OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday,
January 11, 2023

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

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

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 – January 11, 2023

DATE: January 4, 2023

NOTE: No live January meeting. January 2023 is a packet-only meeting.

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

DUR Board Meeting Minutes – Appendix A

Update on the Medication Coverage Authorization Unit/U.S. Food and Drug Administration (FDA) Safety Alerts – Appendix B

Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications – Appendix C

Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications and 30-Day Notice to Prior Authorize Relyvrio™ (Sodium Phenylbutyrate/ Taurursodiol) – Appendix D

Annual Review of Antihyperlipidemics – Appendix E

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

Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize Omlonti® (Omidenepag Isopropyl) – Appendix G

30-Day Notice to Prior Authorize Hyftor™ (Sirolimus Topical Gel) – Appendix H

Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Pedmark® (Sodium Thiosulfate) and Vijoice® (Alpelisib) – Appendix I

Annual Review of Gastrointestinal (GI) Cancer Medications and 30-Day Notice to Prior Authorize Lytgobi® (Futibatinib) – Appendix J

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

Future Business

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Packet – January 11, 2023

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

NOTE: ***No live January meeting. January 2023 is a packet-only meeting***

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **DUR Board Meeting Minutes – See Appendix A**
   A. December 14, 2022 DUR Board Meeting Minutes
   B. December 14, 2022 DUR Board Recommendations Memorandum

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

2. **Update on Medication Coverage Authorization Unit/U.S. Food and Drug Administration (FDA) Safety Alerts – See Appendix B**
   A. Pharmacy Help Desk Activity for December 2022
   B. Medication Coverage Activity for December 2022
   C. FDA Safety Alerts

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

3. **Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications – See Appendix C**
   A. Current Prior Authorization Criteria
   B. Utilization of GnRH Medications
   C. Prior Authorization of GnRH Medications
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of GnRH Medications

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

4. **Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications and 30-Day Notice to Prior Authorize Relyvrio™ (Sodium Phenylbutyrate/ Taurursodiol) – See Appendix D**
   A. Current Prior Authorization Criteria
   B. Utilization of ALS Medications
   C. Prior Authorization of ALS Medications
   D. Market News and Updates
   E. Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Product Summary
   F. College of Pharmacy Recommendations

G. Utilization Details of ALS Medications

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

5. **Annual Review of Antihyperlipidemics – See Appendix E**
   A. Current Prior Authorization Criteria
   B. Utilization of Antihyperlipidemics
   C. Prior Authorization of Antihyperlipidemics
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of Antihyperlipidemics

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

6. **Annual Review of Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitor Medications and 30-Day Notice to Prior Vabysmo™ (Faricimab-svoa) – See Appendix F**
   A. Current Prior Authorization Criteria
   B. Utilization of Ophthalmic VEGF Inhibitor Medications
   C. Prior Authorization of Ophthalmic VEGF Inhibitor Medications
   D. Market News and Updates
   E. Vabysmo™ (Faricimab-svoa) Product Summary
   F. College of Pharmacy Recommendations
   G. Utilization Details of Ophthalmic VEGF Inhibitor Medications

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

7. **Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize Omlonti® (Omidenepag Isopropyl) – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Glaucoma Medications
   C. Prior Authorization of Glaucoma Medications
   D. Market News and Updates
   E. Omlonti® (Omidenepag Isopropyl) Product Summary
   F. College of Pharmacy Recommendations
   G. Utilization Details of Glaucoma Medications

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

8. **30-Day Notice to Prior Authorize Hyftor™ (Sirolimus Topical Gel) – See Appendix H**
   A. Introduction
   B. Hyftor™ (Sirolimus Topical Gel) Product Summary
   C. College of Pharmacy Recommendations

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

9. **Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Pedmark® (Sodium Thiosulfate) and Vijoice® (Alpelisib) – See Appendix I**
   A. Current Prior Authorization Criteria
   B. Utilization of Miscellaneous Cancer Medications
   C. Prior Authorization of Miscellaneous Cancer Medications
   D. Market News and Updates
   E. Pedmark® (Sodium Thiosulfate) Product Summary
   F. Vijoice® (Alpelisib) Product Summary
   G. College of Pharmacy Recommendations
   H. Utilization Details of Miscellaneous Cancer Medications

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

10. **Annual Review of Gastrointestinal (GI) Cancer Medications and 30-Day Notice to Prior Authorize Lytgobi® (Futibatinib) – See Appendix J**
    A. Current Prior Authorization Criteria
    B. Utilization of GI Cancer Medications
    C. Prior Authorization of GI Cancer Medications
    D. Market News and Updates
    E. Lytgobi® (Futibatinib) Product Summary
    F. College of Pharmacy Recommendations

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

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

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

12. **Future Business* (Upcoming Product and Class Reviews)**
    A. Anticonvulsants
    B. Anti-Migraine Medications
    C. Leukemia Medications
    D. Pulmonary Hypertension Medications

    *Future product and class reviews subject to change.

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)**

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.

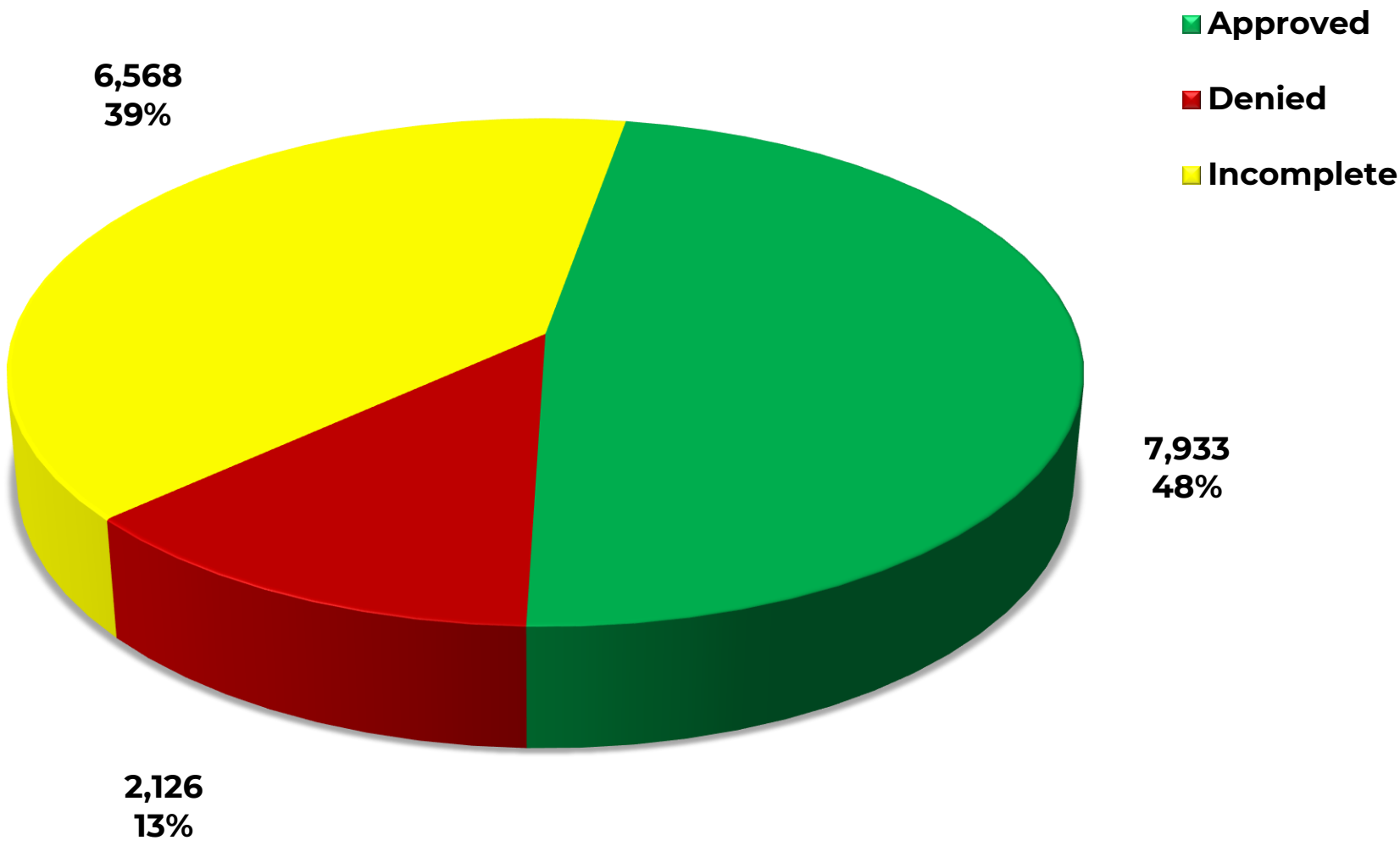
Recommendation 13: Future Business

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

NO ACTION REQUIRED.

