
- Tibsovo® (ivosidenib): June 2039
- Scemblix® (asciminib): May 2040

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

- **May 2022:** The FDA granted accelerated approval to Kymriah® (tisagenlecleucel) for a new indication for the treatment of adults with relapsed or refractory follicular lymphoma (FL) after 2 or more lines of systemic therapy.
- **May 2022:** The FDA approved a new indication for Vidaza® (azacitidine) for the treatment of pediatric patients with newly diagnosed juvenile myelomonocytic leukemia (JMML).
- **May 2022:** The FDA approved a new indication for Tibsovo® (ivosidenib) in combination with azacitidine for the treatment of newly diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adults 75 years or older who have comorbidities that preclude the use of intensive induction chemotherapy.
- **August 2022:** The FDA approved a new indication for Imbruvica® (ibrutinib) for the treatment of pediatric patients 1 year of age or older with chronic graft-versus-host disease (cGVHD) after failure of 1 or more lines of systemic therapy. Additionally, the FDA approved a new oral suspension formulation of ibrutinib for this indication. Imbruvica® was previously available as oral tablets and oral capsules.
- **December 2022:** The FDA approved Rezlidhia™ (olutasidenib) for the treatment of adults with relapsed or refractory AML who have a susceptible IDH1 mutation as detected by an FDA-approved test.

News:

- **February 2022:** Gilead, the manufacturer of Zydelig® (idelalisib), requested the FDA to withdraw the previous accelerated approvals for both FL and small lymphocytic lymphoma (SLL), citing the evolving treatment landscape for FL and SLL and challenges enrolling patients into the required confirmatory study for those indications. Zydelig® remains FDA approved for the treatment of relapsed chronic lymphocytic leukemia (CLL) and will continue to be available in the United States for that indication.

Rezlidhia™ (Olutasidenib) Product Summary[8]

- **Therapeutic Class:** IDH1 inhibitor
- **Indication(s):** Treatment of adults with relapsed or refractory AML with a susceptible IDH1 mutation as detected by an FDA-approved test
- **How Supplied:** 150mg oral capsules
- **Dose:**
  - 150mg twice daily
- **Cost:** The Wholesale Acquisition Cost (WAC) is $536.67 per capsule, resulting in monthly cost of $32,200.20 based on the recommended dosing of 1 capsule twice daily.

Recommendations

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

Rezlidhia™ (Olutasidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Relapsed/refractory AML; and
   a. As a single agent; and
   b. Isocitrate dehydrogenase-1 (IDH1) mutation.

Additionally, the College of Pharmacy recommends updating the prior authorization criteria for Imbruvica® (ibrutinib), Kymriah® (tisagenlecleucel), and Tibsovo® (ivosidenib) based on recent FDA approvals and to be consistent with the other chimeric antigen receptor (CAR) T-cell therapies (changes shown in red):

Imbruvica® (Ibrutinib) Approval Criteria [Chronic Graft-Versus-Host Disease (cGVHD) Diagnosis]:

1. Failure of 1 or more lines of therapy; and
2. Must be an adult or pediatric member 1 year of age or older; and
3. For members younger than 12 years of age:
   a. The member's current body surface area (BSA) must be provided; and

b. Requests for use of the 70mg capsule formulation will require a patient-specific, clinically significant reason why the member cannot use the 70mg/mL oral suspension formulation.

Kymriah® (Tisagenlecleucel) Approval Criteria [Lymphoma Diagnosis]:

1. Large B-cell lymphoma [including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL)] or FL; and
2. Relapsed/refractory disease; and
3. Member must be 18 years of age or older; and
4. Member must not have primary central nervous system lymphoma; and
5. Member must have had ≥2 lines of therapy; and
6. Health care facilities must be on the certified list to administer chimeric antigen receptor (CAR) T-cells, must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities, and must comply with the Kymriah® Risk Evaluation and Mitigation Strategy (REMS) requirements; and
7. Approvals will be for 1 dose per member per lifetime.

Tibsovo® (Ivosidenib) Approval Criteria [Acute Myeloid Leukemia (AML) Diagnosis]:

1. Newly diagnosed AML; and
   a. Member meets 1 of the following:
      i. Member is 75 years of age or older; or
      ii. If the member is younger than 75 years of age, must be unable to tolerate intensive induction chemotherapy; and
   b. As a single agent or in combination with azacitidine; and
   c. Isocitrate dehydrogenase-1 (IDH1) mutation; or
2. Relapsed/refractory AML; and
   a. As a single agent; and
   b. IDH1 mutation.

Lastly, the College of Pharmacy recommends the removal of the Zydelig® (idelalisib) approval criteria for the FL and SLL indications based on the FDA withdrawal of the previous accelerated approvals for those indications (changes shown in red):

Zydelig® (Idelalisib) Approval Criteria [Chronic Lymphocytic Leukemia (CLL)~~/Small Lymphocytic Lymphoma (SLL)~~ Diagnosis]:

1. Relapsed/refractory disease; and
2. In combination with rituximab ~~or rituximab/bendamustine~~; or
3. As a single agent.

~~**Zydelig® (Idelalisib) Approval Criteria [Follicular Lymphoma (FL) Diagnosis]:**~~

~~1. Grade 1 to 2 FL; and~~
~~2. As second-line or subsequent therapy for refractory or progressive disease; and~~
~~3. Refractory to both alkylator and rituximab therapy.~~

Utilization Details of Leukemia Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DASATINIB PRODUCTS						
SPRYCEL TAB 100MG	169	24	$2,528,313.89	$14,960.44	7.04	29.56%
SPRYCEL TAB 70MG	40	7	$360,097.51	$9,002.44	5.71	4.21%
SPRYCEL TAB 20MG	26	3	$308,379.52	$11,860.75	8.67	3.61%
SPRYCEL TAB 140MG	18	5	$280,588.00	$15,588.22	3.6	3.28%
SPRYCEL TAB 50MG	1	1	$17,588.07	$17,588.07	1	0.21%
SPRYCEL TAB 80MG	1	1	$15,854.51	$15,854.51	1	0.19%
SUBTOTAL	**255**	**41**	**$3,510,821.50**	**$13,767.93**	**6.22**	**41.05%**
IBRUTINIB PRODUCTS						
IMBRUVICA TAB 420MG	44	8	$638,814.25	$14,518.51	5.5	7.47%
IMBRUVICA TAB 280MG	24	2	$346,758.10	$14,448.25	12	4.05%
IMBRUVICA CAP 140MG	22	2	$339,477.86	$15,430.81	11	3.97%
IMBRUVICA TAB 560MG	13	2	$192,496.39	$14,807.41	6.5	2.25%
SUBTOTAL	**103**	**14**	**$1,517,546.60**	**$14,733.46**	**7.36**	**17.75%**
VENETOCLAX PRODUCTS						
VENCLEXTA TAB 100MG	78	20	$862,721.93	$11,060.54	3.9	10.09%
VENCLEXTA TAB START PK	2	2	$5,716.21	$2,858.11	1	0.07%
VENCLEXTA TAB 50MG	1	1	$404.81	$404.81	1	0.00%
VENCLEXTA TAB 10MG	1	1	$247.46	$247.46	1	0.00%
SUBTOTAL	**82**	**24**	**$869,090.41**	**$10,598.66**	**3.42**	**10.16%**
NILOTINIB PRODUCTS						
TASIGNA CAP 150MG	38	5	$616,627.03	$16,227.03	7.6	7.21%
TASIGNA CAP 200MG	5	1	$78,767.75	$15,753.55	5	0.92%
SUBTOTAL	**43**	**6**	**$695,394.78**	**$16,171.97**	**7.17**	**8.13%**
ENASIDENIB PRODUCTS						
IDHIFA TAB 100MG	19	2	$548,279.04	$28,856.79	9.5	6.41%
SUBTOTAL	**19**	**2**	**$548,279.04**	**$28,856.79**	**9.5**	**6.41%**
PONATINIB PRODUCTS						
ICLUSIG TAB 45MG	12	2	$220,461.92	$18,371.83	6	2.58%
ICLUSIG TAB 30MG	1	1	$18,816.91	$18,816.91	1	0.22%
ICLUSIG TAB 15MG	1	1	$18,816.91	$18,816.91	1	0.22%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**14**	**4**	**$258,095.74**	**$18,435.41**	**3.5**	**3.02%**
BOSUTINIB PRODUCTS						
BOSULIF TAB 500MG	8	1	$133,554.22	$16,694.28	8	1.56%
BOSULIF TAB 100MG	4	1	$52,114.72	$13,028.68	4	0.61%
SUBTOTAL	**12**	**2**	**$185,668.94**	**$15,472.41**	**6**	**2.17%**
IDELALISIB PRODUCTS						
ZYDELIG TAB 150MG	10	1	$119,798.28	$11,979.83	10	1.40%
SUBTOTAL	**10**	**1**	**$119,798.28**	**$11,979.83**	**10**	**1.40%**
ASCIMINIB PRODUCTS						
SCEMBLIX TAB 40MG	9	3	$519,189.34	$57,687.70	3	6.07%
SUBTOTAL	**9**	**3**	**$519,189.34**	**$57,687.70**	**3**	**6.07%**
AZACITIDINE PRODUCTS						
ONUREG TAB 300MG	8	3	$176,014.08	$22,001.76	2.67	2.06%
SUBTOTAL	**8**	**3**	**$176,014.08**	**$22,001.76**	**2.67**	**2.06%**
GILTERITINIB PRODUCTS						
XOSPATA TAB 40MG	8	2	$151,836.56	$18,979.57	4	1.78%
SUBTOTAL	**8**	**2**	**$151,836.56**	**$18,979.57**	**4**	**1.78%**
TOTAL	**563**	**84***	**$8,551,735.27**	**$15,189.58**	**6.7**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; START PK = starter pack; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
PEGASPARGASE J9266	56	27	$1,354,599.13	$24,189.27	2.07
OBINUTUZUMAB J9301	35	8	$218,399.00	$6,239.97	4.38
INOTUZUMAB OZOGAMICIN J9229	18	3	$431,054.46	$23,947.47	6
ASPARAGINASE J9019	10	1	$85,454.00	$8,545.40	10
TOTAL	**119**	**39**	**$2,089,506.59**	**$17,558.88**	**3.05**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 01/2023. Last accessed 01/10/2023.
[2] U.S. FDA. FDA Approves Tisagenlecleucel for Relapsed or Refractory Follicular Lymphoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-tisagenlecleucel-relapsed-or-refractory-follicular-lymphoma. Issued 05/27/2022. Last accessed 01/06/2023.
[3] U.S. FDA. FDA Approves Azacitidine for Newly Diagnosed Juvenile Myelomonocytic Leukemia. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-azacitidine-newly-diagnosed-juvenile-myelomonocytic-leukemia. Issued 05/20/2022. Last accessed 01/10/2023.
[4] U.S. FDA. FDA Approves Ivosidenib in Combination with Azacitidine for Newly Diagnosed Acute Myeloid Leukemia. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-ivosidenib-combination-azacitidine-newly-diagnosed-acute-myeloid-leukemia. Issued 05/25/2022. Last accessed 01/10/2023.
[5] U.S. FDA. FDA Approves Ibrutinib for Pediatric Patients with Chronic Graft Versus Host Disease, Including a New Oral Suspension. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-ibrutinib-pediatric-patients-chronic-graft-versus-host-disease-including-new-oral. Issued 08/24/2022. Last accessed 01/10/2023.
[6] U.S. FDA. FDA Approves Olutasidenib for Relapsed or Refractory Acute Myeloid Leukemia with a Susceptible IDH1 Mutation. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-olutasidenib-relapsed-or-refractory-acute-myeloid-leukemia-susceptible-idh1-mutation. Issued 12/01/2022. Last accessed 01/06/2023.
[7] Gilead. Gilead Statement on Zydelig® U.S. Indication for Follicular Lymphoma and Small Lymphocytic Leukemia. Available online at: https://www.gilead.com/news-and-press/company-statements/gilead-statement-on-zydelig-us-indication-for-follicular-lymphoma-and-small-lymphocytic-leukemia. Issued 01/14/2022. Last accessed 01/06/2023.
[8] Rezlidhia™ (Olutasidenib) Prescribing Information. Forma Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215814s000lbl.pdf. Last revised 12/2022. Last accessed 01/06/2023.

Appendix Q

Fiscal Year 2022 Annual Review of Anticonvulsants and 30-Day Notice to Prior Authorize Zonisade™ (Zonisamide Oral Suspension) and Ztalmy® (Ganaxolone)

Oklahoma Health Care Authority
February 2023

Current Prior Authorization Criteria

1. Anticonvulsants are included in the mandatory generic plan.
    a. All brand-name anticonvulsants (with a generic equivalent) will require prior authorization.
        i. Brand-name medications (with a generic equivalent) will be approved for all members who are currently stable on these medications and have a seizure diagnosis.
2. Prior authorization will be required for certain non-standard dosage forms of medications when the drug is available in standard dosage forms.
    a. Members 12 years of age and older must have a documented medical reason demonstrating the need for non-standard dosage forms.
    b. Criteria for approval of extended-release formulations:
        i. Previously stabilized on the short-acting formulation; and
        ii. Dosing is not more than once daily; and
        iii. A reason why the short-acting formulation is not adequate must be provided; and
        iv. Dose packs will not be approved if standard dosage forms are available.
3. Quantity limit restrictions will be placed on lower strength tablets and capsules. The highest strengths will continue to have no quantity restrictions unless a maximum dose is specified for a particular medication.

Afinitor® (Everolimus) Approval Criteria* [Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures Diagnosis]:

1. An FDA approved diagnosis of TSC-associated partial-onset seizures; and
2. Initial prescription must be written by a neurologist or neuro-oncologist; and
3. Member must have failed therapy with at least 3 anticonvulsants; and
4. Afinitor® must be used as adjunctive treatment; and

5. Member must not be taking any P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin) concurrently with Afinitor®; and
6. Member must not be taking St. John's wort concurrently with Afinitor®; and
7. Prescriber must verify that Afinitor® trough levels and adverse reactions (e.g., non-infectious pneumonitis, stomatitis, hyperglycemia, dyslipidemia, thrombocytopenia, neutropenia, febrile neutropenia) will be monitored, and dosing changes or discontinuations will correspond with recommendations in the drug labeling; and
8. Prescriber must verify that female members will use contraception while receiving Afinitor® therapy and for 8 weeks after the last dose of Afinitor® and that male members with female partners of reproductive potential will use contraception while receiving Afinitor® therapy and for 4 weeks after the last dose of Afinitor®; and
9. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.
    *Approval criteria for Afinitor® (everolimus) for indications other than seizure diagnoses can be found in the September 2022 DUR Board packet. Afinitor® is reviewed annually with the breast cancer medications.

Aptiom® (Eslicarbazepine) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Member must not currently be taking oxcarbazepine (concurrent use is contraindicated); and
3. A patient-specific, clinically significant reason why the member cannot use oxcarbazepine must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (200mg and 400mg) and 60 tablets per 30 days on the higher strength tablets (600mg and 800mg).

Banzel® (Rufinamide) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); and
2. Initial prescription must be written by a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Members currently stable on Banzel® (rufinamide) and who have a seizure diagnosis will be grandfathered.

Briviact® (Brivaracetam) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be prescribed by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Members currently stable on Briviact® and who have a seizure diagnosis will be grandfathered; and
5. For Briviact® oral solution, an age restriction of 12 years of age and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral tablet formulation; and
6. Approval length for Briviact® intravenous (IV) will be for a maximum of 7 days of therapy. Further approval may be granted if the prescriber documents an ongoing need for Briviact® IV therapy over Briviact® oral formulations.

Diacomit® (Stiripentol) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Dravet syndrome in members 2 years of age and older; and
2. Initial prescription must be written by, or in consultation with, a neurologist; and
3. Member must have failed or be inadequately controlled with clobazam and valproate; and
4. Member must take clobazam and valproate concomitantly with Diacomit® or a reason why concomitant clobazam and valproate are not appropriate for the member must be provided; and
5. Members currently stable on Diacomit® and who have a seizure diagnosis will be grandfathered; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
7. For Diacomit® powder for oral suspension, an age restriction of 12 years and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral capsule formulation; and
8. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Elepsia™ XR [Levetiracetam Extended-Release (ER) Tablet] Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and

2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic formulations of levetiracetam ER must be provided; and
3. A quantity limit of 60 tablets per 30 days will apply.