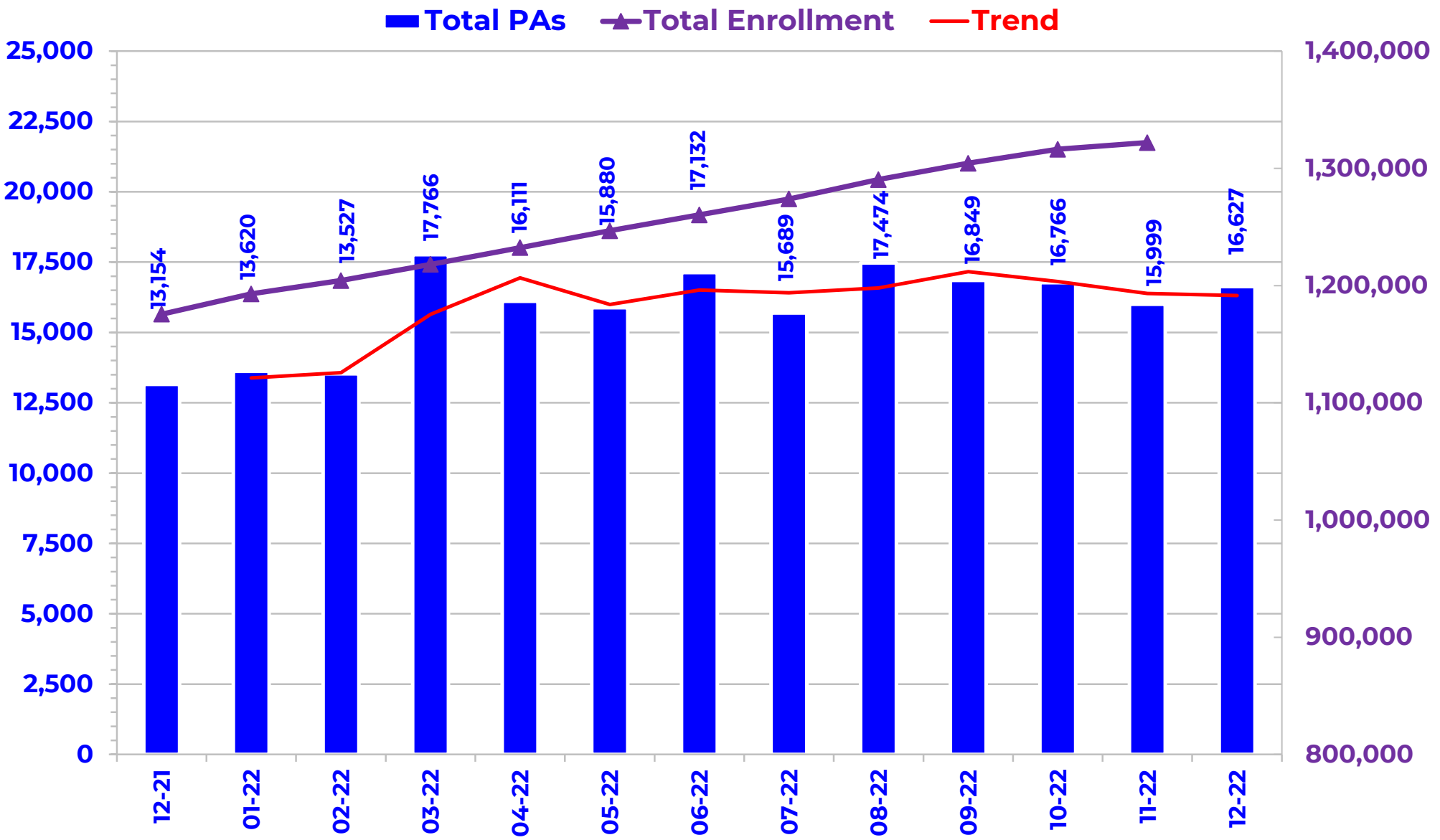
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: DECEMBER 2022



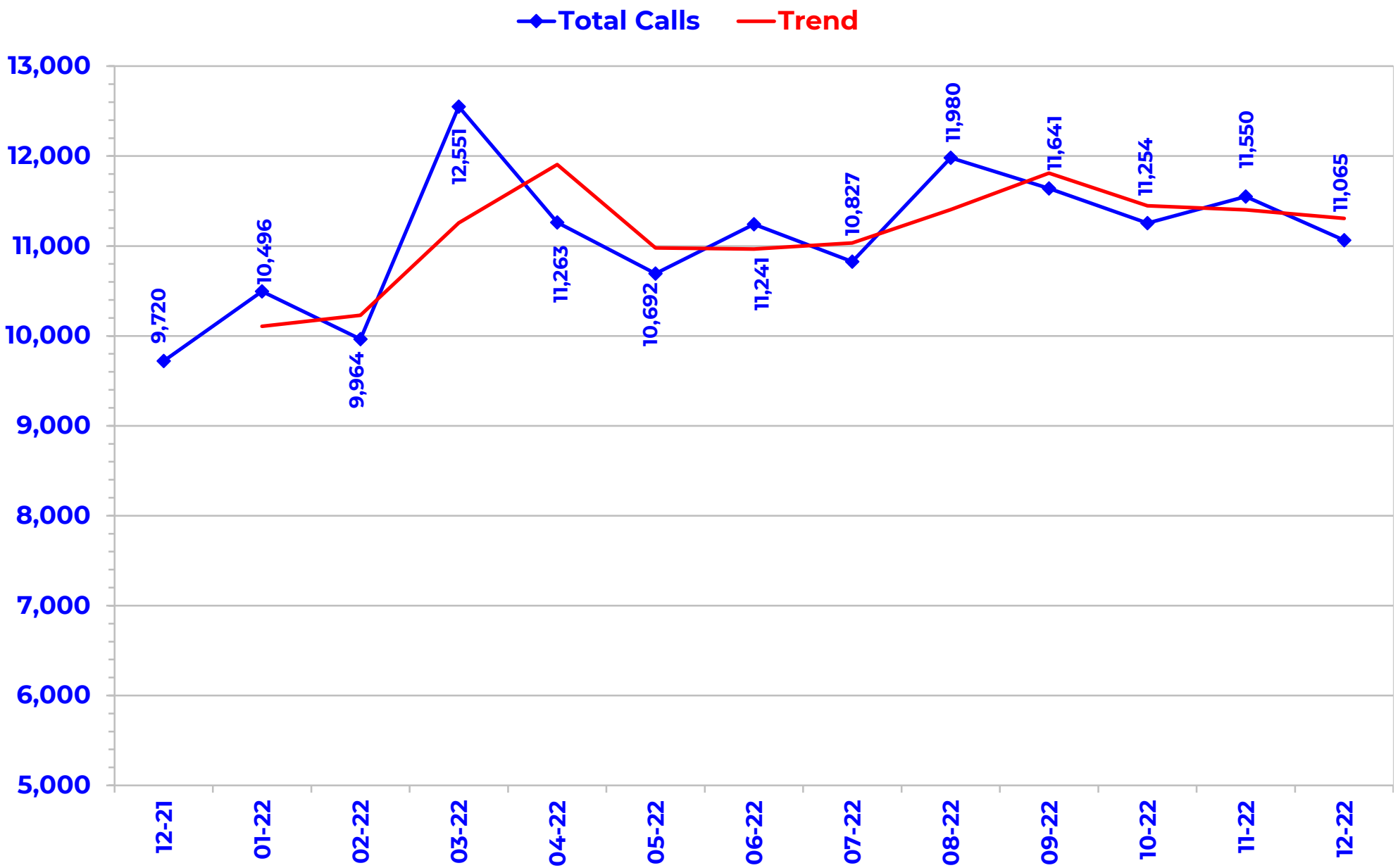
PA totals include approved/denied/incomplete/overrides