Epidiolex® (Cannabidiol Oral Solution) Approval Criteria:

1. Diagnosis* of 1 of the following:
   a. Lennox-Gastaut syndrome (LGS); or
   b. Dravet syndrome; or
   c. Tuberous sclerosis complex (TSC)-associated seizures; or
   d. Intractable epilepsy; and
   *The manufacturer has provided a supplemental rebate to allow Epidiolex® claims to pay at the point of sale if the member has a reported diagnosis of LGS, Dravet syndrome, TSC-associated seizures, or intractable epilepsy within the past 12 months of claims history; however, Epidiolex® will follow the original criteria if the manufacturer chooses not to participate in supplemental rebates.
2. Member must be 1 year of age or older; and
3. Members currently stable on Epidiolex® and who have a seizure diagnosis will be grandfathered.

Eprontia™ (Topiramate Oral Solution) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
   b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
   c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use topiramate tablets and sprinkle capsules must be provided; and
3. An age restriction of 11 years of age and younger will apply. Members older than 11 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
4. A quantity limit of 473mL per 29 days will apply.

Felbatol® (Felbamate) Approval Criteria:

1. Initial prescription must be written by a neurologist; and
2. Member must have failed therapy with at least 3 other anticonvulsants.

Fintepla® (Fenfluramine) Approval Criteria:

1. An FDA approved diagnosis of Dravet syndrome; and
2. Member must be 2 years of age or older; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and

4. Member must not be taking monoamine oxidase inhibitors within 14 days of administration of Fintepla®, and
5. Prescriber must verify the member's blood pressure will be monitored; and
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Fintepla® therapy and throughout treatment; and
7. Member must have failed or be inadequately controlled with at least 2 other anticonvulsants; and
8. Pharmacy and provider must be certified in the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program; and
9. Member must be enrolled in the Fintepla® REMS program; and
10. 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
11. Prescriber must verify that dose titration and maximum maintenance dose will be followed according to package labeling based on member weight and concomitant medications; and
12. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
13. A quantity limit of 360mL per 30 days will apply.

Oxtellar XR® [Oxcarbazepine Extended-Release (ER)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation must be provided; and
2. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (150mg and 300mg).

Qudexy® XR [Topiramate Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
    b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
    c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (150mg and 200mg).

Sabril® (Vigabatrin) Approval Criteria:

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

Spritam® (Levetiracetam Tablet for Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures, myoclonic seizures, or primary generalized tonic-clonic (PGTC) seizures; and
2. A patient-specific, clinically significant reason why the member cannot use generic formulations of levetiracetam must be provided; and
3. A quantity limit of 60 tablets per 30 days will apply.

Sympazan™ (Clobazam Oral Film) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in members 2 years of age and older; and
2. Previous failure of at least 2 non-benzodiazepine anticonvulsants; and
3. Previous failure of clonazepam; and
4. A patient-specific, clinically significant reason why the member cannot use clobazam oral tablets or clobazam oral suspension must be provided; and
5. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Trokendi XR® [Topiramate Extended-Release (ER)] Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
    b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
    c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and

3. A patient-specific, clinically significant reason why the member cannot use Qudexy® XR (topiramate ER) must be provided; and
4. Members currently stable on Trokendi XR® (topiramate ER) and who have a seizure diagnosis will be grandfathered; and
5. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (200mg).

Xcopri® (Cenobamate) Approval Criteria:

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be written by a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants.

Utilization of Anticonvulsants: Fiscal Year 2022

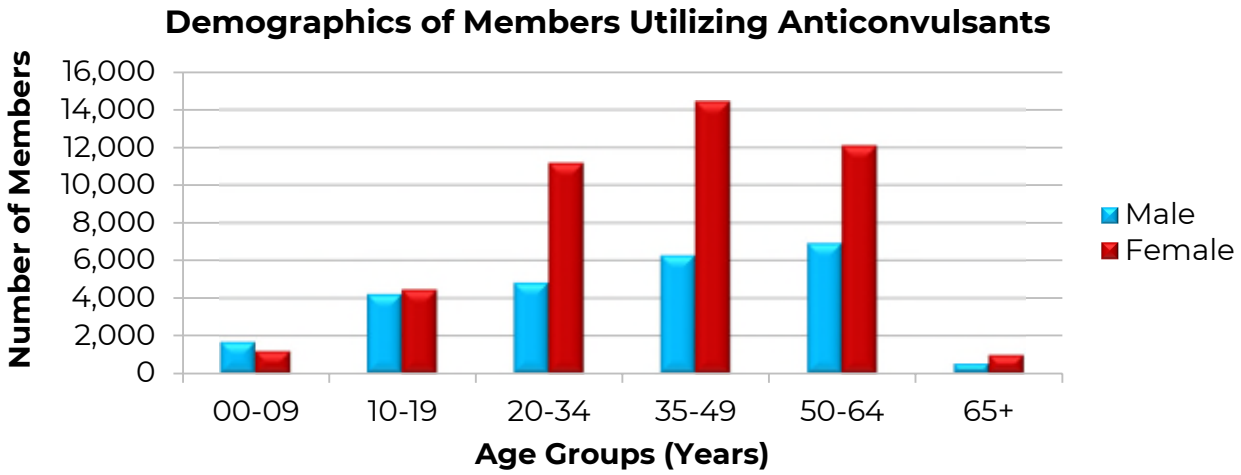
Comparison of Fiscal Years

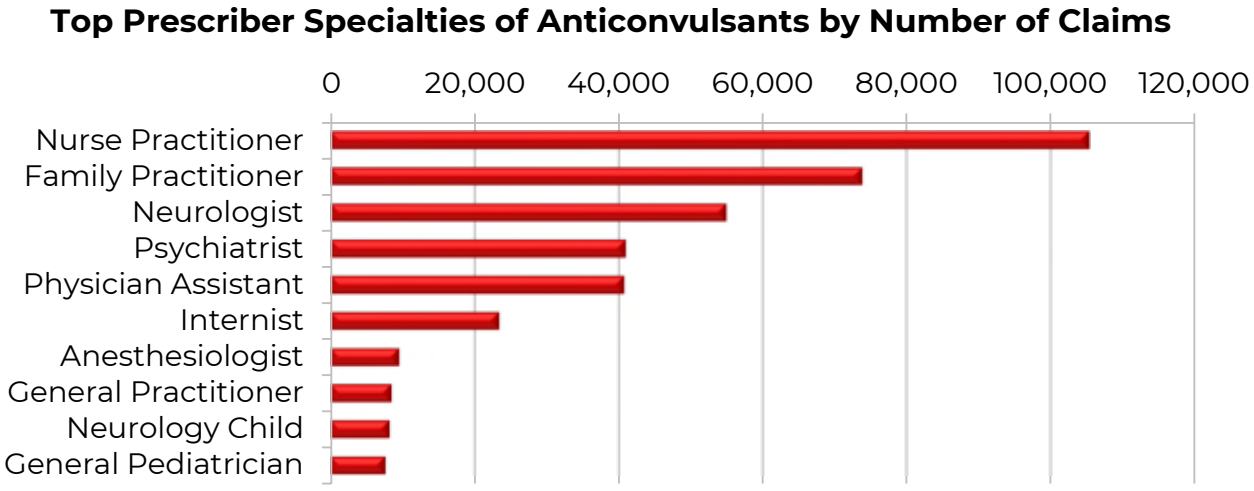
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	44,759	317,958	$28,189,844.99	$88.66	$2.64	33,846,189	10,678,292
2022	68,516	409,613	$33,620,700.99	$82.08	$2.34	42,887,149	14,339,410
% Change	**53.10%**	**28.80%**	**19.30%**	**-7.40%**	**-11.40%**	**26.70%**	**34.30%**
Change	**23,757**	**91,655**	**$5,430,856**	**-$6.58**	**-$0.30**	**9,040,960**	**3,661,118**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

- The following utilization data includes anticonvulsants used for all diagnoses and does not differentiate between seizure diagnoses and other diagnoses, for which use may be appropriate.
- The anticonvulsants are influenced by federal and supplemental rebates. These 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.
    - Aggregate drug rebates collected during fiscal year 2022 for the anticonvulsants: $17,703,310.66[Δ]

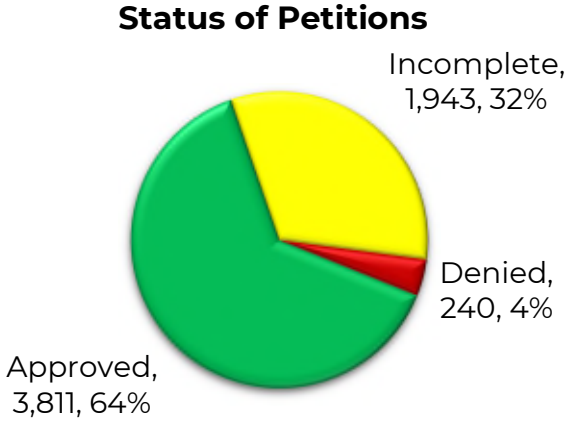
[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.





Prior Authorization of Anticonvulsants

There were 5,994 prior authorization requests submitted for anticonvulsants during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



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

Anticipated Patent Expiration(s):

- Banzel® (rufinamide tablets, oral suspension): May 2023
- Sympazan® (clobazam oral films): April 2024
- Diacomit® (stiripentol capsules, oral suspension): August 2025*
  *Diacomit® does not have any unexpired patents; however, it does currently have exclusivity through August 2025.
- Fycompa® (perampanel tablets, oral suspension): July 2026
- Oxtellar XR® [oxcarbazepine extended-release (ER) tablets]: April 2027
- Elepsia™ XR (levetiracetam ER tablets): October 2027
- Xcopri® (cenobamate tablets): October 2027
- Nayzilam® (midazolam nasal spray): January 2028
- Trokendi XR® (topiramate ER capsules): April 2028
- Valtoco® (diazepam nasal spray): March 2029
- Briviact® (brivaracetam tablets, oral solution, IV solution): April 2030
- Aptiom® (eslicarbazepine tablets): August 2032
- Qudexy® XR (topiramate ER capsules): March 2033
- Spritam® (levetiracetam tablets for oral suspension): March 2034
- Epidiolex® (cannabidiol oral solution): June 2035
- Zonisade™ (zonisamide oral suspension): August 2038
- Fintepla® (fenfluramine oral solution): October 2039

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

- **March 2022:** The first AB-rated generic versions of Vimpat® (lacosamide) tablets have been launched by Tris Pharma, Indoco Remedies, Alembic, Amneal, and Glenmark. In addition, the FDA granted approval to AB-rated generic versions of Vimpat® to Hetero, MSN Laboratories, ScieGen, and Sun Pharmaceuticals. These manufacturers may launch generic Vimpat® at any time. Vimpat® is approved for the treatment of partial-onset seizures in patients 1 month of age and older, and as adjunctive treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older. In addition to the tablet formulation, Vimpat® is also available as an oral solution and injection that carry the same indications as the tablets.
- **March 2022:** The FDA approved a new indication for Fintepla® (fenfluramine) oral solution for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older. Fintepla® was previously approved in June 2020 for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. Additionally, the FDA granted Fintepla® pediatric exclusivity. Fintepla® demonstrated efficacy in the most difficult to treat seizure types, including drop seizures, which cause a person to suddenly lose muscle tone, become limp, and fall to the ground, with a high

likelihood of injury. Fintepla® has a mechanism of action different from and complementary to current anticonvulsants, and it can be used with no disruptions to current anticonvulsant regimens. The FDA approval was supported by safety and efficacy data from a global, randomized, placebo-controlled Phase 3 clinical trial in 263 patients with LGS (2 to 35 years of age), which demonstrated that Fintepla® at a dose of 0.7mg/kg/day significantly reduced monthly drop seizure frequency by a median of 23.7% from baseline compared to 8.7% for the placebo group (P=0.0037). Nearly a fourth of those patients on Fintepla® 0.7mg/kg/day experienced a ≥50% reduction in drop seizure frequency per 28 days (18% with ≥50% to <75% reduction and 6% with ≥75% reduction). The common adverse reactions that occurred in patients treated with Fintepla® (incidence ≥10% and more than placebo) were diarrhea, decreased appetite, fatigue, somnolence, and vomiting. The Fintepla® safety database includes long-term cardiovascular safety data for patients treated for up to 3 years for Dravet syndrome and LGS. Fintepla® is available through a restricted distribution program, called the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program.

- **March 2022:** The FDA approved Ztalmy® (ganaxolone) to treat seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older. This is the first treatment for seizures associated with CDD and the first treatment specifically for CDD. CDD is a rare developmental epileptic encephalopathy caused by CDKL5 gene mutations. The CDKL5 gene is responsible for making proteins that are important for normal brain functioning and development. Patients with CDD typically have infantile-onset epilepsy that responds poorly to currently available treatments. Other symptoms include hypotonia, severe developmental and cognitive delays with little or no speech production, fine and gross motor impairment (including the inability to walk for most patients), cortical visual impairment, behavioral abnormalities, and sleep and digestive difficulties. Although rare, the incidence of CDD is believed to be between 1 in 40,000-60,000 live births, making it one of the most common genetic forms of epilepsy.
- **July 2022:** The FDA approved Zonisade™ (zonisamide oral suspension) 100mg/5mL for the adjunctive treatment of partial seizures in adults and pediatric patients 16 years of age and older with epilepsy. Zonisade™ is the first and only zonisamide oral liquid formulation to be approved by the FDA. The efficacy of Zonisade™ is based upon a bioavailability study comparing Zonisade™ oral suspension to zonisamide capsules in healthy subjects. The efficacy and tolerability of zonisamide have been previously established in 3 double-blind, placebo-controlled, multicenter clinical trials. Zonisade™ should be

administered once or twice daily. Efficacy and safety of Zonisade™ in patients younger than 16 years of age have not been established.

- **September 2022:** The FDA approved an age expansion for Diacomit® (stiripentol) for the treatment of seizures associated with Dravet syndrome in patients 6 months of age and older who weigh ≥7kg and are taking clobazam. Diacomit® first received FDA approval in 2018 for the same indication in children 2 years of age and older. Diacomit® is now the only FDA-approved medication specifically indicated for seizures associated with Dravet syndrome in children as young as 6 months of age; however, there is no clinical data to support the use of Diacomit® as monotherapy in Dravet syndrome. Stiripentol is an effective treatment for seizures that are often resistant to other anticonvulsants. In the 2 original clinical studies, patients were randomized to receive either Diacomit® or placebo added to their treatment regimen with clobazam and valproate, and Diacomit® reduced generalized clonic or tonic-clonic seizures by a median of 84% compared with 5.8% on placebo after 2 months. The effectiveness of Diacomit® for the treatment of seizures associated with Dravet syndrome in patients 6 months of age to younger than 3 years of age was extrapolated from the demonstration of effectiveness in patients 3 years to younger than 18 years of age in the original Diacomit® clinical trials. Additional pharmacokinetic and safety data in patients 6 months of age to younger than 3 years of age also contributed to the age expansion. The safety and effectiveness of Diacomit® have not been established in pediatric patients younger than 6 months of age or who weigh <7kg.

News:

- **August 2022:** The FDA has granted tentative approval for Libervant™ (diazepam buccal film) for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. "Tentative approval" means the FDA has concluded that Libervant™ has met all required quality, safety, and efficacy standards for approval but, due to an existing FDA regulatory grant of orphan drug market exclusivity for Valtoco®, a diazepam nasal spray product, Libervant™ is not yet eligible for marketing in the United States. As a result of the determination, the FDA cannot give final approval for Libervant™ until the expiration or inapplicability of the orphan drug market exclusivity, including, for example, by court order, a selective waiver of the Orphan Drug exclusivity, or a reversal of the FDA's decision and determination that Libervant™ is "clinically superior" to Valtoco®. During the FDA review process, Aquestive Therapeutics also submitted the results of a 2021

Aquestive-sponsored randomized, open-label, 2 sequence, 2 period, 2 treatment crossover study to evaluate the effect of food on the pharmacokinetics of Valtoco® in healthy adult subjects. The results of this study indicated that, when Valtoco® is administered after a high fat meal, the maximum drug concentration was reduced by 48% compared to Valtoco® administered to subjects in a fasted state. The study also showed that the time to maximum drug concentration of Valtoco® doubled from 2 hours to 4 hours when administered after a high fat meal. Aquestive provided the data to the FDA during the review process, along with a cross-study comparison to a similar study performed with Libervant™. The FDA's decision concluded that the information Aquestive submitted was not sufficient to overturn their previous conclusion regarding the lack of food effect for Valtoco™. Aquestive will seek to gain alignment with the FDA on a reasonable path to appropriately characterize the food effect of Valtoco® including potentially conducting a comparative study as indicated by the FDA.

Pipeline:

- **Carisbamate:** SK Biopharmaceuticals Co. and its United States subsidiary SK Life Science submitted a clinical study protocol to the FDA for a Phase 3 clinical trial to evaluate the efficacy and safety of carisbamate for the treatment of seizures associated with LGS. Carisbamate has received Orphan Drug designation from the FDA for the potential treatment of LGS. While the precise mechanism by which carisbamate exerts its therapeutic effect is unknown, it is believed to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents. The Phase 3, global, multicenter, randomized, double-blind, placebo-controlled trial will evaluate the efficacy of 2 doses of carisbamate in more than 250 patients 4 to 55 years of age. A New Drug Application (NDA) is anticipated to be submitted to the FDA in 2024 or 2025.

Ztalmy® (Ganaxolone) Product Summary[11,12]

Indication(s): Ztalmy® is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with CDD in patients 2 years of age and older.

How Supplied: 50mg/mL oral suspension

Dosing and Administration:

- Ztalmy® should be administered orally 3 times daily with food and should be titrated gradually according to the recommended titration schedule based on body weight.
    - Patients weighing ≤28kg:

        - Starting dosage: 6mg/kg 3 times daily
        - Maximum dosage: 21mg/kg 3 times daily
    - Patients weighing >28kg:
        - Starting dose: 150mg 3 times daily
        - Maximum dosage: 600mg 3 times daily
    - Refer to the *Prescribing Information* for the complete recommended titration schedule.
- Dosages should be increased based on tolerability and no more frequently than every 7 days.

Safety:

- Somnolence and Sedation: Ztalmy® can cause somnolence and sedation. In clinical studies, the incidence of somnolence and sedation was 44% in patients treated with Ztalmy®, compared with 24% in patients receiving placebo. Somnolence and sedation appeared early during treatment and were generally dose-related. Other central nervous system (CNS) depressants, including opioids, antidepressants, and alcohol, could potentiate somnolence and sedation in patients receiving Ztalmy®. Patients should be monitored for somnolence and sedation and advised not to drive or operate machinery until they have gained sufficient experience on Ztalmy®.
- Suicidal Behavior and Ideation: Antiepileptic drugs (AEDs), including Ztalmy®, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with an AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior. The risk of suicidal thoughts or behaviors should be balanced with the risk of untreated illness for anyone being prescribed Ztalmy®.
- Withdrawal of AEDs: Ztalmy® should be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. If withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.
- Drug Interactions: Cytochrome P450 inducers will decrease ganaxolone exposure. It is recommended to avoid concomitant use with strong or moderate CYP3A4 inducers. If use of a CYP3A4 inducer is unavoidable, a dosage increase of Ztalmy® should be considered but should not exceed the maximum recommended dosage.

Mechanism of Action: The precise mechanism by which ganaxolone exerts its therapeutic effects in the treatment of seizures associated with CDD is unknown, but its anticonvulsant effects are thought to result from positive allosteric modulation of the GABA A receptor in the CNS.

Contraindication(s): None

Adverse Reactions: The most common adverse reactions in patients treated with Ztalmy® (incidence of ≥5% and at least twice the rate of placebo) were somnolence, pyrexia, salivary hypersecretion, and seasonal allergy.

Efficacy: The effectiveness of Ztalmy® was established in a single, double-blind, randomized, placebo-controlled study in patients 2 to 19 years of age. A total of 101 patients (N=50 for Ztalmy®; N=51 for placebo) were enrolled and had molecular confirmation of a pathogenic or likely pathogenic mutation in the CDKL5 gene, seizures inadequately controlled by at least 2 previous treatment regimens, and a minimum of 16 major motor seizures (i.e., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal to bilateral tonic-clonic) per 28 days during a retrospective 2-month period prior to screening. Patients were randomized in a 1:1 ratio to receive either Ztalmy® or placebo. Following a 21-day titration period, patients in the Ztalmy® arm weighing ≤28kg received a maintenance dosage of 21mg/kg 3 times daily (with a maximum daily dose of 1,800mg) while patients in the Ztalmy® arm weighing >28kg received a maintenance dosage of 600mg 3 times daily. Ninety-six percent of patients were taking between 1 to 4 concomitant AEDs. The most frequently used concomitant AEDs (in at least 20% of patients) were valproate (42%), levetiracetam (32%), clobazam (29%), and vigabatrin (24%).

- Primary Endpoint: The primary efficacy endpoint was the percent change in the 28-day frequency of major motor seizures (defined similarly as in the 2-month period prior to screening) from a 6-week prospective baseline phase during the 17-week double-blind phase.
- Results: Patients treated with Ztalmy® showed a median 30.7% reduction in 28-day major motor seizure frequency, compared to a median 6.9% reduction for those receiving placebo, achieving the study's primary endpoint (P=0.0036). In the Marigold open-label extension study, patients treated with Ztalmy® for at least 12 months (N=48) experienced a median 49.6% reduction in major motor seizure frequency.

Cost: The Wholesale Acquisition Cost (WAC) of Ztalmy® is $22.05 per mL or $2,425.50 per 110mL bottle. This leads to an annual cost of $291,060 for the maximum dose of 600mg 3 times daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Ztalmy® (ganaxolone) and Zonisade™ (zonisamide oral suspension) with the following criteria (shown in red):

Ztalmy® (Ganaxolone) Approval Criteria:

1. An FDA approved diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD); and

   a. Diagnosis must be confirmed by genetic testing identifying a mutation in the CDKL5 gene that is pathogenic or likely pathogenic; and
2. Member must be 2 years of age or older; and
3. The initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must have failed at least 2 other anticonvulsants; and
5. Members currently stable on Ztalmy® and who have a CDD diagnosis confirmed by genetic testing will be grandfathered; and
6. The member's recent weight (kg), taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
7. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
8. Subsequent approvals will be for the duration of 1 year; and
9. A quantity limit of 1,100mL per 30 days will apply.

Zonisade™ (Zonisamide Oral Suspension) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of partial-onset seizures; and
2. A patient-specific, clinically significant reason why the member cannot use zonisamide capsules must be provided; and
3. A quantity limit of 900mL per 30 days will apply.

Additionally, the College of Pharmacy recommends updating the Fintepla® (fenfluramine) approval criteria based on the new FDA approved indication (changes shown in red):

Fintepla® (Fenfluramine) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Dravet syndrome; or
   b. Lennox-Gastaut syndrome (LGS); and
2. Member must be 2 years of age or older; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must not be taking monoamine oxidase inhibitors within 14 days of administration of Fintepla®; and
5. Prescriber must verify the member's blood pressure will be monitored; and
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Fintepla therapy and throughout treatment; and

7. For a diagnosis of Dravet syndrome, the member must have failed or be inadequately controlled with at least 2 other anticonvulsants; and
8. For a diagnosis of LGS, the member must have failed or be inadequately controlled with at least 3 other anticonvulsants; and
9. Pharmacy and provider must be certified in the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Fintepla REMS program; 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; and
12. Prescriber must verify that dose titration and maximum maintenance dose will be followed according to package labeling based on member weight and concomitant medications; and
13. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
14. A quantity limit of 360mL per 30 days will apply.

The College of Pharmacy also recommends updating the Diacomit® (stiripentol) approval criteria based on the new FDA approved age expansion (changes shown in red):

Diacomit® (Stiripentol) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Dravet syndrome ~~in members 2 years of age and older~~; and
2. Member must be 6 months of age or older and weigh ≥7kg; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must have failed or be inadequately controlled with clobazam and valproate; and
5. Member must take clobazam and valproate concomitantly with Diacomit® or a reason why concomitant clobazam and valproate are not appropriate for the member must be provided; and
6. Members currently stable on Diacomit® and who have a seizure diagnosis will be grandfathered; 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. For Diacomit® powder for oral suspension, an age restriction of 12 years and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral capsule formulation; and

9. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

Finally, the College of Pharmacy recommends updating the Banzel® (rufinamide) criteria based on net costs (changes shown in red):

Banzel® (Rufinamide) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); and
2. Initial prescription must be written by a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Authorization of generic rufinamide (in place of brand Banzel®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
5. Members currently stable on Banzel® (rufinamide) and who have a seizure diagnosis will be grandfathered.

Utilization Details of Anticonvulsants: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
GABAPENTIN PRODUCTS					
GABAPENTIN CAP 300MG	52,335	17,381	$766,907.31	$14.65	3.01
GABAPENTIN TAB 600MG	28,458	6,790	$582,743.17	$20.48	4.19
GABAPENTIN TAB 800MG	23,536	4,436	$553,511.56	$23.52	5.31
GABAPENTIN CAP 100MG	17,496	7,632	$216,611.95	$12.38	2.29
GABAPENTIN CAP 400MG	8,759	2,471	$137,978.43	$15.75	3.54
GABAPENTIN SOL 250MG/5ML	1,560	283	$67,401.04	$43.21	5.51
NEURONTIN CAP 300MG	9	1	$4,910.68	$545.63	9
GABAPENTIN SOL 300MG/6ML	3	1	$274.20	$91.40	3
SUBTOTAL	**132,156**	**38,995**	**$2,330,338.34**	**$17.63**	**3.39**
LAMOTRIGINE PRODUCTS					
LAMOTRIGINE TAB 100MG	14,830	3,871	$181,437.06	$12.23	3.83
LAMOTRIGINE TAB 25MG	12,612	4,952	$151,327.56	$12.00	2.55
LAMOTRIGINE TAB 200MG	9,361	1,884	$141,211.35	$15.09	4.97
LAMOTRIGINE TAB 150MG	5,626	1,347	$77,698.87	$13.81	4.18
LAMOTRIGINE CHW 25MG	234	46	$11,518.42	$49.22	5.09
LAMOTRIGINE TAB 200MG ER	207	34	$21,727.84	$104.97	6.09
LAMOTRIGINE CHW 5MG	158	41	$7,287.18	$46.12	3.85
LAMOTRIGINE TAB 300MG ER	131	22	$24,999.49	$190.84	5.95
LAMOTRIGINE TAB 100MG ER	89	20	$7,033.08	$79.02	4.45
LAMICTAL TAB 200MG	88	10	$88,078.37	$1,000.89	8.8

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LAMOTRIGINE ODT 50MG	83	13	$26,905.96	$324.17	6.38
LAMOTRIGINE TAB 50MG ER	83	27	$6,084.59	$73.31	3.07
LAMOTRIGINE TAB 250MG ER	82	17	$27,016.11	$329.46	4.82
LAMOTRIGINE ODT 25MG	65	13	$48,744.70	$749.92	5
LAMICTAL TAB 150MG	50	7	$86,642.76	$1,732.86	7.14
LAMICTAL TAB 100MG	39	4	$45,459.57	$1,165.63	9.75
LAMOTRIGINE TAB 100MG	29	8	$4,695.67	$161.92	3.63
LAMICTAL XR TAB 200MG	29	3	$81,477.48	$2,809.57	9.67
LAMOTRIGINE TAB 200MG	26	6	$6,106.57	$234.87	4.33
LAMOTRIGINE TAB 25MG ER	14	7	$1,101.61	$78.69	2
SUBVENITE TAB 200MG	10	5	$166.15	$16.62	2
SUBVENITE TAB 25MG	9	9	$113.57	$12.62	1
LAMOTRIGINE ODT 100MG	7	3	$2,170.70	$310.10	2.33
SUBVENITE TAB 100MG	5	3	$37.62	$7.52	1.67
LAMICTAL XR TAB 250MG	4	1	$20,693.32	$5,173.33	4
LAMICTAL CHW 25MG	4	1	$32,916.88	$8,229.22	4
LAMICTAL TAB 25MG	3	1	$7,510.66	$2,503.55	3
LAMOTRIGINE STARTER KIT 35	1	1	$443.12	$443.12	1
LAMOTRIGINE STARTER KIT 49	1	1	$644.49	$644.49	1
SUBVENITE TAB 150MG	1	1	$12.21	$12.21	1
SUBVENITE KIT STARTER 49	1	1	$394.49	$394.49	1
SUBTOTAL	**43,882**	**12,359**	**$1,111,657.45**	**$25.33**	**3.55**
LEVETIRACETAM PRODUCTS					
LEVETIRACETAM SOL 100MG/ML	11,756	1,758	$261,728.97	$22.26	6.69
LEVETIRACETAM TAB 500MG	11,232	3,055	$196,432.83	$17.49	3.68
LEVETIRACETAM TAB 1000MG	6,931	1,404	$200,336.77	$28.90	4.94
LEVETIRACETAM TAB 750MG	5,236	1,130	$130,151.06	$24.86	4.63
LEVETIRACETAM TAB 250MG	1,749	406	$27,298.63	$15.61	4.31
LEVETIRACETAM TAB 500MG ER	728	165	$22,431.30	$30.81	4.41
LEVETIRACETAM TAB 750MG ER	670	116	$28,027.03	$41.83	5.78
KEPPRA XR TAB 750MG	69	7	$72,981.57	$1,057.70	9.86
KEPPRA XR TAB 500MG	67	8	$62,171.10	$927.93	8.38
KEPPRA TAB 1000MG	45	5	$62,033.14	$1,378.51	9
KEPPRA TAB 500MG	25	5	$21,444.08	$857.76	5
KEPPRA SOL 100MG/ML	22	3	$13,420.21	$610.01	7.33
KEPPRA TAB 750MG	17	3	$22,918.07	$1,348.12	5.67
LEVETIRACETAM INJ 500MG/5ML	16	1	$718.59	$44.91	16
KEPPRA TAB 250MG	7	1	$2,929.50	$418.50	7
SUBTOTAL	**38,570**	**8,067**	**$1,125,022.85**	**$29.17**	**4.78**
CLONAZEPAM PRODUCTS					
CLONAZEPAM TAB 1MG	15,204	2,911	$168,332.16	$11.07	5.22
CLONAZEPAM TAB 0.5MG	13,867	3,461	$144,246.09	$10.40	4.01
CLONAZEPAM TAB 2MG	3,504	606	$39,124.47	$11.17	5.78

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
CLONAZEPAM ODT 0.25MG	1,206	437	$51,213.30	$42.47	2.76
CLONAZEPAM ODT 0.125MG	760	301	$27,758.18	$36.52	2.52
CLONAZEPAM ODT 0.5MG	698	222	$27,087.37	$38.81	3.14
CLONAZEPAM ODT 1MG	355	125	$13,647.03	$38.44	2.84
CLONAZEPAM ODT 2MG	85	22	$3,576.28	$42.07	3.86
SUBTOTAL	**35,679**	**8,085**	**$474,984.88**	**$13.31**	**4.41**
TOPIRAMATE PRODUCTS					
TOPIRAMATE TAB 50MG	10,963	3,629	$141,471.83	$12.90	3.02
TOPIRAMATE TAB 25MG	10,276	4,281	$122,784.61	$11.95	2.4
TOPIRAMATE TAB 100MG	7,921	2,002	$114,525.18	$14.46	3.96
TOPIRAMATE TAB 200MG	2,812	572	$48,344.84	$17.19	4.92
TOPIRAMATE CAP 25MG	398	73	$36,901.75	$92.72	5.45
TOPIRAMATE CAP 15MG	287	87	$19,016.52	$66.26	3.3
TROKENDI XR CAP 200MG	92	17	$165,572.53	$1,799.70	5.41
TROKENDI XR CAP 100MG	74	17	$111,532.88	$1,507.20	4.35
TOPIRAMATE CAP ER 100MG	58	12	$32,987.50	$568.75	4.83
TOPIRAMATE CAP ER 200MG	48	9	$35,620.01	$742.08	5.33
TOPIRAMATE CAP ER 150MG	24	7	$34,983.46	$1,457.64	3.43
TOPAMAX TAB 200MG	21	3	$34,015.62	$1,619.79	7
TROKENDI XR CAP 50MG	20	5	$8,620.72	$431.04	4
TOPAMAX TAB 100MG	15	3	$28,173.77	$1,878.25	5
TOPAMAX TAB 50MG	12	2	$11,235.62	$936.30	6
TROKENDI XR CAP 25MG	10	2	$9,843.93	$984.39	5
EPRONTIA SOL 25MG/ML	10	6	$1,999.42	$199.94	1.67
TOPIRAMATE CAP ER 50MG	6	3	$3,281.76	$546.96	2
QUDEXY XR CAP 100MG/24HR	5	1	$3,450.81	$690.16	5
TOPAMAX SPR CAP 25MG	4	1	$31,718.94	$7,929.74	4
TOPIRAMATE CAP ER 25MG	4	3	$1,787.63	$446.91	1.33
TOPAMAX TAB 25MG	1	1	$554.71	$554.71	1
SUBTOTAL	**33,061**	**10,736**	**$998,424.04**	**$30.20**	**3.08**
DIVALPROEX, VALPROATE, AND VALPROIC ACID PRODUCTS					
DIVALPROEX TAB 500MG DR	8,538	1,915	$178,550.79	$20.91	4.46
DIVALPROEX TAB 500MG ER	7,481	1,681	$187,957.46	$25.12	4.45
DIVALPROEX TAB 250MG DR	5,754	1,506	$87,613.98	$15.23	3.82
DIVALPROEX TAB 250MG ER	3,614	910	$77,029.61	$21.31	3.97
VALPROIC ACID SOL 250MG/5ML	2,232	301	$43,954.49	$19.69	7.42
DIVALPROEX CAP 125MG	1,673	249	$108,951.87	$65.12	6.72
DIVALPROEX TAB 125MG DR	1,601	418	$23,236.98	$14.51	3.83
VALPROIC ACID CAP 250MG	779	173	$25,633.68	$32.91	4.5
DEPAKOTE SPR CAP 125MG	86	10	$41,169.22	$478.71	8.6
DEPAKOTE TAB 500MG DR	40	4	$24,738.35	$618.46	10
DEPAKOTE ER TAB 500MG	38	5	$31,541.35	$830.04	7.6
DEPAKOTE ER TAB 250MG	30	4	$5,235.90	$174.53	7.5