PRIOR AUTHORIZATION (PA) REPORT: DECEMBER 2021 – DECEMBER 2022



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: DECEMBER 2021 – DECEMBER 2022



Prior Authorization Activity

12/1/2022 Through 12/31/2022

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	83	16	1	66	345
Analgesic - NonNarcotic	19	1	4	14	177
Analgesic, Narcotic	346	165	25	156	140
Angiotensin Receptor Antagonist	15	3	2	10	358
Antiasthma	122	45	20	57	247
Antibiotic	69	30	8	31	190
Anticonvulsant	241	119	18	104	315
Antidepressant	356	67	56	233	336
Antidiabetic	1,827	634	415	778	357
Antifungal	16	4	1	11	58
Antihemophilic Factor	19	15	0	4	304
Antihistamine	38	12	9	17	336
Antimalarial Agent	136	103	3	30	353
Antimigraine	565	90	180	295	243
Antineoplastic	271	197	7	67	172
Antiobesity	26	2	19	5	360
Antiparasitic	24	8	3	13	11
Antiparkinsons	11	0	4	7	0
Antiulcers	40	7	7	26	120
Antiviral	14	5	1	8	85
Anxiolytic	34	3	3	28	269
Atypical Antipsychotics	596	266	42	288	352
Benign Prostatic Hypertrophy	14	1	6	7	177
Biologics	421	216	59	146	290
Bladder Control	126	21	27	78	333
Blood Thinners	758	469	27	262	349
Botox	75	42	20	13	325
Buprenorphine Medications	117	46	18	53	83
Calcium Channel Blockers	26	6	2	18	246
Cardiovascular	143	59	15	69	326
Chronic Obstructive Pulmonary Disease	325	78	63	184	342
Constipation/Diarrhea Medications	269	53	69	147	224
Contraceptive	42	10	5	27	359
Corticosteroid	13	4	1	8	199
Dermatological	589	231	135	223	234
Diabetic Supplies	917	361	162	394	266
Diuretic	14	11	0	3	332
Endocrine & Metabolic Drugs	107	46	15	46	198
Erythropoietin Stimulating Agents	19	15	2	2	109

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Estrogen Derivative	17	2	5	10	355
Fibric Acid Derivatives	12	0	3	9	0
Fibromyalgia	12	3	3	6	249
Fish Oils	31	6	8	17	359
Gastrointestinal Agents	226	40	43	143	169
Glaucoma	15	6	2	7	171
Growth Hormones	86	58	8	20	157
Hematopoietic Agents	31	14	4	13	195
Hepatitis C	38	19	7	12	10
HFA Rescue Inhalers	410	298	2	110	289
Insomnia	152	11	37	104	201
Insulin	349	123	35	191	343
Miscellaneous Antibiotics	26	6	3	17	14
Multiple Sclerosis	94	39	12	43	247
Muscle Relaxant	83	11	20	52	166
Nasal Allergy	37	0	12	25	0
Neurological Agents	193	60	43	90	216
Neuromuscular Agents	13	3	0	10	240
NSAIDs	40	2	8	30	184
Ocular Allergy	16	2	6	8	84
Ophthalmic	20	5	6	9	236
Ophthalmic Anti-infectives	29	9	1	19	95
Ophthalmic Corticosteroid	14	3	2	9	360
Osteoporosis	27	9	7	11	301
Other*	377	113	55	209	284
Otic Antibiotic	28	3	6	19	7
Respiratory Agents	42	31	1	10	309
Statins	52	12	13	27	141
Stimulant	2,102	1,431	83	588	346
Synagis	87	46	18	23	26
Testosterone	213	60	48	105	327
Thyroid	29	8	7	14	245
Topical Antifungal	52	10	6	36	60
Topical Corticosteroids	28	2	9	17	360
Vitamin	120	26	55	39	127
Pharmacotherapy	130	129	0	1	303
Emergency PAs	0	0	0	0	
Total	**14,074**	**6,061**	**2,032**	**5,981**	

* 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	52	36	4	12	196
Compound	24	21	1	2	45
Cumulative Early Refill	1	1	0	0	10
Diabetic Supplies	3	3	0	0	129
Dosage Change	460	435	0	25	19
High Dose	1	1	0	0	358
Ingredient Duplication	1	0	0	1	0
Lost/Broken Rx	145	132	5	8	23
MAT Override	265	219	5	41	74
NDC vs Age	314	197	25	92	261
NDC vs Sex	12	10	0	2	108
Nursing Home Issue	78	74	0	4	19
Opioid MME Limit	117	39	8	70	126
Opioid Quantity	42	33	1	8	148
Other	75	56	4	15	22
Prescriber Temp Unlock	1	0	0	1	0
Quantity vs. Days Supply	849	527	40	282	228
STBS/STBSM	17	15	0	2	80
Step Therapy Exception	19	10	1	8	360
Stolen	14	12	0	2	30
Temporary Unlock	1	1	0	0	11
Third Brand Request	62	50	0	12	38
Overrides Total	**2,553**	**1,872**	**94**	**587**	
Total Regular PAs + Overrides	**16,627**	**7,933**	**2,126**	**6,568**	

Denial Reasons	
Unable to verify required trials.	5,392
Does not meet established criteria.	2,136
Lack required information to process request.	1,151
Other PA Activity	
Duplicate Requests	1,651
Letters	39,138
No Process	5
Changes to existing PAs	1,357
Helpdesk Initiated Prior Authorizations	1,099
PAs Missing Information	2,279

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

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

Oklahoma Health Care Authority
January 2023

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

The following are recent FDA safety alerts included for the Drug Utilization Review (DUR) Board's consideration. SoonerCare specific data may be presented where applicable. The College of Pharmacy will make recommendations as well as take recommendations from the DUR Board.

Date	Drug	Issue
01/12/2022	**Buprenorphine Medications**	**Dental problems associated with medications dissolved in mouth**

Issue Details: The FDA issued a Drug Safety Communication warning that dental problems have been reported with medications containing buprenorphine that are dissolved in the mouth. Examples of dental problems include tooth decay, cavities, oral infections, and loss of teeth. These issues can be very serious and have been reported in patients with no history of dental issues. The buprenorphine-containing medications associated with dental problems are the tablets and films dissolved under the tongue or placed against the side of the cheek.
FDA Recommendation(s): The FDA is requiring a new warning about the risk of dental problems be added to the *Prescribing Information* for all buprenorphine-containing medications dissolved in the mouth. The information will also include strategies to maintain or improve oral health while undergoing treatment with these medications. Health care providers should refer patients to dental care services and encourage them to have regular checkups while taking these products. For those suffering from an opioid use disorder (OUD), the benefits of using buprenorphine medications outweigh the risk and should continue taking it as prescribed.
Pharmacy Claims Evaluation: During fiscal year (FY) 2022 (07/01/2021 to 06/30/2022), a total of 5,274 SoonerCare members had paid claims for buprenorphine or buprenorphine/naloxone sublingual films or tablets, accounting for 41,954 paid claims and an average of 7.95 claims per member.
SoonerCare Action: Currently, buprenorphine/naloxone sublingual tablets are available without prior authorization, but other products included in the Drug Safety Communication require prior authorization. An article addressing the warning, "Dental Care and Buprenorphine: What You Need to Know!", was included in the March 2022 SoonerCare member newsletter. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
06/01/2022	**Ukoniq® (umbralisib)**	**Removal of Ukoniq® (umbralisib) due to safety concerns**

Issue Details: Due to safety concerns, the FDA issued a Drug Safety communication about the withdrawal of the approval for the cancer medication Ukoniq® (umbralisib). Ukoniq® was FDA approved in February 2021 to treat marginal zone lymphoma (MZL) and follicular lymphoma (FL). Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq®. As a result, the FDA determined the risks of treatment with Ukoniq® outweighs the benefits. Based on this determination, the drug's manufacturer, TG Therapeutics, announced it was voluntarily withdrawing Ukoniq® from the market.
FDA Recommendation(s): The FDA recommends all health care professionals stop prescribing Ukoniq® and switch patients to alternative treatment.
Pharmacy Claims Evaluation: During FY 2022, there was no SoonerCare utilization of Ukoniq®.
SoonerCare Action: Ukoniq® previously required prior authorization, but it currently is inactivated in the pharmacy claims payment system and is not currently covered through SoonerCare. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
06/30/2022	**Copiktra® (duvelisib)**	**Possible risk of death and serious side effects**