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DEPAKOTE TAB 250MG DR	23	2	$4,870.62	$211.77	11.5
DEPAKOTE TAB 125MG DR	3	2	$133.92	$44.64	1.5
SUBTOTAL	**31,892**	**7,180**	**$840,618.22**	**$26.36**	**4.44**
OXCARBAZEPINE PRODUCTS					
OXCARBAZEPINE TAB 300MG	10,933	2,503	$228,619.11	$20.91	4.37
OXCARBAZEPINE TAB 600MG	8,224	1,356	$306,299.29	$37.24	6.06
OXCARBAZEPINE TAB 150MG	7,216	1,918	$138,379.66	$19.18	3.76
OXCARBAZEPINE SUS 300MG/5ML	3,757	550	$538,303.84	$143.28	6.83
OXTELLAR XR TAB 600MG	142	21	$204,055.19	$1,437.01	6.76
TRILEPTAL SUS 300MG/5ML	112	20	$80,530.61	$719.02	5.6
OXTELLAR XR TAB 300MG	55	7	$17,353.79	$315.52	7.86
TRILEPTAL TAB 600MG	10	1	$18,590.44	$1,859.04	10
OXTELLAR XR TAB 150MG	10	1	$2,371.32	$237.13	10
TRILEPTAL TAB 300MG	1	1	$312.00	$312.00	1
SUBTOTAL	**30,460**	**6,378**	**$1,534,815.25**	**$50.39**	**4.78**
PREGABALIN PRODUCTS					
PREGABALIN CAP 150MG	5,225	1,215	$82,480.76	$15.79	4.3
PREGABALIN CAP 75MG	4,993	1,753	$72,609.59	$14.54	2.85
PREGABALIN CAP 100MG	4,304	1,196	$65,400.78	$15.20	3.6
PREGABALIN CAP 50MG	2,892	1,251	$43,428.97	$15.02	2.31
PREGABALIN CAP 200MG	2,141	426	$34,839.49	$16.27	5.03
PREGABALIN CAP 300MG	1,375	246	$22,942.96	$16.69	5.59
PREGABALIN CAP 25MG	753	399	$10,718.08	$14.23	1.89
PREGABALIN CAP 225MG	332	67	$5,351.92	$16.12	4.96
LYRICA CAP 150MG	107	27	$64,682.93	$604.51	3.96
LYRICA CAP 200MG	103	15	$67,010.21	$650.58	6.87
LYRICA CAP 100MG	72	18	$31,717.37	$440.52	4
LYRICA CAP 300MG	55	11	$26,675.34	$485.01	5
LYRICA CAP 75MG	49	10	$25,429.10	$518.96	4.9
LYRICA CAP 50MG	32	9	$19,272.03	$602.25	3.56
PREGABALIN SOL 20MG/ML	26	4	$1,133.20	$43.58	6.5
LYRICA CAP 225MG	10	2	$7,096.87	$709.69	5
LYRICA CAP 25MG	7	3	$614.00	$87.71	2.33
SUBTOTAL	**22,476**	**6,652**	**$581,403.60**	**$25.87**	**3.38**
LACOSAMIDE PRODUCTS					
VIMPAT TAB 200MG	2,133	301	$2,197,474.85	$1,030.23	7.09
VIMPAT SOL 10MG/ML	1,597	215	$1,635,273.45	$1,023.97	7.43
VIMPAT TAB 100MG	1,283	259	$1,174,532.27	$915.46	4.95
VIMPAT TAB 150MG	991	171	$941,931.25	$950.49	5.8
VIMPAT TAB 50MG	739	158	$417,364.65	$564.77	4.68
LACOSAMIDE TAB 200MG	319	165	$15,978.86	$50.09	1.93
LACOSAMIDE TAB 100MG	251	139	$11,788.12	$46.96	1.81
LACOSAMIDE TAB 50MG	142	80	$4,324.34	$30.45	1.78

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LACOSAMIDE TAB 150MG	141	79	$6,486.32	$46.00	1.78
LACOSAMIDE SOL 10MG/ML	53	50	$6,387.52	$120.52	1.06
SUBTOTAL	**7,649**	**1,617**	**$6,411,541.63**	**$838.22**	**4.73**
CARBAMAZEPINE PRODUCTS					
CARBAMAZEPINE TAB 200MG	3,259	745	$101,703.92	$31.21	4.37
CARBAMAZEPINE TAB 400MG ER	496	91	$77,113.12	$155.47	5.45
CARBAMAZEPINE CHW 100MG	453	92	$20,414.12	$45.06	4.92
CARBAMAZEPINE TAB 200MG ER	403	107	$36,904.28	$91.57	3.77
CARBAMAZEPINE CAP 300MG ER	337	67	$41,731.07	$123.83	5.03
CARBAMAZEPINE TAB 100MG ER	233	75	$12,497.01	$53.64	3.11
CARBAMAZEPINE CAP 200MG ER	231	55	$31,728.82	$137.35	4.2
CARBAMAZEPINE SUS 100MG/5ML	157	18	$15,985.93	$101.82	8.72
CARBAMAZEPINE CAP 100MG ER	88	33	$7,999.38	$90.90	2.67
EPITOL TAB 200MG	69	45	$2,747.96	$39.83	1.53
TEGRETOL TAB 200MG	46	7	$21,870.29	$475.44	6.57
CARBATROL CAP 200MG	38	6	$7,932.58	$208.75	6.33
TEGRETOL-XR TAB 400MG	37	5	$15,510.16	$419.19	7.4
TEGRETOL-XR TAB 200MG	34	4	$12,316.80	$362.26	8.5
TEGRETOL SUS 100MG/5ML	23	3	$13,806.29	$600.27	7.67
CARBATROL CAP 300MG	13	2	$2,650.77	$203.91	6.5
TEGRETOL-XR TAB 100MG	2	1	$8.00	$4.00	2
SUBTOTAL	**5,919**	**1,356**	**$422,920.50**	**$71.45**	**4.37**
ZONISAMIDE PRODUCTS					
ZONISAMIDE CAP 100MG	3,576	555	$76,156.76	$21.30	6.44
ZONISAMIDE CAP 50MG	760	151	$12,083.21	$15.90	5.03
ZONISAMIDE CAP 25MG	452	109	$7,274.30	$16.09	4.15
SUBTOTAL	**4,788**	**815**	**$95,514.27**	**$19.95**	**5.87**
CLOBAZAM PRODUCTS					
CLOBAZAM SUS 2.5MG/ML	1,867	246	$261,014.28	$139.80	7.59
CLOBAZAM TAB 10MG	1,539	208	$45,606.73	$29.63	7.4
CLOBAZAM TAB 20MG	1,108	147	$54,648.38	$49.32	7.54
ONFI TAB 20MG	68	10	$298,922.43	$4,395.92	6.8
ONFI TAB 10MG	17	2	$14,300.79	$841.22	8.5
SYMPAZAN MIS 10MG	12	1	$21,369.72	$1,780.81	12
ONFI SUS 2.5MG/ML	8	2	$17,854.76	$2,231.85	4
SUBTOTAL	**4,619**	**616**	**$713,717.09**	**$154.52**	**7.5**
PHENYTOIN AND FOSPHENYTOIN PRODUCTS					
PHENYTOIN EX CAP 100MG	2,644	504	$81,820.11	$30.95	5.25
DILANTIN CAP 100MG	171	29	$40,763.55	$238.38	5.9
PHENYTOIN SUS 125MG/5ML	145	23	$4,554.46	$31.41	6.3
PHENYTOIN CHW 50MG	117	20	$4,680.28	$40.00	5.85
PHENYTOIN EX CAP 200MG	112	35	$12,255.83	$109.43	3.2
PHENYTOIN EX CAP 300MG	109	33	$8,673.07	$79.57	3.3

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DILANTIN CAP 30MG	73	10	$13,818.34	$189.29	7.3
DILANTIN CHW 50MG	19	3	$2,393.42	$125.97	6.33
FOSPHENYTOIN INJ 100MG/2ML	17	2	$1,977.17	$116.30	8.5
DILANTIN-125 SUS 125MG/5ML	8	1	$2,149.58	$268.70	8
SUBTOTAL	**3,415**	**660**	**$173,085.81**	**$50.68**	**5.17**
DIAZEPAM PRODUCTS					
DIAZEPAM GEL 10MG	957	667	$371,613.03	$388.31	1.43
VALTOCO NS 10MG	688	466	$655,426.64	$952.66	1.48
DIAZEPAM GEL 20MG	238	107	$110,826.49	$465.66	2.22
VALTOCO NS 15MG	200	150	$209,750.00	$1,048.75	1.33
DIASTAT ACDL GEL 5-10MG	170	142	$79,308.03	$466.52	1.2
VALTOCO NS 20MG	136	80	$119,330.37	$877.43	1.7
VALTOCO NS 5MG	108	71	$115,456.14	$1,069.04	1.52
DIAZEPAM GEL 2.5MG	66	56	$24,125.74	$365.54	1.18
DIASTAT ACDL GEL 12.5-20MG	58	34	$28,340.07	$488.62	1.71
DIASTAT PED GEL 2.5MG	14	14	$5,481.98	$391.57	1
SUBTOTAL	**2,635**	**1,787**	**$1,719,658.49**	**$652.62**	**1.47**
PHENOBARBITAL PRODUCTS					
PHENOBARBITAL SOL 20MG/5ML	536	96	$23,129.83	$43.15	5.58
PHENOBARBITAL TAB 64.8MG	454	57	$14,933.16	$32.89	7.96
PHENOBARBITAL TAB 32.4MG	326	45	$10,606.52	$32.54	7.24
PHENOBARBITAL TAB 97.2MG	158	20	$5,468.34	$34.61	7.9
PHENOBARBITAL ELX 20MG/5ML	154	62	$5,772.05	$37.48	2.48
PHENOBARBITAL TAB 30MG	114	22	$2,757.93	$24.19	5.18
PHENOBARBITAL TAB 16.2MG	87	11	$2,167.95	$24.92	7.91
PHENOBARBITAL TAB 60MG	82	14	$2,193.07	$26.74	5.86
PHENOBARBITAL TAB 100MG	52	7	$1,429.28	$27.49	7.43
PHENOBARBITAL TAB 15MG	10	4	$148.02	$14.80	2.5
SUBTOTAL	**1,973**	**338**	**$68,606.15**	**$34.77**	**5.84**
CANNABIDIOL PRODUCTS					
EPIDIOLEX SOL 100MG/ML	1,739	220	$4,168,630.32	$2,397.14	7.9
SUBTOTAL	**1,739**	**220**	**$4,168,630.32**	**$2,397.14**	**7.9**
ETHOSUXAMIDE PRODUCTS					
ETHOSUXIMIDE CAP 250MG	1,020	148	$62,617.74	$61.39	6.89
ETHOSUXIMIDE SOL 250MG/5ML	543	96	$28,407.03	$52.31	5.66
SUBTOTAL	**1,563**	**244**	**$91,024.77**	**$58.24**	**6.41**
BRIVARACETAM PRODUCTS					
BRIVIACT TAB 100MG	655	94	$821,564.24	$1,254.30	6.97
BRIVIACT TAB 50MG	374	71	$453,004.94	$1,211.24	5.27
BRIVIACT SOL 10MG/ML	166	23	$210,774.35	$1,269.73	7.22
BRIVIACT TAB 25MG	54	13	$71,563.92	$1,325.26	4.15
BRIVIACT TAB 75MG	54	11	$70,634.04	$1,308.04	4.91
BRIVIACT TAB 10MG	2	1	$6,096.47	$3,048.24	2

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**1,305**	**213**	**$1,633,637.96**	**$1,251.83**	**6.13**
PRIMIDONE PRODUCTS					
PRIMIDONE TAB 50MG	871	214	$16,434.36	$18.87	4.07
PRIMIDONE TAB 250MG	261	40	$6,395.68	$24.50	6.53
MYSOLINE TAB 250MG	18	2	$96,042.14	$5,335.67	9
SUBTOTAL	**1,150**	**256**	**$118,872.18**	**$103.37**	**4.49**
ACETAZOLAMIDE PRODUCTS					
ACETAZOLAMIDE TAB 250MG	572	180	$17,619.48	$30.80	3.18
ACETAZOLAMIDE CAP 500MG ER	425	151	$15,634.98	$36.79	2.81
ACETAZOLAMIDE TAB 125MG	81	34	$1,875.10	$23.15	2.38
ACETAZOLAMIDE INJ 500MG	1	1	$118.51	$118.51	1
SUBTOTAL	**1,079**	**366**	**$35,248.07**	**$32.67**	**2.95**
CENOBAMATE PRODUCTS					
XCOPRI TAB 150MG	220	40	$306,367.36	$1,392.58	5.5
XCOPRI TAB 100MG	208	58	$188,314.51	$905.36	3.59
XCOPRI TAB 50MG	96	35	$93,141.95	$970.23	2.74
XCOPRI TAB 200MG	84	25	$85,193.86	$1,014.21	3.36
XCOPRI PAK 100-150MG	43	10	$39,662.75	$922.39	4.3
XCOPRI PAK 50-100MG	34	32	$34,733.32	$1,021.57	1.06
XCOPRI PAK 12.5-25MG	32	32	$3,214.08	$100.44	1
XCOPRI PAK 150-200MG	24	5	$50,462.08	$2,102.59	4.8
XCOPRI PAK 150-200MG	4	4	$4,220.72	$1,055.18	1
SUBTOTAL	**745**	**241**	**$805,310.63**	**$1,080.95**	**3.09**
PERAMPANEL PRODUCTS					
FYCOMPA SUS 0.5MG/ML	221	37	$262,680.66	$1,188.60	5.97
FYCOMPA TAB 8MG	116	21	$100,466.93	$866.09	5.52
FYCOMPA TAB 4MG	102	30	$104,766.11	$1,027.12	3.4
FYCOMPA TAB 6MG	101	18	$116,541.55	$1,153.88	5.61
FYCOMPA TAB 10MG	73	10	$80,949.16	$1,108.89	7.3
FYCOMPA TAB 12MG	72	9	$73,206.09	$1,016.75	8
FYCOMPA TAB 2MG	57	18	$33,295.25	$584.13	3.17
SUBTOTAL	**742**	**143**	**$771,905.75**	**$1,040.30**	**5.19**
MIDAZOLAM PRODUCTS					
NAYZILAM SPR 5MG	584	337	$528,239.78	$904.52	1.73
SUBTOTAL	**584**	**337**	**$528,239.78**	**$904.52**	**1.73**
RUFINAMIDE PRODUCTS					
BANZEL TAB 400MG	198	24	$815,497.15	$4,118.67	8.25
RUFINAMIDE SUS 40MG/ML	151	20	$215,464.93	$1,426.92	7.55
RUFINAMIDE TAB 400MG	82	20	$81,040.65	$988.30	4.1
BANZEL SUS 40MG/ML	80	12	$178,055.87	$2,225.70	6.67
BANZEL TAB 200MG	29	3	$25,120.84	$866.24	9.67
RUFINAMIDE TAB 200MG	12	2	$10,251.06	$854.26	6
SUBTOTAL	**552**	**81**	**$1,325,430.50**	**$2,401.14**	**6.81**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
FELBAMATE PRODUCTS					
FELBAMATE TAB 600MG	165	17	$28,041.86	$169.95	9.71
FELBAMATE SUS 600MG/5ML	90	10	$35,415.09	$393.50	9
FELBAMATE TAB 400MG	45	6	$4,457.74	$99.06	7.5
FELBATOL TAB 400MG	14	2	$24,347.16	$1,739.08	7
FELBATOL TAB 600MG	11	2	$23,492.40	$2,135.67	5.5
SUBTOTAL	**325**	**37**	**$115,754.25**	**$356.17**	**8.78**
VIGABATRIN PRODUCTS					
SABRIL POW 500MG	188	22	$4,329,916.62	$23,031.47	8.55
VIGABATRIN PAK 500MG	23	5	$86,263.65	$3,750.59	4.6
VIGADRONE POW 500MG	12	1	$45,259.12	$3,771.59	12
VIGABATRIN TAB 500MG	11	1	$53,082.56	$4,825.69	11
SABRIL TAB 500MG	9	3	$79,226.42	$8,802.94	3
SUBTOTAL	**243**	**32**	**$4,593,748.37**	**$18,904.31**	**7.59**
ESLICARBAZEPINE PRODUCTS					
APTIOM TAB 600MG	89	11	$149,859.32	$1,683.81	8.09
APTIOM TAB 800MG	76	11	$117,578.91	$1,547.09	6.91
APTIOM TAB 400MG	26	4	$35,809.73	$1,377.30	6.5
APTIOM TAB 200MG	4	2	$11,199.36	$2,799.84	2
SUBTOTAL	**195**	**28**	**$314,447.32**	**$1,612.55**	**6.96**
TIAGABINE PRODUCTS					
TIAGABINE TAB 4MG	68	9	$22,644.04	$333.00	7.56
TIAGABINE TAB 2MG	22	2	$5,373.03	$244.23	11
TIAGABINE TAB 12MG	13	1	$2,671.01	$205.46	13
TIAGABINE TAB 16MG	6	1	$1,429.05	$238.18	6
SUBTOTAL	**109**	**13**	**$32,117.13**	**$294.65**	**8.38**
FENFLURAMINE PRODUCTS					
FINTEPLA SOL 2.2MG/ML	70	11	$414,181.82	$5,916.88	6.36
SUBTOTAL	**70**	**11**	**$414,181.82**	**$5,916.88**	**6.36**
METHSUXIMIDE PRODUCTS					
CELONTIN CAP 300MG	23	3	$5,176.42	$225.06	7.67
SUBTOTAL	**23**	**3**	**$5,176.42**	**$225.06**	**7.67**
STIRIPENTOL PRODUCTS					
DIACOMIT CAP 250MG	14	1	$63,155.74	$4,511.12	14
DIACOMIT PAK 250MG	1	1	$1,511.41	$1,511.41	1
SUBTOTAL	**15**	**2**	**$64,667.15**	**$4,311.14**	**7.5**
TOTAL	**409,613**	**68,516***	**$33,620,700.99**	**$82.08**	**5.98**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACDL = AcuDial; CAP = capsule; CHW = chewable; DR = delayed-release; ELX = elixir; ER = extended-release; EX = extended; HR = hour; INJ = injection; NS = nasal spray; ODT = orally disintegrating tablet; PAK = pack; PED = pediatric; POW = powder; SOL = solution; SPR = spray or sprinkle; SUS = suspension; TAB = tablet; XR = extended-release
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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Appendix R

Fiscal Year 2022 Annual Review of Pulmonary Hypertension Medications and 30-Day Notice to Prior Authorize Tadliq® (Tadalafil Oral Suspension) and Tyvaso DPI® (Treprostinil Powder for Inhalation)

Oklahoma Health Care Authority
February 2023

Current Prior Authorization Criteria

Adcirca® (Tadalafil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral tablets must be provided; or
4. A clinical exception for use as initial combination therapy with Letairis® (ambrisentan) applies; and
5. A quantity limit of 60 tablets per 30 days will apply.

Adempas® (Riociguat) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension or chronic thromboembolic pulmonary hypertension (CTEPH); and
    a. Members with a diagnosis of pulmonary arterial hypertension must have previous failed trials of at least 1 medication in each of the following categories:
        i. Adcirca® (tadalafil) or Revatio® (sildenafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. Members with a diagnosis of CTEPH must currently be on anticoagulation therapy; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. Member must not be on any concurrent phosphodiesterase (PDE) inhibitor therapy; and
4. Member must not have a diagnosis of pulmonary hypertension associated with idiopathic interstitial pneumonia (PH-IIP); and
5. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Adempas® Risk Evaluation and Mitigation Strategy (REMS) program; and
6. A quantity limit of 90 tablets per 30 days will apply.

Generic Ambrisentan (Letairis®) Approval Criteria:

1. A patient-specific, clinically significant reason the member cannot use the brand formulation must be provided.

Opsumit® (Macitentan) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. Female members and all health care professionals (prescribers and dispensing pharmacies) must be enrolled in the Opsumit® Risk Evaluation and Mitigation Strategy (REMS) program; and
5. A quantity limit of 30 tablets per 30 days will apply.

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
   a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Tablets) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A quantity limit of 90 tablets per 30 days will apply.

Revatio® (Sildenafil Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. An age restriction will apply. The oral suspension formulation may be approvable for members 6 years of age and younger. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member is not able to use the oral tablet formulation; and
4. A quantity limit of 224mL (2 bottles) per 30 days will apply.

Uptravi® (Selexipag) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must be 18 years of age or older; and
3. Member must have previous failed trials of at least 1 medication in each of the following categories (alone or in combination):
   a. Adcirca® (tadalafil), Adempas® (riociguat), or Revatio® (sildenafil); and
   b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
   c. Orenitram® (treprostinil); and

4. Medical supervision by a pulmonary specialist or cardiologist; and
5. A quantity limit of 2 tablets daily will apply for all strengths with an upper dose limit of 1,600mcg twice daily.

Utilization of Pulmonary Hypertension Medications: Fiscal Year 2022

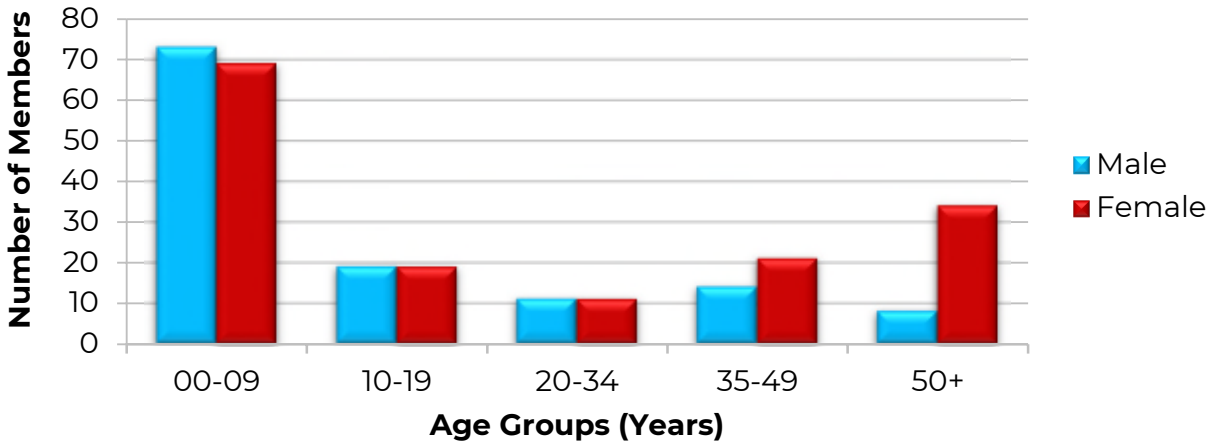
Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	243	1,818	$7,395,803.33	$4,068.10	$131.61	142,072	56,194
2022	279	1,974	$9,166,892.95	$4,643.82	$147.36	151,612	62,207
% Change	**14.80%**	**8.60%**	**23.90%**	**14.20%**	**12.00%**	**6.70%**	**10.70%**
Change	**36**	**156**	**$1,771,089.62**	**$575.72**	**$15.75**	**9,540**	**6,013**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

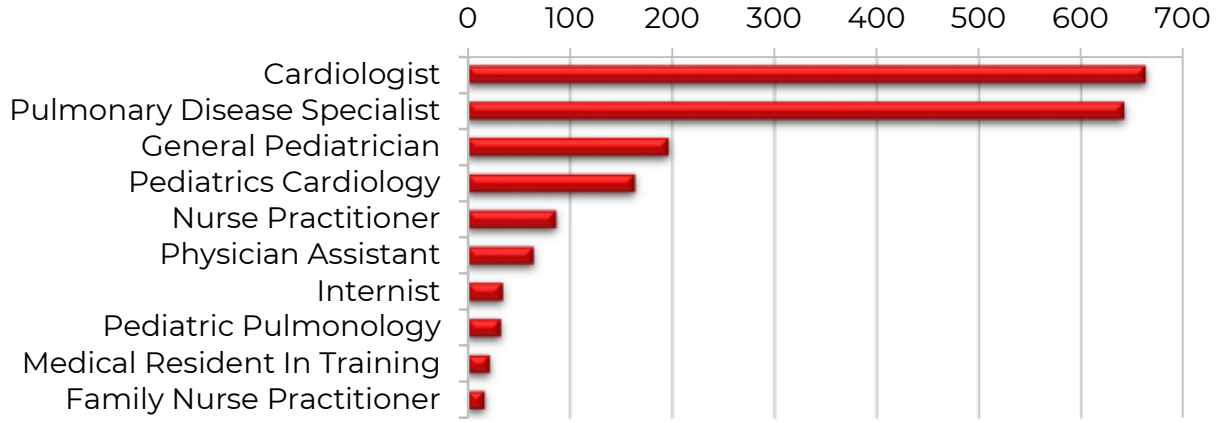
- Aggregate drug rebates collected during fiscal year 2022 for pulmonary hypertension medications: $5,164,861.31.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Pulmonary Hypertension 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.

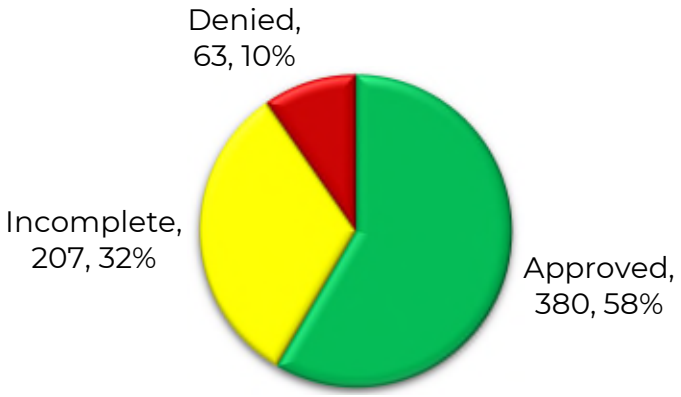
Top Prescriber Specialties of Pulmonary Hypertension Medications by Number of Claims



Prior Authorization of Pulmonary Hypertension Medications

There were 650 prior authorization requests submitted for pulmonary hypertension medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Veletri® (epoprostenol injection): March 2027
- Tracleer® (bosentan tablet for oral suspension): December 2027
- Tyvaso® (treprostinil inhalation solution): December 2028
- Remodulin® (treprostinil injection): March 2029
- Opsumit® (macitentan tablet): April 2029
- Orenitram® (treprostinil tablet): August 2031
- Letairis® (ambrisentan tablet): October 2031
- Adempas® (riociguat tablet): February 2034
- Tyvaso DPI® (treprostinil powder for inhalation): April 2035

- Uptravi® (selexipag tablet): December 2036
- Tadliq® (tadalafil oral suspension): December 2038

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

- **May 2022:** The FDA approved Tyvaso DPI® (treprostinil powder for inhalation), a prostacyclin mimetic, for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) to improve exercise ability. Tyvaso DPI® contains a new formulation of treprostinil and is available as single-dose cartridges containing dry powder for inhalation in 16mcg, 32mcg, 48mcg, and 64mcg strengths. The FDA previously approved Tyvaso® (treprostinil) inhalation solution for the treatment of PAH in 2009 and for the treatment of PH-ILD in 2021. Tyvaso DPI® is administered as 4 separate treatment sessions (approximately 4 hours apart) every day during waking hours. The recommended initial dose is 16mcg per treatment session, and the dosage should be increased in 16mcg increments at 1- to 2-week intervals, as tolerated, up to a target maintenance dose of 48mcg to 64mcg per treatment session, 4 times daily. The FDA approval of Tyvaso DPI® was based on safety and efficacy data from patients treated with Tyvaso® inhalation solution and supported by an additional open-label study in 51 patients with PAH who were receiving stable doses of Tyvaso® inhalation solution and were transitioned to Tyvaso DPI®. The study demonstrated the safety and tolerability of the new dry powder formulation of treprostinil, with comparable systemic exposure between the 2 formulations. The Wholesale Acquisition Cost (WAC) of Tyvaso DPI® is $186.66 per cartridge for either the 48mcg or 64mcg cartridge, resulting in an estimated cost of $20,905.92 per 28 days and $271,776.96 per year based on the recommended target maintenance dose of 48mcg or 64mcg administered 4 times daily.
- **June 2022:** The FDA approved Tadliq® (tadalafil oral suspension), a phosphodiesterase-5 (PDE-5) inhibitor, for the treatment of PAH to improve exercise ability. Tadliq® is the only FDA approved liquid formulation of tadalafil and is available in a 20mg/5mL peppermint flavored oral suspension in 150mL bottles. The recommended dose is 40mg (10mL) once daily. The WAC of Tadliq® is $12.63 per milliliter, resulting in an estimated cost of $3,789 per 30 days and $45,468 per year based on the recommended dose of 40mg (10mL) once daily.

Recommendations

The College of Pharmacy recommends the prior authorization of Tadliq® (tadalafil oral suspension) and Tyvaso DPI® (treprostinil) with the following criteria (shown in red):

Tadliq® (Tadalafil Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. A patient-specific, clinically significant reason why the member cannot use generic sildenafil oral suspension must be provided; and
4. An age restriction will apply. Members 7 years of age and older must have a patient-specific, clinically significant reason why the member cannot use generic tadalafil 20mg oral tablets, even when the tablets are crushed; and
5. A quantity limit of 300mL per 30 days (2 bottles) will apply.

Tyvaso DPI® (Treprostinil Powder for Inhalation) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Pulmonary arterial hypertension (PAH); or
    b. Pulmonary hypertension associated with interstitial lung disease (PH-ILD); and
        i. Diagnosis of PH-ILD must be confirmed by right-sided heart catheterization; and
2. Medical supervision by a pulmonary specialist or cardiologist; and
3. For a diagnosis of PAH:
    a. Member must have previous failed trials of at least 1 of each of the following categories:
        i. Revatio® (sildenafil) or Adcirca® (tadalafil); and
        ii. Letairis® (ambrisentan) or Tracleer® (bosentan); and
    b. A patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution) and Remodulin® (treprostinil injection), which are available without a prior authorization, are not appropriate for the member must be provided; and
4. For a diagnosis of PH-ILD, a patient-specific, clinically significant reason why Tyvaso® (treprostinil inhalation solution), which is available without a prior authorization, is not appropriate for the member must be provided.

Additionally, the College of Pharmacy recommends updating the approval criteria for Orenitram® (treprostinil) to be more consistent with FDA approved dosing and clinical practice (changes shown in red):

Orenitram® (Treprostinil) Approval Criteria:

1. An FDA approved diagnosis of pulmonary arterial hypertension; and
2. Member must have previous failed trials of at least 1 medication in each of the following categories:
    a. Adcirca® (tadalafil) or Revatio® (sildenafil); and
    b. Letairis® (ambrisentan) or Tracleer® (bosentan); and
3. Medical supervision by a pulmonary specialist or cardiologist; and
4. A quantity limit of ~~90~~ 180 tablets per 30 days will apply.