Issue Details: The FDA issued a Drug Safety Communication warning that results from a clinical trial showed a possible increased risk of death with Copiktra® (duvelisib) compared to another medication to treat leukemia and lymphoma. The trial also found that Copiktra® was associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzymes in the blood. The FDA plans to hold a future public meeting to discuss the findings from the clinical trial and whether Copiktra® should continue to be prescribed.
FDA Recommendation(s): The FDA recommends health care providers consider the risks and benefits of starting or continuing Copiktra® treatment compared to other available treatments.
Pharmacy Claims Evaluation: During FY 2022, there was no SoonerCare utilization of Copiktra®.
SoonerCare Action: Copiktra® currently requires prior authorization for SoonerCare coverage. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
11/22/2022	**Prolia® (denosumab)**	**Risk of hypocalcemia in patients on dialysis receiving Prolia®**

Issue Details: The FDA issued a Drug Safety Communication stating they are investigating the risk of severe hypocalcemia with serious outcomes, including hospitalization and death, in patients on dialysis receiving Prolia®. The initial review suggests an increased risk of hypocalcemia in patients with advanced kidney disease. The FDA is alerting health care professionals and patients about the risks and will continue to evaluate this potential safety issue. The FDA will communicate their final conclusions and recommendations when they have completed the review or have more information to share.

FDA Recommendation(s): Health care professionals should consider the risks of hypocalcemia with the use of Prolia® in patients on dialysis. When Prolia® is used in these patients, adequate calcium and vitamin D supplementation and frequent blood calcium monitoring may help decrease the likelihood or severity of these risks. Patients on dialysis should be advised to immediately seek help if they experience symptoms of hypocalcemia.

Pharmacy Claims Evaluation: During FY 2022, a total of 45 SoonerCare members had paid claims for Prolia®, accounting for 62 paid claims and an average of 1.38 claims per member.

Medical Claims Evaluation: During FY 2022, a total of 49 SoonerCare members had paid medical claims for Prolia®, accounting for 64 paid claims and an average of 1.31 claims per member.

SoonerCare Action: Currently, the use of Prolia® requires prior authorization for all SoonerCare members. The College of Pharmacy will continue to monitor the FDA recommendations and will take further action if indicated based on the FDA's final conclusions.

[1] U.S. Food and Drug Administration (FDA). 2022 Drug Safety Communications. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/2022-drug-safety-communications. Last revised 11/22/2022. Last accessed 12/19/2022.

[2] U.S. FDA. FDA Warns About Dental Problems with Buprenorphine Medicines Dissolved in the Mouth to Treat Opioid Use Disorder and Pain. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-dental-problems-buprenorphine-medicines-dissolved-mouth-treat-opioid-use-disorder. Issued 01/12/2022. Last Accessed 12/19/2022.

[3] U.S. FDA. FDA Approval of Lymphoma Medicine Ukoniq® (Umbralisib) is Withdrawn due to Safety Concerns. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-approval-lymphoma-medicine-ukoniq-umbralisib-withdrawn-due-safety-concerns. Issued 06/01/2022. Last accessed 12/19/2022.

[4] U.S. FDA. FDA Warns about Possible Increased Risk of Death and Serious Side Effects with Cancer Drug Copiktra® (Duvelisib). Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-possible-increased-risk-death-and-serious-side-effects-cancer-drug-copiktra. Issued 06/30/2022. Last Accessed 12/19/2022

[5] U.S. FDA. FDA Investigates Risk of Severe Hypocalcemia in Patients on Dialysis Receiving Osteoporosis Medicine Prolia®. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-investigating-risk-severe-hypocalcemia-patients-dialysis-receiving-osteoporosis-medicine-prolia. Issued 11/22/2022. Last Accessed 12/20/2022.

Appendix C

Fiscal Year 2022 Annual Review of Gonadotropin-Releasing Hormone (GnRH) Medications

Oklahoma Health Care Authority
January 2023

Current Prior Authorization Criteria

Gonadotropin-Releasing Hormone (GnRH) Agonist Medications		
Tier-1	**Tier-2**	**Tier-3**
histrelin (Supprelin® LA)		
leuprolide (Fensolvi®)		
leuprolide (Lupron Depot®)		
leuprolide (Lupron Depot-Ped®)		
nafarelin (Synarel®)		
triptorelin (Triptodur®)		

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).

Lupaneta Pack® [Leuprolide Acetate for Depot Suspension (3.75mg for Intramuscular Injection) and Norethindrone Acetate Tablet (5mg for Oral Administration)] Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the individual components must be provided.

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

1. An FDA approved diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women; or
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); 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®, a combined cumulative maximum treatment duration of 24 months will apply.

Oriahnn® (Elagolix/Estradiol/Norethindrone and Elagolix) Approval Criteria:

1. An FDA approved diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) 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 Oriahnn®; and
   h. Prescriber must verify the member will not use Oriahnn® concomitantly with an organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine, gemfibrozil); 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); 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 patient-specific, clinically significant reason why the member cannot use leuprolide depot formulations available without prior authorization must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use Myfembree® (relugolix/estradiol/norethindrone) must be provided; and
9. A quantity limit of 56 tablets per 28 days will apply; and
10. Lifetime approval duration will be limited to a maximum of 24 months. For members previously approved for Myfembree®, a combined cumulative maximum treatment duration of 24 months will apply.

Orilissa® (Elagolix) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe pain associated with endometriosis; and
2. Member must be 18 years of age or older; and
3. Member must not have known osteoporosis; and
4. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
5. Female members of reproductive potential must be willing to use effective non-hormonal contraception during treatment with Orilissa® and for at least 1 week after discontinuing treatment; and
6. Member must not have severe hepatic impairment (Child-Pugh C); and
7. Member must not be taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine, gemfibrozil); and
8. Orilissa® must be prescribed by, or in consultation with, an obstetrician/gynecologist or a specialist with expertise in the treatment of endometriosis; and
9. 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 must be provided; and
10. 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 must be provided; and
11. Dosing and lifetime approval duration will be limited based on the following:
    a. Coexisting condition of moderate hepatic impairment (Child-Pugh B):
        i. 150mg once daily for a maximum of 6 months; or
    b. Normal liver function or mild hepatic impairment (Child-Pugh A):
        i. 150mg once daily for a maximum of 24 months; or
        ii. 200mg twice daily for a maximum of 6 months.

Utilization of GnRH 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	137	313	$1,910,213.86	$6,102.92	$82.37	4,333	23,191
2022	213	527	$2,732,003.11	$5,184.07	$79.83	8,866	34,224
% Change	**55.50%**	**68.40%**	**43.00%**	**-15.10%**	**-3.10%**	**104.60%**	**47.60%**
Change	**76**	**214**	**$821,789.25**	**-$918.85**	**-$2.54**	**4,533**	**11,033**

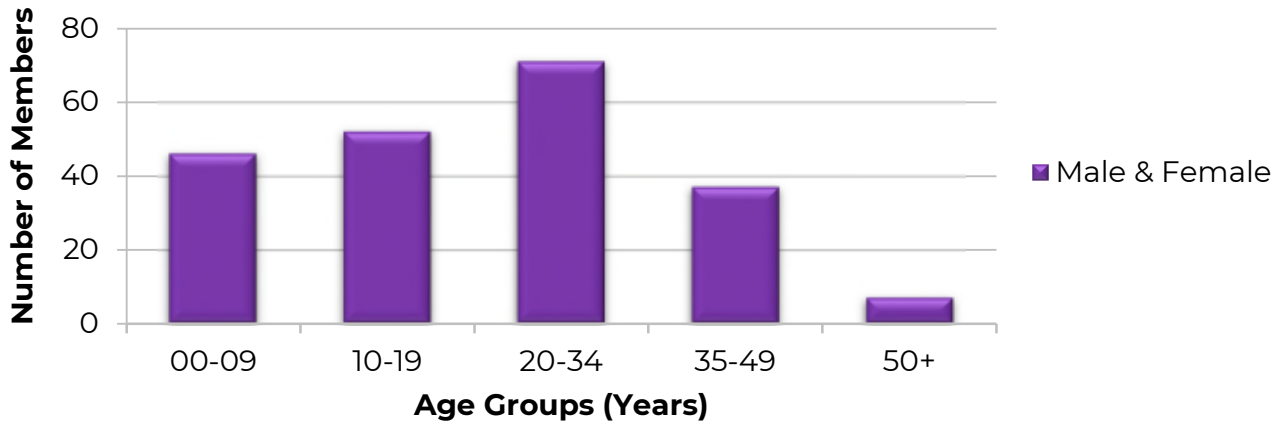
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