Lastly, the College of Pharmacy recommends removing the approval criteria for generic ambrisentan, based on net cost (changes shown in red):

~~**Generic Ambrisentan (Letairis®) Approval Criteria:**~~

~~1. A patient-specific, clinically significant reason the member cannot use the brand formulation must be provided.~~

Utilization Details of Pulmonary Hypertension Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PHOSPHODIESTERASE-5 (PDE-5) INHIBITORS						
TADALAFIL TAB 20MG	684	131	$19,726.35	$28.84	5.22	0.22%
SILDENAFIL TAB 20MG	414	80	$7,403.54	$17.88	5.18	0.08%
SILDENAFIL SUS 10MG/ML	153	40	$255,651.97	$1,670.93	3.83	2.79%
SUBTOTAL	**1,251**	**251**	**$282,781.86**	**$226.04**	**4.98**	**3.08%**
ENDOTHELIN RECEPTOR ANTAGONISTS (ERA)						
LETAIRIS TAB 10MG	163	31	$1,790,359.96	$10,983.80	5.26	19.53%
TRACLEER TAB 32MG	89	18	$685,048.26	$7,697.17	4.94	7.47%
OPSUMIT TAB 10MG	76	16	$763,689.71	$10,048.55	4.75	8.33%
LETAIRIS TAB 5MG	62	21	$779,375.03	$12,570.57	2.95	8.50%
BOSENTAN TAB 62.5MG	42	5	$59,152.78	$1,408.40	8.4	0.65%
BOSENTAN TAB 125MG	10	1	$30,229.70	$3,022.97	10	0.33%
SUBTOTAL	**442**	**92**	**$4,107,855.44**	**$9,293.79**	**4.8**	**44.81%**
PROSTACYCLIN VASODILATORS						
TYVASO REFILL SOL 0.6MG/ML	39	13	$787,672.32	$20,196.73	3	8.59%
ORENITRAM TAB 5MG	32	6	$1,028,289.49	$32,134.05	5.33	11.22%
ORENITRAM TAB 1MG	23	8	$389,033.44	$16,914.50	2.88	4.24%
UPTRAVI TAB 200MCG	22	5	$570,582.34	$25,935.56	4.4	6.22%
REMODULIN INJ 1MG/ML	15	1	$23,516.35	$1,567.76	15	0.26%
UPTRAVI TAB 800MCG	13	2	$256,460.77	$19,727.75	6.5	2.80%
UPTRAVI TAB 1600MCG	11	3	$216,921.36	$19,720.12	3.67	2.37%
UPTRAVI TAB 1400MCG	11	1	$216,881.36	$19,716.49	11	2.37%
UPTRAVI TAB 1000MCG	10	1	$197,637.05	$19,763.71	10	2.16%
ORENITRAM TAB 0.125MG	10	5	$12,987.21	$1,298.72	2	0.14%
TYVASO START SOL 0.6MG/ML	9	9	$168,645.92	$18,738.44	1	1.84%
REMODULIN INJ 10MG/ML	8	1	$93,354.48	$11,669.31	8	1.02%
REMODULIN INJ 2.5MG/ML	8	3	$74,524.23	$9,315.53	2.67	0.81%
REMODULIN INJ 5MG/ML	7	3	$75,336.77	$10,762.40	2.33	0.82%
VELETRI INJ 1.5MG	5	1	$17,013.13	$3,402.63	5	0.19%
ORENITRAM TAB 0.25MG	4	1	$14,312.32	$3,578.08	4	0.16%
TREPROSTINIL INJ 5MG/ML	4	1	$45,689.00	$11,422.25	4	0.50%
TREPROSTINIL INJ 2.5MG/ML	2	1	$11,482.70	$5,741.35	2	0.13%
UPTRAVI TAB 400MCG	1	1	$20,287.10	$20,287.10	1	0.22%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
UPTRAVI PACK TAB 200/800MCG	1	1	$28,873.79	$28,873.79	1	0.31%
SUBTOTAL	**235**	**67**	**$4,249,501.13**	**$18,082.98**	**3.51**	**46.36%**
SOLUBLE GUANYLATE CYCLASE (sGC) STIMULATORS						
ADEMPAS TAB 2.5MG	34	6	$379,606.20	$11,164.89	5.67	4.14%
ADEMPAS TAB 2MG	5	2	$61,605.05	$12,321.01	2.5	0.67%
ADEMPAS TAB 0.5MG	3	3	$36,265.63	$12,088.54	1	0.40%
ADEMPAS TAB 1MG	2	2	$24,638.82	$12,319.41	1	0.27%
ADEMPAS TAB 1.5MG	2	2	$24,638.82	$12,319.41	1	0.27%
SUBTOTAL	**46**	**15**	**$526,754.52**	**$11,451.19**	**3.07**	**5.75%**
TOTAL	**1,974**	**279***	**$9,166,892.95**	**$4,643.82**	**7.08**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 01/2023. Last accessed 01/12/2023.
[2] United Therapeutics Corporation. United Therapeutics Announces FDA Approval of Tyvaso DPI®. Available online at: https://ir.unither.com/news/press-releases/press-release-details/2022/United-Therapeutics-Announces-FDA-Approval-of-Tyvaso-DPI/default.aspx. Issued 05/24/2022. Last accessed 01/18/2023.
[3] Tyvaso DPI® (Treprostinil) Prescribing Information. United Therapeutics Corporation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214324s000lbl.pdf. Last revised 05/2022. Last accessed 01/18/2023.
[4] Spikes LA, Bajwa AA, Burger CD, et al. BREEZE: Open-Label Clinical Study to Evaluate the Safety and Tolerability of Treprostinil Inhalation Powder as Tyvaso DPI® in Patients with Pulmonary Arterial Hypertension. *Pulm Circ* 2022; 12(2):e12063.
[5] Tadliq® (Tadalafil) Prescribing Information. CMP Pharma, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214522s000lbl.pdf. Last revised 06/2022. Last accessed 01/18/2023.
[6] CMP Pharma, Inc. CMP Pharma, Inc Announces that Tadliq®, the First and Only FDA-approved Liquid Suspension of Tadalafil, is Now Available. Available online at: https://www.prnewswire.com/news-releases/cmp-pharma-inc-announces-that-tadliq-the-first-and-only-fda-approved-liquid-suspension-of-tadalafil-is-now-available-301656771.html. Issued 10/24/2022. Last accessed 01/18/2023.

Appendix S

Fiscal Year 2022 Annual Review of Dojolvi® (Triheptanoin)

Oklahoma Health Care Authority
February 2023

Current Prior Authorization Criteria

Dojolvi® (Triheptanoin) Approval Criteria:

1. An FDA approved diagnosis of molecularly confirmed long-chain fatty acid oxidation disorder (LC-FAOD); and
2. Molecular testing confirms 1 of the following types of LC-FAOD:
    a. Carnitine-acylcarnitine translocase (CACT) deficiency; or
    b. Carnitine palmitoyltransferase I (CPT I) deficiency; or
    c. Carnitine palmitoyltransferase II (CPT II) deficiency; or
    d. Long-chain 3-hydroxyacyl-CoA dehydrogenase (LCHAD) deficiency; or
    e. Trifunctional protein (TFP) deficiency; or
    f. Very long-chain acyl-CoA dehydrogenase (VLCAD) deficiency; and
3. Prescriber must verify member has a history of at least 1 significant or recurrent manifestation of LC-FAOD (e.g., cardiomyopathy, rhabdomyolysis, hypoglycemia); and
4. Member must have tried and failed dietary management with an alternate medium chain triglyceride (MCT) product (e.g., MCT oil) or a patient-specific, clinically significant reason why dietary management with an alternate MCT product is not appropriate for the member must be provided; and
5. Dojolvi® will not be approved for concomitant use with another MCT product (other MCT products must be discontinued prior to the first dose of Dojolvi®); and
6. Member must not be taking a pancreatic lipase inhibitor concomitantly with Dojolvi®; and
7. Prescriber must verify the member does not have pancreatic insufficiency; and
8. Prescriber must verify that member or member's caregiver has been counseled on the proper storage, preparation, and administration of Dojolvi®, including specific considerations for use in a feeding tube, if applicable; and
9. Dojolvi® must be prescribed by a geneticist or other specialist with expertise in the treatment of LC-FAOD; and
10. Prescriber must verify the member is under the care of a clinical specialist knowledgeable in appropriate disease-related dietary

management based on member's specific LC-FAOD and current nutritional recommendations; and

11. The member's daily caloric intake (DCI) must be provided (in kcal) on the prior authorization request to verify appropriate dosing based on package labeling; and
12. Initial approvals will be for the duration of 3 months. After 3 months of treatment, compliance will be required, and the prescriber must verify the member has had a positive response to and is tolerating treatment with Dojolvi®. Additionally, for members who switched from another MCT product due to adverse effects, the prescriber must verify the member has experienced fewer adverse effects with Dojolvi®; and
13. Quantity limits according to package labeling will apply, with the maximum approvable dosing regimen based on a target daily dosage of Dojolvi® up to 35% of the member's total DCI.

Utilization of Dojolvi® (Triheptanoin): Fiscal Year 2022

Fiscal Year 2022 Utilization

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	2	4	$63,165.71	$15,791.43	$535.30	6,108	118

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
Please note: There was no SoonerCare utilization of Dojolvi® (triheptanoin) during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

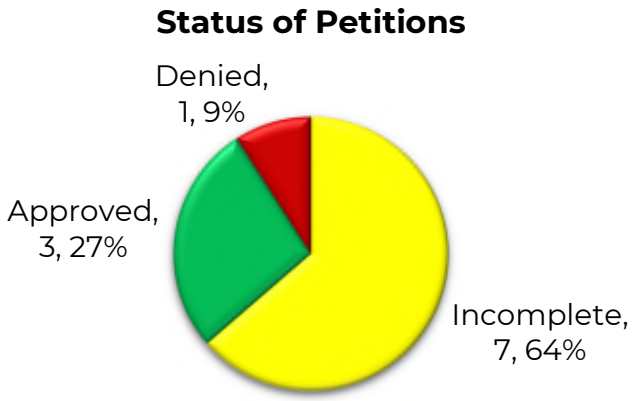
Demographics of Members Utilizing Dojolvi® (Triheptanoin)

- Due to the limited number of members utilizing Dojolvi® (triheptanoin) during fiscal year 2022, detailed demographic information could not be provided.

Top Prescriber Specialties of Dojolvi® (Triheptanoin) by Number of Claims

Prior Authorization of Dojolvi® (Triheptanoin)

There were 11 prior authorization requests submitted for 3 unique members for Dojolvi® (triheptanoin) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Dojolvi® (triheptanoin): October 2025

Recommendations

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

Utilization Details of Dojolvi® (Triheptanoin): Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DOJOLVI LIQ 100%	4	2	$63,165.71	$15,791.43	2	100%
TOTAL	**4**	**2***	**$63,165.71**	**$15,791.43**	**2**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 01/2023. Last accessed 01/04/2023.

Appendix T

Fiscal Year 2022 Annual Review of Topical Acne, Psoriasis, and Rosacea Products and 30-Day Notice to Prior Authorize Brimonidine 0.33% Topical Gel (Generic Mirvaso®), Vtama® (Tapinarof), and Zoryve™ (Roflumilast)

Oklahoma Health Care Authority
February 2023

Current Prior Authorization Criteria

Aczone® (Dapsone Gel) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris; and
2. For Aczone® 7.5% gel, the member must be 9 years of age or older; and
3. Aczone® will not be covered for members older than 20 years of age; and
4. A previous trial of benzoyl peroxide or a patient-specific, clinically significant reason why benzoyl peroxide is not appropriate for the member must be provided; and
5. A previous trial of a topical antibiotic, such as clindamycin or erythromycin, or a patient-specific, clinically significant reason why a topical antibiotic is not appropriate for the member must be provided.

Amzeeq® (Minocycline 4% Topical Foam) Approval Criteria:

1. An FDA approved indication of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and
3. Amzeeq® will not be covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution, clindamycin 1% topical solution, benzoyl peroxide, brand name Tazorac®, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
5. A quantity limit of 30 grams per 30 days will apply.

Clindagel® (Clindamycin 1% Topical Gel) and Evoclin® (Clindamycin 1% Topical Foam) Approval Criteria:

1. Member must have failed a trial of a different formulation of topical clindamycin such as lotion, solution, swabs, or the preferred generic clindamycin gel (generic for Cleocin T®; this generic medication is not interchangeable with Clindagel®); and

2. Member must be 20 years of age or younger.

Duobrii® (Halobetasol Propionate/Tazarotene 0.01%/0.045% Lotion) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis in adults; and
2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
3. A patient-specific, clinically significant reason why they member cannot use individual components of tazarotene and a topical corticosteroid separately must be provided; and
4. A quantity limit of 100 grams per 30 days will apply.

Erythromycin 2% Swabs and 2% Topical Gel Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use erythromycin 2% topical solution must be provided; and
2. Member must be 20 years of age or younger.

MetroGel® (Metronidazole 1% Gel) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metronidazole 0.75% gel, which is available without prior authorization for members 20 years of age and younger, must be provided; and
2. MetroGel® will not be covered for members older than 20 years of age.

Noritate® (Metronidazole 1% Cream) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use metronidazole 0.75% cream, which is available without prior authorization for members 20 years of age or younger, must be provided; and
2. Noritate® will not be covered for members older than 20 years of age.

Sorilux® (Calcipotriene 0.005% Foam) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis of the scalp and body in members 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use the generic formulations of topical calcipotriene, which are available without a prior authorization, must be provided; and
3. A quantity limit of 120 grams per 30 days will apply.

Tazorac® (Tazarotene Cream and Gel) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris or plaque psoriasis; and
2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
3. For the diagnosis of acne vulgaris, the following must be met:
    a. Member must be 20 years of age or younger; and

b. Tazorac® 0.1% cream, Tazorac® 0.05% gel, Tazorac® 0.1% gel, and tazarotene 0.1% cream will not require prior authorization for members 20 years of age or younger; and

4. A quantity limit of 100 grams per 30 days will apply.

Winlevi® (Clascoterone 1% Cream) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris; and
2. Member must be 12 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution, clindamycin 1% solution, benzoyl peroxide, preferred tazarotene formulations, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
4. A quantity limit of 60 grams per 30 days will apply.

Zilxi® (Minocycline 1.5% Topical Foam) Approval Criteria:

1. An FDA approved diagnosis of inflammatory lesions of rosacea in adults; and
2. Member must be 18 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot utilize clindamycin topical solution (generic), metronidazole topical gel and cream 0.75%, erythromycin topical 2% solution, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
4. A quantity limit of 30 grams per 30 days will apply.

Utilization of Topical Acne, Psoriasis, and Rosacea Products: Fiscal Year 2022

Comparison of Fiscal Years

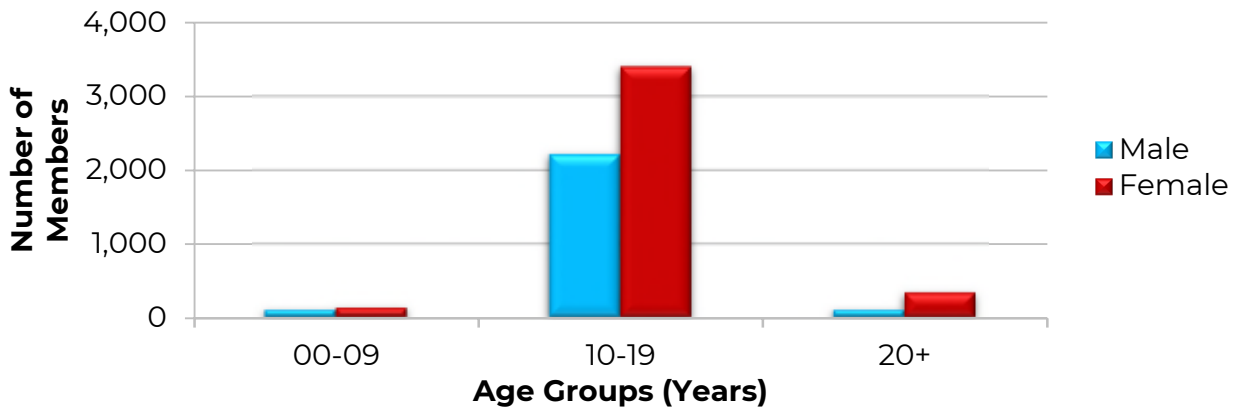
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	6,250	12,538	$1,430,218.03	$114.07	$4.40	642,348	325,335
2022	6,252	12,501	$814,561.18	$65.16	$2.48	654,807	328,747
% Change	**0.0%**	**-0.3%**	**-43.0%**	**-42.9%**	**-43.6%**	**1.9%**	**1.0%**
Change	**2**	**-37**	**-$615,656.85**	**-$48.91**	**-$1.92**	**12,459**	**3,412**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

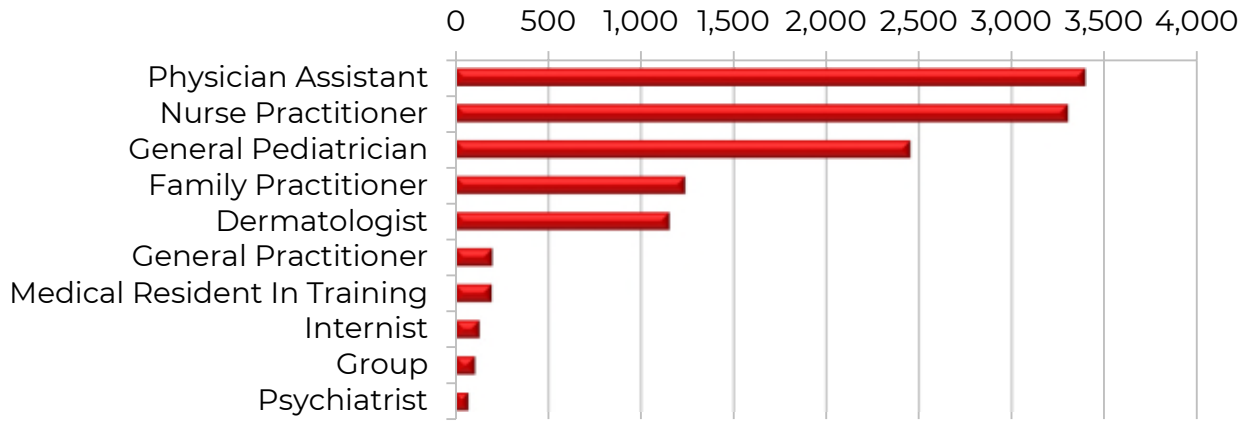
- Aggregate drug rebates collected during fiscal year 2022 for topical acne, psoriasis, and rosacea products: $117,711.00.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[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 Topical Acne, Psoriasis, and Rosacea Products



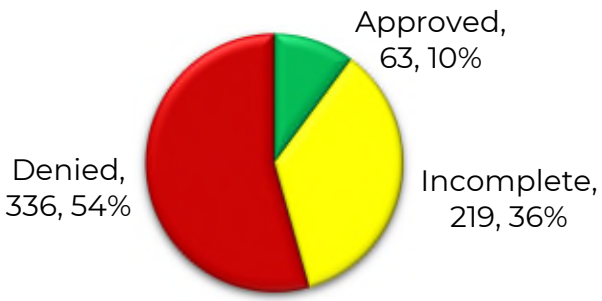
Top Prescriber Specialties of Topical Acne, Psoriasis, and Rosacea Products by Number of Claims



Prior Authorization of Topical Acne, Psoriasis, and Rosacea Products

There were 618 prior authorization requests submitted for topical acne, psoriasis, and rosacea products during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Evoclin® (clindamycin 1% foam): February 2024
- Sorilux® (calcipotriene 0.005% foam): May 2028
- Winlevi® (clascoterone 1% cream): July 2030
- Zilxi® (minocycline 1.5% foam): October 2030
- Mirvaso® (brimonidine 0.33% gel): June 2031
- Aczone® (dapsone 7.5% gel): November 2033
- Duobrii® (halobetasol propionate/tazarotene 0.01%/0.045% lotion): June 2036
- Amzeeq® (minocycline 4% foam): September 2037

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

- **May 2022:** The FDA approved Vtama® (tapinarof) 1% cream for the topical treatment of plaque psoriasis in adults. Vtama® is an aryl hydrocarbon receptor agonist (AhR) and is the first and only FDA approved steroid free topical medication in its class.
- **July 2022:** The FDA approved Zoryve™ (roflumilast) 0.3% cream for the treatment of plaque psoriasis, including intertriginous area in patients 12 years of age or older. This is the first and only topical phosodiesterase-4 (PDE-4) inhibitor approved for the treatment of plaque psoriasis. Zoryve™ provides rapid clearance of psoriasis plaques and reduces itch in all affected areas of the body.
- **September 2022:** The FDA approved Cosette Pharmaceuticals Abbreviated New Drug Application (ANDA) for the first generic versions of Tazorac® (tazarotene 0.05% and 0.1% gel). Tazarotene® gel is indicated for the treatment of plaque psoriasis and acne vulgaris.

News:

- **January 2023:** Padagis Israel launched a generic version of Galderma's Mirvaso® (brimonidine 0.33% gel). Mirvaso® was FDA approved in 2013 as the first topical agent for the treatment of facial erythema of rosacea in adults 18 years of age or older.

Pipeline:

- **Roflumilast (ARQ-154):** ARQ-154 is a once daily roflumilast topical foam in development by Arcutis Biotherapeutics for the treatment of scalp and body psoriasis. The Phase 3 ARRECTOR study evaluating roflumilast foam in patients 12 years of age and older with scalp and body psoriasis was completed in October 2022. The study met it primary endpoints, with 67.3% of patients treated with ARQ-154 achieving Scalp-Investigator's Global Assessment (S-IGA) success and 46.5% achieving Body-IGA success. All secondary endpoints were met.

Arcutis plans to submit a new drug application (NDA) to the FDA for roflumilast topical foam in the first quarter of 2023.

Brimonidine 0.33% Topical Gel Product Summary[8]

Indication(s): Brimonidine is an alpha-adrenergic agonist indicated for the topical treatment of persistent (non-transient) facial erythema of rosacea in adults 18 years of age or older.

How Supplied: 0.33% gel containing 5mg of brimonidine tartrate per gram

Dosing and Administration:

- A pea-sized amount should be applied once daily to each of the 5 areas of the face (forehead, chin, nose, and each cheek) avoiding the eyes and lips.
- Hands should be washed immediately after applying brimonidine gel.
- Brimonidine gel is for topical use only and is not for oral, ophthalmic, or intravaginal use.

Mechanism of Action: Brimonidine is a selective alpha-2 adrenergic agonist. Topical application of brimonidine topical gel may reduce erythema through direct vasoconstriction.

Contraindication(s): Known hypersensitivity to any component of brimonidine topical gel

Warnings and Precautions:

- Potentiation of Vascular Insufficiency: Brimonidine topical gel should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, thrombangiitis obliterans, scleroderma, or Sjögren's syndrome.
- Severe Cardiovascular Disease: Alpha-2 adrenergic agonists can lower blood pressure. Brimonidine topical gel should be used with caution in patients with severe, unstable, or uncontrolled cardiovascular disease.
- Serious Adverse Reactions Following Ingestion of Brimonidine Topical Gel: Two young children of participants in a clinical study experienced serious adverse reactions following accidental ingestion of brimonidine topical gel. Adverse reactions experienced by 1 or both children included lethargy, respiratory distress with apneic episodes (requiring intubation), sinus bradycardia, confusion, psychomotor hyperactivity, and diaphoresis. Both children were hospitalized overnight and discharged the following day without sequelae. Brimonidine topical gel should be kept out of the reach of children.
- Systemic Adverse Reactions of Alpha-2 Adrenergic Agonists: Post marketing cases of bradycardia, hypotension (including orthostatic hypotension), and dizziness have been reported. Some cases required

hospitalization. Some cases involved application of brimonidine topical gel in unapproved dosing regimens and for unapproved indications, including the application of brimonidine topical gel following laser procedures. Applying brimonidine topical gel to irritated skin or open wounds should be avoided.

- Local Vasomotor Adverse Reactions:
  - Erythema: Some patients in the clinical studies discontinued use of brimonidine topical gel because of erythema and some reported a rebound phenomenon, where erythema was reported to return worse compared to the severity at baseline. Erythema appeared to resolve after discontinuation of brimonidine topical gel.
  - Flushing: Some patients in the clinical studies discontinued use of brimonidine topical gel because of flushing. Intermittent flushing occurred in some patients treated with brimonidine topical gel in the clinical studies. The onset of flushing relative to application of brimonidine topical gel varied, ranging from approximately 30 minutes to several hours.
  - Pallor and Excessive Whitening: From postmarketing reports, some patients have experienced pallor or excessive whitening at or outside the application site following treatment with brimonidine topical gel.
- Hypersensitivity: Allergic contact dermatitis was reported in the clinical studies for brimonidine topical gel. Postmarketing reports of adverse events with the use of brimonidine topical gel include angioedema, throat tightening, tongue swelling, and urticaria. Appropriate therapy should be instituted and brimonidine should be discontinued if clinically significant hypersensitivity reaction occurs.

Safety:

- Pregnancy: There are no adequate and well-controlled studies of brimonidine topical gel in pregnant women. In animal studies, brimonidine crossed the placenta and entered fetal circulation to a limited extent. Brimonidine topical gel should be used during pregnancy only if the potential benefits justify the potential risk to the fetus.
- Lactation: It is not known whether brimonidine is excreted in human milk, although in animal studies, brimonidine has been shown to be excreted in breast milk. Because of the potential for serious adverse reactions from brimonidine topical gel in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, considering the importance of the drug to the mother.
- Pediatrics: The safety and effectiveness of brimonidine topical gel have not been established in pediatric patients. Brimonidine topical gel should be kept out of reach of children. Serious adverse reactions were

experienced by 2 children of a patient in a clinical study who accidentally ingested brimonidine topical gel.
- Geriatrics: In clinical studies with brimonidine topical gel, there were 105 patients 65 years of age and older. No overall differences in safety or effectiveness were observed between patients 65 years of age and older and younger adult patients.

Adverse Reactions:
- The most common adverse reactions (incidence ≥1%) in patients treated with brimonidine topical gel include erythema, flushing, skin burning sensation, contact dermatitis, dermatitis, warm skin, paresthesia, acne, pain of skin, blurred vision, and nasal congestion.

Efficacy:
- Brimonidine topical gel was evaluated for the treatment of moderate-to-severe, persistent (non-transient) facial erythema of rosacea in 2 randomized, double-blind, vehicle-controlled clinical studies, which were identical in design. A total of 553 patients 18 years of age and older were treated once daily for 4 weeks with either brimonidine topical gel or vehicle. Baseline disease severity was graded using a 5-point Clinical Erythema Assessment (CEA) scale and a 5-point Patient Self-Assessment (PSA) scale, on which patients scored either "moderate" or "severe" on both scales. The primary efficacy endpoint in both studies was 2-grade composite success, defined as the proportion of patients with a 2-grade improvement on both CEA and PSA measured at hours 3, 6, 9, and 12 on day 29. In study 1, 23% of patients treated with brimonidine topical gel showed a clinical improvement at hour 12 compared to 9% treated with vehicle. In study 2, 22% compared to 10% showed improvement at hour 12 on day 29.

Cost: The Wholesale Acquisition Cost (WAC) of brimonidine 0.33% topical gel is $17.35 per gram which results in a cost of $520.50 per 30 gram tube.

Vtama® (Tapinarof 1% Cream) Product Summary[9]

Indication(s): Tapinarof is an AhR agonist indicated for the topical treatment of plaque psoriasis in adults.

How Supplied: 1% topical cream containing 10mg of tapinarof per gram

Dosing and Administration:
- A thin layer should be applied to affected areas once daily.
- Vtama® cream is not for oral, ophthalmic, or intravaginal use.

Mechanism of Action: The specific mechanism by which Vtama® cream exerts its therapeutic action in plaque psoriasis is unknown.

Contraindication(s): None

Safety:

- Pregnancy: The available data of Vtama® cream use in pregnant women is insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.
- Lactation: No data is available regarding the presence of tapinarof in human milk, the effects of tapinarof on the breastfed infant, or on milk production. Tapinarof was detected in rat offspring following subcutaneous administration to pregnant female rats which suggests the tapinarof was transferred into the milk of lactating rates. When a drug is present in animal milk, it is likely that the drug will be present in human milk.
- Pediatrics: Safety and efficacy of Vtama® cream have not been established in pediatric patients with plaque psoriasis younger than 18 years of age.
- Geriatrics: Of the 683 patients exposed to Vtama® cream in the PSOARING 1 or PSOARING 2 clinical studies, 99 (14.5%) were 65 years of age and older, including 8 (1.2%) patients who were 75 years of age and older. No overall differences in efficacy, safety, or tolerability were observed between elderly patients and younger adult patients in clinical studies.

Adverse Reactions:

- The most common adverse reactions (incidence ≥1%) in patients treated with Vtama® cream were folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza.
- Two of the patients using Vtama® cream developed urticaria, and the adverse reactions that led to treatment discontinuation in >1% of the patients who received Vtama® were contact dermatitis (2.9%) and folliculitis (2.8%) in PSOARING 1 and 2.
- In addition to the adverse reactions reported in PSOARING 1 and PSOARING 2 clinical studies, urticaria (1.0%) and drug eruption (0.7%) were also reported in PSOARING 3.

Efficacy:

- PSOARING 1 and PSOARING 2: Two randomized, double-blind, multicenter, vehicle-controlled clinical studies treated 1,025 adult patients with plaque psoriasis with Vtama® cream or vehicle cream applied once daily to any lesion regardless of anatomic location for up to 12 weeks. Baseline disease severity was determined using the 5-point Physician's Global Assessment (PGA), with 82% of patients having moderate disease. The extent of disease involvement assessed by mean body surface area (BSA), excluding the scalp, palms, and soles, was 8%. Patients were included if they had a BSA involvement of ≥3% and ≤20%.

The primary efficacy endpoint in both studies was the proportion of patients who achieved treatment success, which was defined as a PGA score of clear (0) or almost clear (1) and at least a 2-grade improvement from baseline. Patients treated with Vtama® demonstrated statistically significant improvement versus vehicle in PGA score with 36% vs. 6% [95% confidence interval (CI): 2.9, 11.6; P<0.001] of patients in PSOARING 1 and 40% vs. 6% (95% CI: 3.3, 11.4; P<0.001) of patients in PSOARING 2 achieving treatment success.

- PSOARING 3: This was an open-label safety study in which 763 patients were treated for up to an additional 40 weeks after completing PSOARING 1 or PSOARING 2. Over 40% of patients in this study achieved complete disease clearance at least once during the study period.

Zoryve™ (Roflumilast 0.3% Cream) Product Summary[10]

Indication(s): Zoryve™ is a PDE-4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

How Supplied: 0.3% cream containing 3mg of roflumilast per gram.

Dosing and Administration:

- Apply once daily to affected areas.
- For topical use only. Not for ophthalmic, oral, or intravaginal use

Mechanism of Action: Roflumilast inhibits PDE-4 activity and this leads to accumulation of intracellular cyclic adenosine monophosphate (AMP). The specific mechanism by which roflumilast exerts its therapeutic action is not well defined.

Contraindication(s):

- Moderate-to-severe hepatic impairment (Child-Pugh B or C)

Safety:

- Pregnancy: There are no clinical studies of oral or topical roflumilast in pregnant women. In animal reproduction studies, roflumilast administered orally to pregnant rats and rabbits during the period of organogenesis produced no fetal structural abnormalities at doses up to 8 and 9 times the maximum recommended human dose.
- Lactation: There is no information regarding the presence of Zoryve™ in human milk, the effects on the breast fed infant, or the effects on milk production. Roflumilast and/or its metabolites are excreted into the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will present in human milk.

- Pediatrics: The safety and effectiveness of Zoryve™ have been established in pediatric patients 12 years of age and older for the treatment of plaque psoriasis. Use of Zoryve™ in this age group is supported by data from (2) 8-week vehicle-controlled safety and efficacy studies which included 14 adolescent patients 12 to 17 years of age, of whom 8 received Zoryve™. Eighteen adolescent patients were treated with Zoryve™ in open-label studies of 2- and 24-weeks duration. The safety and effectiveness of Zoryve™ have not been established in pediatric patients younger than 12 years of age.
- Geriatrics: Of the 881 patients with psoriasis exposed to Zoryve™ or vehicle for up to 8 weeks in 2 controlled clinical studies, 106 were 65 years of age or older. No overall differences in safety or effectiveness were observed between these patients and younger patients.
- Hepatic Impairment: Oral roflumilast 250mcg once daily for 14 days was studied in patients with hepatic impairment. The area under the curve (AUC) and maximum serum concentration (Cmax) values of roflumilast and roflumilast N-oxide were increased in patients with moderate (Child-Pugh B) hepatic impairment. Zoryve™ is contraindicated in patients with moderate-to-severe hepatic impairment (Child-Pugh B or C).

Adverse Reactions: The most common adverse reactions (reported in ≥1% of patients) are diarrhea, headache, insomnia, application site pain, upper respiratory tract infections, and urinary tract infections.