Comparison of Fiscal Years: Medical Claims

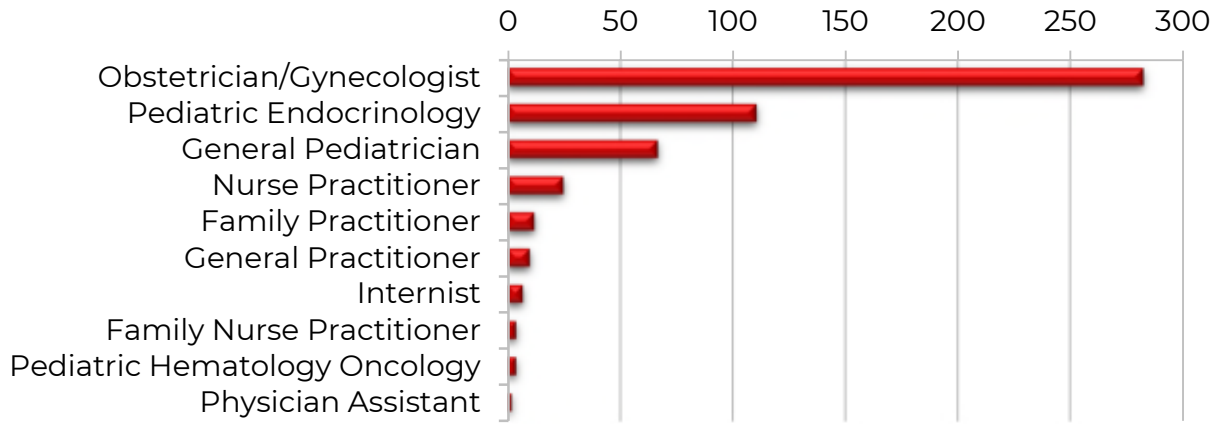
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Total Units
2021	90	231	$187,591.29	$812.08	455
2022	137	364	$361,206.58	$992.33	842
% Change	**52.22%**	**57.58%**	**92.55%**	**22.20%**	**85.05%**
Change	**47**	**133**	**$173,615.29**	**$180.25**	**387**

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

Demographics of Members Utilizing GnRH Medications: Pharmacy Claims



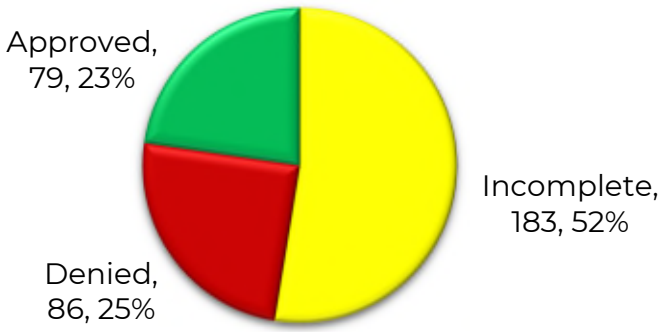
Top Prescriber Specialties of GnRH Medications by Number of Claims: Pharmacy Claims



Prior Authorization of GnRH Medications

There were 348 prior authorization requests submitted for GnRH 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]

Anticipated Patent Expiration(s):

- Fensolvi® (leuprolide acetate injection): October 2023
- Supprelin® LA (histrelin implant): June 2026
- Triptodur® (triptorelin injection): June 2029
- Oriahnn® (elagolix/estradiol/norethindrone and elagolix capsule): March 2034
- Orilissa® (elagolix tablet): September 2036
- Myfembree® (relugolix/estradiol/norethindrone tablet): September 2037

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.

Utilization Details of GnRH Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
GONADOTROPIN-RELEASING HORMONE (GnRH) AGONIST PRODUCTS						
TRIPTODUR SUS 22.5MG	81	52	$1,436,863.39	$17,739.05	1.56	52.59%
LUPRON DEPOT INJ 11.25MG	53	35	$235,680.97	$4,446.81	1.51	8.63%
LUPRON DEP-PED INJ 30MG	43	22	$446,863.36	$10,392.17	1.95	16.36%
LUPRON DEPOT INJ 3.75MG	41	18	$56,114.93	$1,368.66	2.28	2.05%
LUPRON DEP-PED INJ 11.25MG	20	11	$196,009.34	$9,800.47	1.82	7.17%
LUPRON DEP-PED INJ 15MG	17	3	$16,052.24	$944.25	5.67	0.59%
LUPRON DEP-PED INJ 7.5MG	10	2	$18,219.19	$1,821.92	5	0.67%
LUPRON DEPOT INJ 22.5MG	10	6	$53,096.34	$5,309.63	1.67	1.94%
LUPRON DEP-PED INJ 11.25MG	8	2	$26,005.92	$3,250.74	4	0.95%
LUPRON DEPOT INJ 7.5MG	6	2	$10,551.54	$1,758.59	3	0.39%
SUPPRELIN LA KIT 50MG	1	1	$1,497.39	$1,497.39	1	0.05%
SUBTOTAL	**290**	**147***	**$2,496,954.61**	**$8,610.19**	**1.97**	**91.40%**
GnRH ANTAGONIST PRODUCTS						
ORILISSA TAB 150MG	167	40	$165,140.22	$988.86	4.18	6.04%
ORILISSA TAB 200MG	50	18	$49,738.69	$994.77	2.78	1.82%
ORIAHNN CAP 300-1-0.5MG & 300MG	19	8	$19,187.64	$1,009.88	2.38	0.70%
MYFEMBREE TAB 40-1-0.5MG	1	1	$981.95	$981.95	1	0.04%
SUBTOTAL	**237**	**67***	**$235,048.50**	**$991.77**	**3.54**	**8.60%**
TOTAL	**527**	**213***	**$2,732,003.11**	**$5,184.07**	**2.47**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
J9217 LEUPROLIDE DEPOT 7.5MG	219	86	$102,103.71	$466.23
J1950 LEUPROLIDE DEPOT 3.75MG	133	39	$258,557.01	$1,944.04
J9218 LEUPROLIDE INJ 1MG	12	12	$545.86	$45.49
TOTAL	**364**	**137**	**$361,206.58**	**$992.33**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2022. Last accessed 12/20/2022.

[2] 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 12/20/2022.

[3] 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 12/20/2022.

[4] 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 D

Fiscal Year 2022 Annual Review of Amyotrophic Lateral Sclerosis (ALS) Medications and 30-day Notice to Prior Authorize Relyvrio™ (Sodium Phenylbutyrate/ Taurursodiol)

Oklahoma Health Care Authority
January 2023

Current Prior Authorization Criteria

Exservan™ (Riluzole Oral Film) and Tiglutik® (Riluzole Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of amyotrophic lateral sclerosis (ALS); and
2. A patient-specific, clinically significant reason why the member cannot use riluzole tablets, even when tablets are crushed, must be provided; and
3. The following quantity limits apply:
    a. A quantity limit of 2 films per day or 60 films per 30 days will apply for Exservan™; or
    b. A quantity limit of 20mL per day or 600mL per 30 days will apply for Tiglutik®.

Radicava® (Edaravone) 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.

Utilization of ALS Medications: Fiscal Year 2022

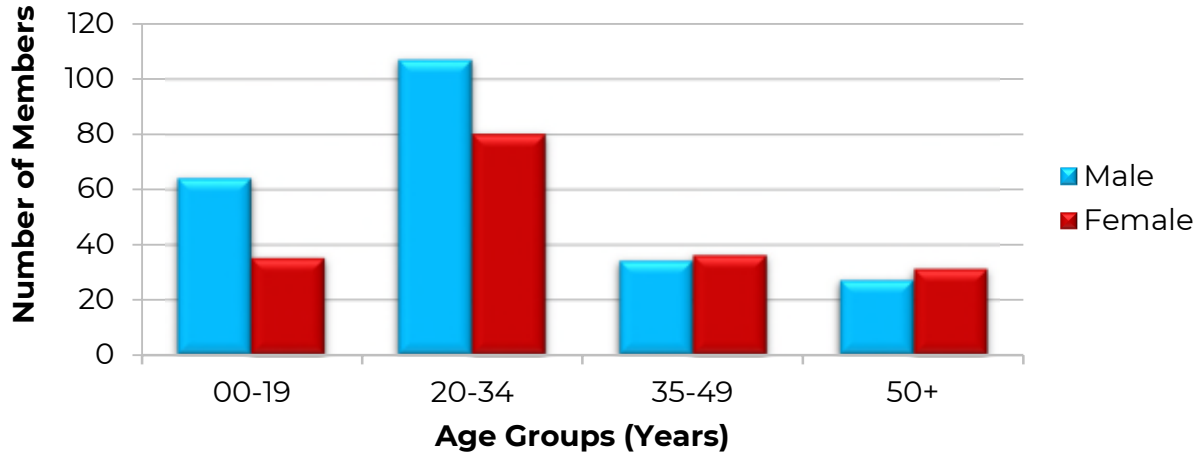
Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	4	31	$139,378.79	$4,496.09	$178.23	25,108	782
2022	414	1,470	$210,808.27	$143.41	$5.11	123,383	41,288
% Change	**10,250.00%**	**4,641.90%**	**51.20%**	**-96.80%**	**-97.10%**	**391.40%**	**5,179.80%**
Change	**410**	**1,439**	**$71,429.48**	**-$4,352.68**	**-$173.12**	**98,275**	**40,506**

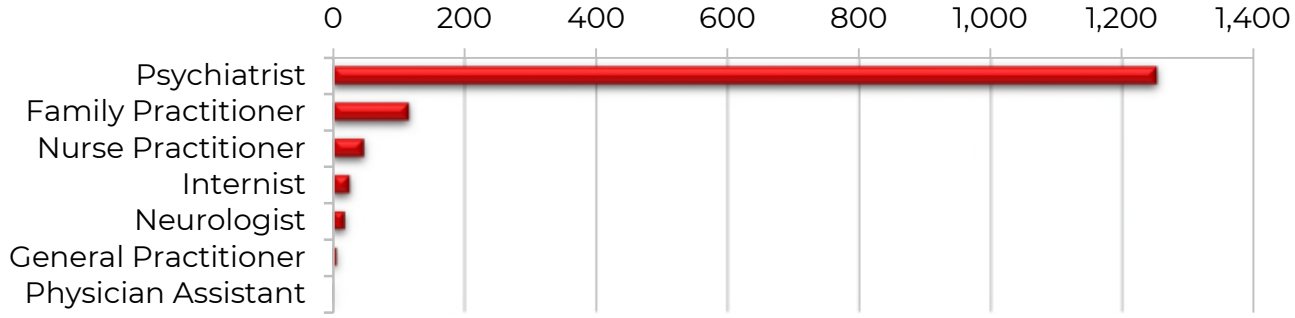
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022
Utilization data includes generic riluzole 50mg tablets used for all diagnoses and does not differentiate between use for ALS and other diagnoses. Riluzole 50mg tablets do not require prior authorization.

- There were no medical claims for Radicava® (edaravone) during fiscal year 2022.

Demographics of Members Utilizing ALS Medications

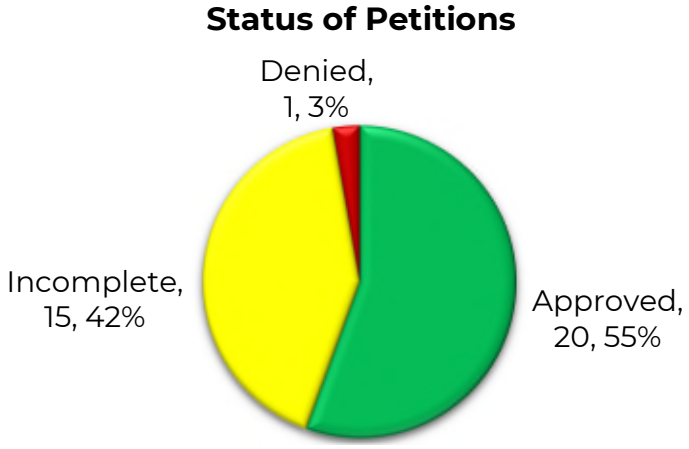


Top Prescriber Specialties of ALS Medications by Number of Claims



Prior Authorization of ALS Medications

There were 36 prior authorization requests submitted for 28 unique members for ALS medications 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]

Anticipated Patent and/or Exclusivity Expiration(s):

- Exservan™ (riluzole oral film): April 2024
- Radicava® [edaravone intravenous (IV) infusion]: May 2024
- Tiglutik® (riluzole oral suspension): March 2029
- Relyvrio™ (sodium phenylbutyrate/taurursodiol powder for oral suspension): December 2033
- Radicava ORS® (edaravone oral suspension): November 2039

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 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.

Pipeline:

- **NurOwn®:** BrainStorm Cell Therapeutics is developing NurOwn® for the treatment of ALS. NurOwn® cells are autologous, bone marrow-derived mesenchymal stem cells (MSCs) that have been converted ex vivo into MSCs which secrete high levels of neurotrophic factors (NTFs). It is expected that these MSC-NTF cells can deliver NTFs and immunomodulatory cytokines directly to sites of damage to ultimately slow or stabilize disease progression in ALS. Results from a Phase 3 study were previously announced, indicating NurOwn® did not meet its primary efficacy endpoint. Following new study analyses, a Biologics License Application (BLA) was submitted to the FDA for NurOwn®; however, in November 2022, BrainStorm received a refusal to file letter from the FDA regarding the BLA submission. BrainStorm has submitted a Type A Meeting Request to the FDA to discuss the refusal to file letter.
- **Tofersen:** Biogen is developing tofersen for the treatment of superoxide dismutase 1 (SOD1) ALS, a rare genetic form of ALS. The SOD1 mutation may be responsible for approximately 2% of all ALS cases. Tofersen is an antisense oligonucleotide that binds to SOD1 mRNA, leading to its degradation and reduced synthesis of SOD1 protein. In September 2022, results from the Phase 3 VALOR study and its open-label extension period were published in *The New England Journal of Medicine*. The primary endpoint, change from baseline to week 28 in the ALS Functional Rating Scale-Revised (ALSFRS-R), was not met in the study. However, there were trends observed showing reduced disease progression across secondary and exploratory endpoints. In July 2022, the FDA accepted a New Drug Application (NDA) for tofersen for the treatment of SOD1 ALS. In October 2022, Biogen announced a 3-month extension for reviewing the tofersen NDA. The current Prescription Drug User Fee Act (PDUFA) date is April 25, 2023.

Relyvrio™ (Sodium Phenylbutyrate/Taurursodiol) Product Summary[9,10]

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 mechanism by which sodium phenylbutyrate/ taurursodiol exerts its therapeutic effects in patients with ALS is unknown. Although the specific mechanism of action of Relyvrio™ in patients with ALS is unknown, 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 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 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:

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.

Utilization Details of ALS Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
RILUZOLE TAB 50MG	1,457	413	$55,039.04	$37.78	3.53	26.11%
RADICAVA INJ 30MG	13	1	$155,769.23	$11,982.25	13	73.89%
TOTAL	**1,470**	**414***	**$210,808.27**	**$143.41**	**3.55**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
INJ = injection; TAB = tablet
Fiscal Year 2022 = 07/01/2021 to 06/30/2022
Utilization data includes generic riluzole 50mg tablets used for all diagnoses and does not differentiate between use for ALS and other diagnoses. Riluzole 50mg tablets do not require prior authorization.