Efficacy:

- DERMIS-1 and DERMIS-2: Two multicenter, randomized, double-blind, vehicle-controlled studies enrolled a total of 881 patients with mild-to-severe plaque psoriasis and an affected BSA of 2-20%. Patients were randomized 2:1 to receive Zoryve™ or vehicle applied once daily for 8 weeks. The primary endpoint was the proportion of patients who achieved IGA treatment success at week 8. Success was defined as a score of clear (0) or almost clear (1), plus a 2-grade improvement from baseline. In DERMIS-1, 41.5% of patients treated with Zoryve™ compared to 5.8% of patients treated with vehicle had IGA success. In DERMIS-2, 36.7% versus 7.1% of patients treated with Zoryve™ and vehicle, respectively, achieved IGA success. Secondary endpoints included the proportion of patients who achieved intertriginous IGA (I-IGA) success at week 8 and Worst Itch-Numeric Rating Score (WI-NRS) success at weeks 2, 4, and 8. WI-NRS success was defined as reduction of at least 4 points from baseline in patients with a baseline WI-NRS score of at least 4. In patients treated with Zoryve™ compared to vehicle, 72% vs. 14% in DERMIS-1 and 68% vs. 17% in DERMIS-2 at week 8 ($P<0.0001$) showed an improvement in I-IGA score. The majority of patients with a WI-NRS

score of 4 or higher at baseline achieved a ≥4 point reduction in itch at week 8 with Zoryve™ compared to placebo [67% vs. 26% in DERMIS-1 and 69% vs. 33% in DERMIS-2 (P<0.0001)].

Cost Comparison: Topical Plaque Psoriasis Medications

Product	Cost Per Gram	Cost Per Tube
Vtama® (tapinarof 1% cream)*	**$21.31**	**$1,278.60**
Zoryve™ (roflumilast 0.3% cream)*	**$13.75**	**$825.00**
Sorilux® (calcipotriene 0.005% foam)*	$17.73	$1,063.80
Duobrii® (halobetasol propionate/tazarotene 0.01%/0.045% lotion)⁺	$9.71	$971.00
tazarotene 0.1% cream (generic)±	$1.90	$57.00
tazarotene 0.1% gel (generic)±	$13.99	$419.70
tazarotene 0.05% gel(generic)±	$13.17	$395.10

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).
*Vtama®, Zoryve™, and Sorilux® cost is based on a 60 gram tube
⁺Duobrii® cost is based on a 100 gram tube
±Tazarotene 0.1% cream, 0.1% gel, and 0.05% gel cost is based on a 30 gram tube.

Recommendations

The College of Pharmacy recommends the prior authorization of brimonidine 0.33% topical gel, Vtama®, and Zoryve™ with the following criteria (shown in red):

Brimonidine 0.33% Topical Gel (Generic Mirvaso®) Approval Criteria:

1. An FDA approved diagnosis of persistent (non-transient) facial erythema of rosacea; and
2. Member must be 18 to 20 years of age; and
3. A patient-specific, clinically significant reason why the member cannot utilize clindamycin topical solution (generic), metronidazole topical gel and cream 0.75%, erythromycin topical 2% solution, oral isotretinoin medications, or other generically available preferred oral or topical antibiotic products; and
4. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
5. Brand name Mirvaso® is not a covered product; and
6. A quantity limit of 30 grams per 30 days will apply.

Vtama® (Tapinarof 1% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 18 years of age or older; and
3. Member must have a body surface area (BSA) involvement of ≤20%; and

4. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
5. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
    a. An ultra-high to high potency topical corticosteroid (TCS); or
    b. A generic topical calcipotriene product; or
    c. A topical tazarotene product; and
6. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 60 grams per 30 days will apply.

Zoryve™ (Roflumilast 0.3% Cream) Approval Criteria:

1. An FDA approved diagnosis of plaque psoriasis; and
2. Member must be 12 years of age or older; and
3. Member must have a body surface (BSA) ≤20%; and
4. Member must not have moderate-to-severe hepatic impairment (Child-Pugh B or C); and
5. Must be prescribed by, or in consultation with, a dermatologist (or an advanced care practitioner with a supervising physician who is a dermatologist); and
6. Member must have documented trials within the last 6 months for a minimum of 2 weeks that resulted in failure with at least 2 of the following therapies (or have a contraindication or documented intolerance):
    a. An ultra-high to high potency topical corticosteroid (TCS); or
    b. A generic topical calcipotriene product; or
    c. A topical tazarotene product; and
7. Initial approvals will be for the duration of 1 month. Reauthorization may be granted if the prescriber documents the member is responding well to treatment; and
8. A quantity limit of 60 grams per 30 days will apply.

Additionally, the College of Pharmacy recommends updating the approval criteria for Amzeeq® (minocycline 4% topical foam) and Tazorac® (tazarotene cream and gel) based on the new tazarotene generic approvals and product availability (changes shown in red):

Amzeeq® (Minocycline 4% Topical Foam) Approval Criteria:

1. An FDA approved indication of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and

3. Amzeeq® will not be covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use erythromycin 2% topical solution, clindamycin 1% topical solution, benzoyl peroxide, ~~brand name Tazorac®;~~ preferred tazarotene formulations, oral isotretinoin medications, and other generically available preferred oral or topical antibiotic products must be provided; and
5. A quantity limit of 30 grams per 30 days will apply.

Tazorac® (Tazarotene Cream and Gel) Approval Criteria:

1. An FDA approved diagnosis of acne vulgaris or plaque psoriasis; and
2. Female members must not be pregnant and must be willing to use an effective method of contraception during treatment; and
3. For the diagnosis of acne vulgaris, the following must be met:
   a. Member must be 20 years of age or younger; and
   b. ~~Tazorac® 0.1% cream, Tazorac® 0.05% gel, Tazorac® 0.1% gel, and~~ tazarotene 0.1% cream will not require prior authorization for members 20 years of age or younger; and
4. Tazarotene 0.05% gel and tazarotene 0.1% gel will require a patient specific, clinically significant reason why the member cannot use tazarotene 0.1% cream, which is available without prior authorization for members 20 years of age and younger; and
5. A quantity limit of 100 grams per 30 days will apply.

Utilization Details of Topical Acne, Psoriasis, and Rosacea Products: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CLINDAMYCIN PRODUCTS						
CLINDAMYCIN GEL 1%	4,777	2,583	$198,704.31	$41.60	1.85	24.39%
CLINDAMYCIN SOL 1%	2,455	1,395	$52,804.34	$21.51	1.76	6.48%
CLINDAMYCIN LOT 1%	1,544	1,023	$107,359.53	$69.53	1.51	13.18%
CLINDAMYCIN SWAB 1%	819	353	$25,232.91	$30.81	2.32	3.10%
CLINDAMYCIN LOT 10MG/ML	471	347	$33,105.00	$70.29	1.36	4.06%
CLINDACIN-P SWAB 1%	16	9	$569.51	$35.59	1.78	0.07%
CLINDACIN ETZ SWAB 1%	2	2	$65.94	$32.97	1	0.01%
CLINDAGEL GEL 1%	1	1	$1,788.67	$1,788.67	1	0.22%
SUBTOTAL	**10,085**	**5,713**	**$419,630.21**	**$41.61**	**1.77**	**51.51%**
TAZAROTENE PRODUCTS						
TAZAROTENE CRE 0.1%	1,840	1,184	$290,364.09	$157.81	1.27	35.65%
TAZORAC GEL 0.05%	58	40	$35,391.74	$610.20	1.46	4.34%
TAZORAC CRE 0.05%	33	25	$19,624.65	$594.69	1.22	2.41%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TAZORAC GEL 0.1%	13	12	$9,335.67	$718.13	1.33	1.15%
TAZORAC CRE 0.1%	2	2	$1,800.78	$900.39	1.14	0.22%
SUBTOTAL	**1,946**	**1,263**	**$356,516.93**	**$183.21**	**1.54**	**43.77%**
ERYTHROMYCIN PRODUCTS						
ERYTHROMYCIN SOL 2%	262	151	$11,882.05	$45.35	1.74	1.46%
SUBTOTAL	**262**	**151**	**$11,882.05**	**$45.35**	**1.74**	**1.46%**
METRONIDAZOLE PRODUCTS						
METRONIDAZOLE CRE 0.75%	86	73	$4,443.10	$51.66	1.18	0.55%
METRONIDAZOLE GEL 0.75%	68	54	$2,571.48	$37.82	1.26	0.32%
METRONIDAZOLE LOT 0.75%	13	8	$1,423.62	$109.51	1.63	0.17%
SUBTOTAL	**167**	**135**	**$8,438.20**	**$50.53**	**1.24**	**1.04%**
DAPSONE PRODUCTS						
DAPSONE GEL 5%	14	9	$7,850.19	$560.73	1.56	0.96%
DAPSONE GEL 7.5%	11	7	$3,349.34	$304.49	1.57	0.41%
SUBTOTAL	**25**	**16**	**$11,199.53**	**$447.98**	**1.56**	**1.37%**
MINOCYCLINE PRODUCTS						
AMZEEQ AER 4%	14	5	$6,680.24	$477.16	2.8	0.82%
SUBTOTAL	**14**	**5**	**$6,680.24**	**$477.16**	**2.80**	**0.82%**
SULFACETAMIDE PRODUCTS						
SULFACETAMIDE LOT 10%	2	2	$214.02	$107.01	1	0.03%
SUBTOTAL	**2**	**2**	**$214.02**	**$107.01**	**1**	**0.03%**
TOTAL	**12,501**	**6,252***	**$814,561.18**	**$65.16**	**2.00**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AER = aerosol foam; CRE = cream; ETZ = pledgets; LOT = lotion; SOL = solution
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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Appendix U

U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates (additional information can be found at http://www.fda.gov/Drugs/default.htm)

FDA NEWS RELEASE

For Immediate Release: January 26, 2023

FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward

Given the growing cannabidiol (CBD) products market, the FDA convened a high-level internal working group to explore potential regulatory pathways for CBD products. After careful review, the FDA has concluded that a new regulatory pathway for CBD is needed that balances individuals' desire for access to CBD products with the regulatory oversight needed to manage risks. The FDA is prepared to work with Congress on this matter. They are also denying 3 citizen petitions that had asked the FDA to conduct rulemaking to allow the marketing of CBD products as dietary supplements.

The use of CBD raises various safety concerns, especially with long-term use. Studies have shown the potential for harm to the liver, interactions with certain medications and possible harm to the male reproductive system. CBD exposure is also concerning when it comes to certain vulnerable populations such as children and those who are pregnant. A new regulatory pathway would benefit consumers by providing safeguards and oversight to manage and minimize risks related to CBD products. Some risk management tools could include clear labels, prevention of contaminants, CBD content limits, and measures, such as minimum purchase age, to mitigate the risk of ingestion by children. In addition, a new pathway could provide access and oversight for certain CBD-containing products for animals.

The FDA's existing foods and dietary supplement authorities provide only limited tools for managing many of the risks associated with CBD products. Under the law, any substance, including CBD, must meet specific safety standards to be lawfully marketed as a dietary supplement or food additive. A working group has closely examined studies related to the CBD-based drug Epidiolex®, published scientific literature, information submitted to a public docket, as well as studies both conducted and commissioned by the FDA. Given the available evidence, it is not apparent how CBD products could meet safety standards for dietary supplements or food additives. For example, adequate evidence has not been found to determine how much CBD can be consumed, and for how long, before causing harm. Therefore, they do not intend to pursue rulemaking allowing the use of CBD in dietary supplements or conventional foods. CBD also poses risks to animals, and people could be unknowingly exposed to CBD through meat, milk and eggs from animals fed CBD. Because it is not apparent how CBD products could meet the safety standard for substances in animal food, they also do not intend to pursue rulemaking allowing the use of CBD in animal food. A new regulatory pathway could provide access and oversight for certain CBD-containing products for animals.

The FDA will continue to take action against CBD and other cannabis-derived products to protect the public, in coordination with state regulatory partners, when appropriate. They will remain diligent in monitoring the marketplace, identifying products that pose risks and acting within our authorities. The FDA looks forward to working with Congress to develop a cross-agency strategy for the regulation of these products to protect the public's health and safety.

FDA NEWS RELEASE

For Immediate Release: January 6, 2023

FDA Grants Accelerated Approval for Alzheimer's Disease Treatment

The FDA approved Leqembi™ (lecanemab-irmb) via the Accelerated Approval pathway for the treatment of Alzheimer's disease. Leqembi™ is the second of a new category of medications approved for Alzheimer's disease that target the fundamental pathophysiology of the disease. These medications represent an important advancement in the ongoing fight to effectively treat Alzheimer's disease. Alzheimer's disease is an irreversible, progressive brain disorder affecting more than 6.5 million Americans that slowly destroys memory and thinking skills and, eventually, the ability to carry out simple tasks. While the specific causes of Alzheimer's are not fully known, it is characterized by changes in the brain – including amyloid beta plaques and neurofibrillary, or tau, tangles – that result in loss of neurons and their connections. These changes affect a person's ability to remember and think.

Leqembi™ was approved using the Accelerated Approval pathway, under which the FDA may approve drugs for serious conditions where there is an unmet medical need and a drug is shown to have an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. The results of a Phase 3 randomized, controlled clinical trial to confirm the drug's clinical benefit have recently been reported and the FDA anticipates receiving the data soon.

Researchers evaluated the efficacy of Leqembi™ in a double-blind, placebo-controlled, parallel-group, dose-finding study of 856 patients with Alzheimer's disease. Treatment was initiated in patients with mild cognitive impairment or mild dementia stage of disease and confirmed presence of amyloid beta pathology. Patients receiving the treatment had significant dose- and time-dependent reduction of amyloid beta plaque, with patients receiving the approved dose of lecanemab, 10mg/kg every 2 weeks, having a statistically significant reduction in brain amyloid plaque from baseline to week 79 compared to the placebo arm, which had no reduction of amyloid beta plaque.

These results support the accelerated approval of Leqembi™, which is based on the observed reduction of amyloid beta plaque, a marker of Alzheimer's disease. Amyloid beta plaque was quantified using positron emission tomography (PET) imaging to estimate the brain levels of amyloid beta plaque in a composite of brain regions expected to be widely affected by Alzheimer's disease pathology compared to a brain region expected to be spared of such pathology.

The *Prescribing Information* for Leqembi™ includes a warning for amyloid-related imaging abnormalities (ARIA), which are known to occur with antibodies of this class. ARIA usually does not have symptoms, although serious and life-threatening events rarely may occur. ARIA most commonly presents as temporary swelling in areas of the brain that usually resolves over time and may be accompanied by small spots of bleeding in or on the surface of the brain, though some people may have symptoms such as headache, confusion, dizziness, vision changes, nausea, and seizure. Another warning for Leqembi™ is for a risk of infusion-related reactions, with symptoms such as flu-like symptoms, nausea, vomiting, and changes in blood pressure. The most common side effects of Leqembi™ were infusion-related reactions, headache, and ARIA.

As specified in the *Prescribing Information*, Leqembi™ is indicated for the treatment of Alzheimer's disease. The labeling states that treatment with Leqembi™ should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was studied in clinical trials. The labeling also

states that there are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.

Current Drug Shortages Index (as of January 26, 2022):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma.

Albuterol Sulfate Inhalational Solution	***Currently in Shortage***
Alprostadil (Muse) Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amoxicillin Oral Powder for Suspension	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Belladonna and Opium Suppositories	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Collagenase Ointment	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Conjugated Estrogens/Bazedoxifene (DUAVEE) Tablet, Film Coated	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 10% Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 5% Injection	***Currently in Shortage***

Dextrose 50% Injection	***Currently in Shortage***
Diazepam Rectal Gel	***Currently in Shortage***
Diflunisal Tablets	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide (Trulicity) Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Edetate Calcium Disodium Injection	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1 mg/mL	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Floxuridine for Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Iomeprol injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
IV Fat Emulsion	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Lyophilized Powder for Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
Lithium Oral Solution	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***

Methyldopa Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Neomycin Sulfate Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Oxytocin Injection	***Currently in Shortage***
Paclitaxel Injection (protein-bound particles)	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone (Natpara) Injection	***Currently in Shortage***
Pentostatin Injection	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Concentrate Injection	***Currently in Shortage***
Remifentanil Injection	***Currently in Shortage***
Rifampin Capsules	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide (Ozempic) Injection	***Currently in Shortage***
Semaglutide (Wegovy) Injection	***Currently in Shortage***
Sincalide (Kinevac) Lyophilized Powder for Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***
Sterile Water for Injection	***Currently in Shortage***
Streptozocin (Zanosar) Sterile Powder	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Technetium TC-99M Mebrofenin Injection	***Currently in Shortage***
Technetium TC-99m Sodium Pertechnetate Generator	***Currently in Shortage***
Technetium Tc99m Succimer Injection (DMSA)	***Currently in Shortage***
Teprotumumab-trbw	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***

Triamcinolone Acetonide Injectable Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***
Verteporfin (Visudyne) Injection	***Currently in Shortage***