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2022. Last Accessed 12/09/2022.
[2] 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 12/12/2022.
[3] 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 12/12/2022.
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[5] BrainStorm Cell Therapeutics, Inc. BrainStorm Cell Therapeutics Receives Refusal to File Letter from FDA for its New Biologics License Application for NurOwn® for the Treatment of ALS. Available online at: https://ir.brainstorm-cell.com/2022-11-10-BrainStorm-Cell-Therapeutics-Receives-Refusal-to-File-Letter-from-FDA-for-its-New-Biologics-License-Application-for-NurOwn-for-the-treatment-of-ALS. Issued 11/10/2022. Last accessed 12/22/2022.
[6] BrainStorm Cell Therapeutics, Inc. BrainStorm Cell Therapeutics Submits Type A Meeting Request to U.S. Food and Drug Administration. Available online at: https://ir.brainstorm-cell.com/2022-12-12-BrainStorm-Cell-Therapeutics-Submits-Type-A-Meeting-Request-to-U-S-Food-and-Drug-Administration. Issued 12/12/2022. Last accessed 12/22/2022.
[7] Biogen Inc. The New England Journal of Medicine Publishes Pivotal Tofersen Data that Show Benefits in Rare, Genetic Form of ALS. Available online at: https://investors.biogen.com/news-releases/news-release-details/new-england-journal-medicine-publishes-pivotal-tofersen-data. Issued 09/21/2022. Last accessed 12/22/2022.
[8] Biogen Inc. Biogen Announces FDA's 3-Month Extension of Review Period for the New Drug Application for Tofersen. Available online at: https://investors.biogen.com/news-releases/news-release-details/biogen-announces-fdas-3-month-extension-review-period-new-drug. Issued 10/17/2022. Last accessed 12/22/2022.
[9] 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 12/12/2022.
[10] 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 E

Fiscal Year 2022 Annual Review of Antihyperlipidemics

Oklahoma Health Care Authority
January 2023

Current Prior Authorization Criteria

Evkeeza® (Evinacumab-dgnb) Approval Criteria:

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

compliance will be checked at that time and every 6 months thereafter for continued approval.

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

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
cap = capsule; DR = delayed release; tab = tablet

Fibric Acid Derivative Medications Tier-2 Approval Criteria:

1. Laboratory documented failure with a Tier-1 medication after a 6-month trial; or
2. Documented adverse drug effect, drug interaction, or contraindication to all Tier-1 medication(s); or
3. Prior stabilization on the Tier-2 medication documented within the last 100 days.

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. 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. An untreated LDL >500mg/dL and triglycerides <300mg/dL and at least 1 of the following:
        i. Documentation that both parents have untreated LDL >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 Repatha® (evolocumab) at least 12 weeks in duration; and
5. Member requires additional lowering of LDL-cholesterol (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.

Leqvio® (Inclisiran) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
      i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing; or
      ii. Both of the following:
         1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
         2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
      iii. Dutch Lipid Clinic Network Criteria score of >8; or
   b. Established atherosclerotic cardiovascular disease (ASCVD); and
      i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; and
2. Member must be 18 years of age or older; and
3. Documented trial of all of the following for at least 12 weeks in duration each:
   a. High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or maximally tolerated statin therapy; and
   b. Ezetimibe; and
   c. Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Praluent®, Repatha®); and
4. Members with statin intolerance must meet 1 of the following:
   a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
   b. An FDA labeled contraindication to all statins; or

    c. Documented intolerance to at least 2 different statins at lower doses (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C must be provided); and
6. Leqvio® must be administered by a health care professional. Approvals will not be granted for self-administration; and
    a. Prior authorization requests must indicate how Leqvio® will be administered (e.g., prescriber, pharmacist, home health care provider); and
        i. Leqvio® must be shipped to the facility where the member is scheduled to receive treatment; or
        ii. Prescriber must verify the member has been counseled on the proper storage of Leqvio®; and
7. Initial approvals will be for the duration of 6 months. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of this medication, and compliance will be checked at that time and every 6 months thereafter for continued approval.

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

1. An FDA approved indication as an adjunct to diet and maximally tolerated statin therapy for the treatment of 1 of the following:
    a. Heterozygous familial hypercholesterolemia (HeFH) as confirmed by 1 of the following:
        i. Documented functional mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality via genetic testing; or
        ii. Both of the following:
            1. Pre-treatment total cholesterol >290mg/dL or LDL-cholesterol (LDL-C) >190mg/dL; and
            2. History of tendon xanthomas in either the member, first degree relative, or second degree relative; or
        iii. Dutch Lipid Clinic Network Criteria score of >8; or
    b. Established atherosclerotic cardiovascular disease (ASCVD); and
        i. Supporting diagnoses/conditions and dates of occurrence signifying established ASCVD; and
2. Member must be 18 years of age or older; and

3. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
    a. LDL-C levels should be included following at least 4 weeks of treatment; and
    b. Member must not be taking simvastatin at doses >20mg or pravastatin at doses >40mg due to drug interactions with Nexletol® and Nexlizet®; and
4. Members with statin intolerance must meet 1 of the following:
    a. Creatine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
5. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
6. A quantity limit of 30 tablets per 30 days will apply; and
7. Initial approvals will be for the duration of 3 months, after which time compliance and recent LDL-C levels to demonstrate the effectiveness of this medication will be required for continued approval. Subsequent approvals will be for the duration of 1 year.

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

1. An FDA approved indication of 1 of the following:
    a. Severe hypertriglyceridemia; and
        i. Laboratory documentation of severe hypertriglyceridemia (fasting triglycerides ≥500mg/dL) and controlled diabetes (fasting glucose <150mg/dL at the time of triglycerides measurement and HgA1c <7.5%); and
        ii. Previous failure with fibric acid medications; and
        iii. Use of Vascepa® (icosapent ethyl) or Epanova® (omega-3-carboxylic acids) requires a previous failure of or a patient-specific, clinically significant reason why the member cannot use omega-3-acid ethyl esters (generic Lovaza®), which is available without prior authorization; or
    b. For the use of Vascepa® (icosapent ethyl) as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride levels; and

i. Member must be on a stable dose of maximally tolerated statin therapy for at least 4 weeks (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
ii. Laboratory documentation of fasting triglycerides ≥150mg/dL; and
iii. Member must have 1 of the following:
1. Established cardiovascular disease; or
2. Diabetes mellitus and ≥2 additional risk factors for cardiovascular disease; and

2. Use of Vascepa® 0.5 gram requires a patient-specific, clinically significant reason why the member cannot use Vascepa® 1 gram.

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

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

    i. Member's untreated LDL-C level must be ≥190mg/dL; and
    ii. Current LDL-C level is ≥100mg/dL; and
2. For the use of Repatha® in members with HeFH or HoFH, member must be 10 years of age or older; and
3. For the use of Repatha® for FDA approved indications other than HeFH or HoFH or for the use of Praluent® for all FDA approved indications, the member must be 18 years of age or older; and
4. Member must be on high dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40mg) or on maximally tolerated statin therapy; and
    a. Statin trials must be at least 12 weeks in duration (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
    b. LDL-C levels should be included following at least 12 weeks of treatment; and
5. Members with statin intolerance must meet 1 of the following:
    a. Creatinine kinase (CK) labs verifying rhabdomyolysis; or
    b. An FDA labeled contraindication to all statins; or
    c. Documented intolerance to at least 2 different lower dose statins (dosing, dates, duration of treatment, and reason for discontinuation must be provided); or
    d. Documented intolerance to at least 2 different statins at intermittent dosing (dosing, dates, duration of treatment, and reason for discontinuation must be provided); and
6. Member must have a recent trial with a statin with ezetimibe, or a recent trial of ezetimibe without a statin for members with a documented statin intolerance, or a patient-specific, clinically significant reason why ezetimibe is not appropriate must be provided; and
7. Member requires additional lowering of LDL-C (baseline, current, and goal LDL-C levels must be provided); and
8. Prescriber must verify that member has been counseled on appropriate use, storage of the medication, and administration technique; and
9. A quantity limit of 2 syringes or pens per 28 days will apply for Praluent®. A quantity limit of 2 syringes or auto-injectors per 28 days will apply for Repatha® 140mg and a quantity limit of 1 auto-injector per 28 days will apply for Repatha® 420mg. Requests for the Repatha® 420mg dose will not be approved for multiple 140mg syringes or auto-injectors, but instead members need to use (1) 420mg auto-injector; and
10. Initial approvals will be for the duration of 3 months. Continued authorization at that time will require the prescriber to provide recent LDL-C levels to demonstrate the effectiveness of the medication, and

compliance will be checked at that time and every 6 months thereafter for continued approval.

Statin Medications and Ezetimibe	
Tier-1	**Special PA**
atorvastatin (Lipitor®)	fluvastatin (Lescol® & Lescol® XL)
ezetimibe (Zetia®)	lovastatin ER (Altoprev®)
lovastatin (Mevacor®)	pitavastatin (Livalo®)
pravastatin (Pravachol®)	pitavastatin magnesium (Zypitamag®)
rosuvastatin (Crestor®)	rosuvastatin capsule (Ezallor Sprinkle™)
simvastatin (Zocor®)	simvastatin suspension (FloLipid®)
	simvastatin/ezetimibe (Vytorin®)

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).
ER = extended-release; PA = prior authorization

Statin Medications Special Prior Authorization (PA) Approval Criteria:

1. Use of any Special PA medication will require a patient-specific, clinically significant reason why lower tiered medications with similar or higher low-density lipoprotein-cholesterol (LDL-C) reduction cannot be used; and
2. Use of FloLipid® (simvastatin oral suspension) will require a patient specific, clinically significant reason why the member cannot use simvastatin oral tablets, even when the tablets are crushed; and
3. Use of Ezallor Sprinkle™ (rosuvastatin capsule) will require a patient-specific, clinically significant reason why the member cannot use rosuvastatin oral tablets, even when the tablets are crushed.

Welchol® (Colesevelam) Chewable Bar Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use other formulations of colesevelam, including oral tablets and packets for oral suspension, which are available without prior authorization, must be provided; and
3. A quantity limit of 30 chewable bars per 30 days will apply.

Utilization of Antihyperlipidemics: Fiscal Year 2022

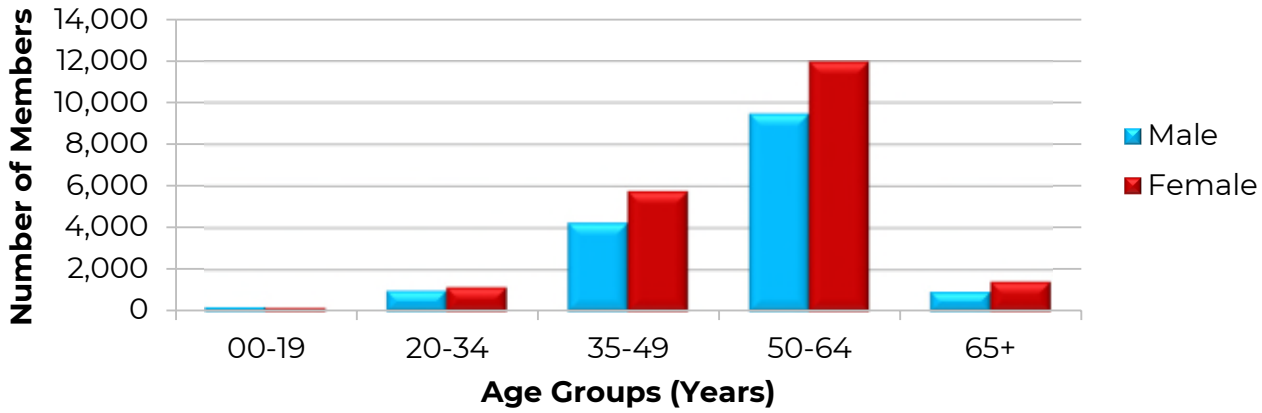
Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	19,527	72,917	$1,196,038.17	$16.40	$0.28	4,444,752	4,238,307
2022	36,373	117,616	$1,871,573.54	$15.91	$0.26	7,532,472	7,214,766
% Change	**86.3%**	**61.3%**	**56.5%**	**-3%**	**-7.1%**	**69.5%**	**70.2%**
Change	**16,846**	**44,699**	**$675,535.37**	**-$0.49**	**-$0.02**	**3,087,720**	**2,976,459**

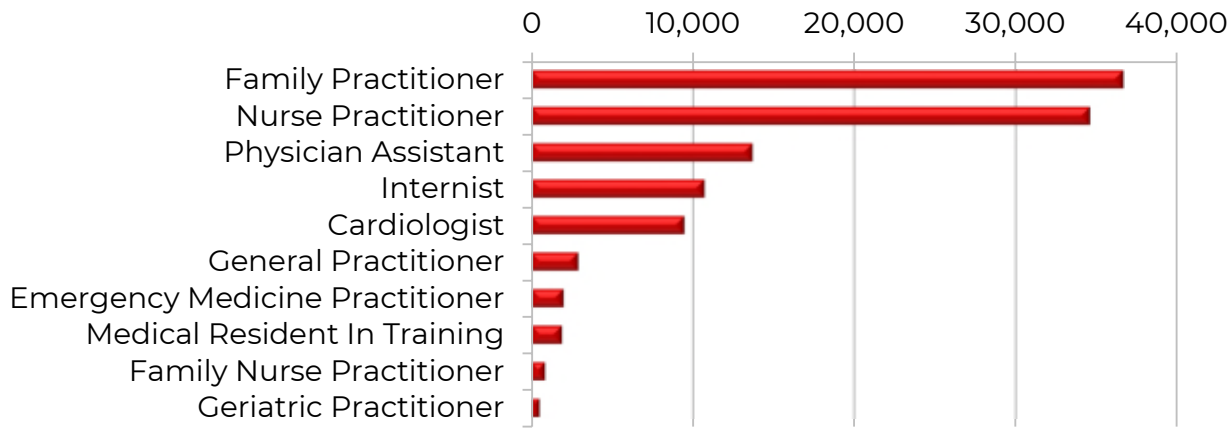
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022

- There were no SoonerCare paid medical claims for antihyperlipidemics during fiscal year 2022 (07/01/2021 to 06/30/2022).
- The antihyperlipidemics 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 antihyperlipidemics: $175,048.86[Δ]

Demographics of Members Utilizing Antihyperlipidemics



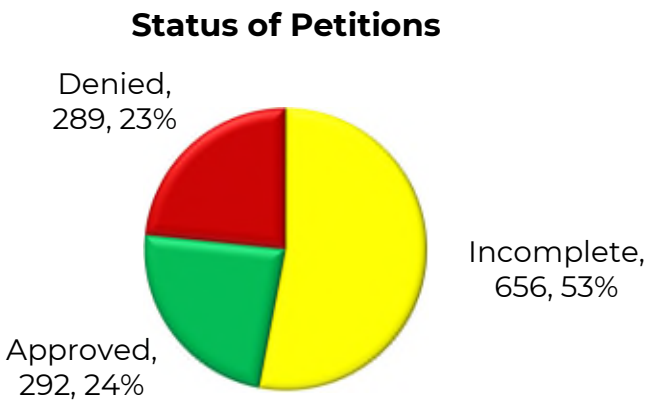
Top Prescriber Specialties of Antihyperlipidemics by Number of Claims



Prior Authorization of Antihyperlipidemics

There were 1,237 prior authorization requests submitted for antihyperlipidemics during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

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



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

Anticipated Patent Expiration(s):

- Livalo® (pitavastatin calcium tablet): August 2024
- Nexletol® (bempedoic acid tablet): December 2025
- Juxtapid® (lomitapide capsule): August 2027
- FloLipid® (simvastatin oral suspension): February 2030
- Zypitamag® (pitavastatin magnesium tablet): January 2031
- Epanova® (omega-3-carboxylic acids capsule): January 2033
- Antara® (fenofibrate micronized capsule): May 2033
- Vascepa® (icosapent ethyl capsule): June 2033
- Ezallor™ Sprinkle (rosuvastatin capsule): February 2036
- Nexlizet® (bempedoic acid/ezetimibe tablet): March 2036

Guideline Update(s):

- **American Diabetes Association (ADA) Guideline Update:** The ADA has issued the annual ADA Standards of Care in Diabetes – 2023 with new targets in cardiovascular disease (CVD) and risk management, including new lipid targets. For people with diabetes 40 to 75 years of age at increased cardiovascular (CV) risk, including those with 1 or more atherosclerotic risk factors, high-intensity statin therapy is recommended to reduce low-density lipoprotein cholesterol (LDL-C) by ≥50% from baseline and to a target of <70mg/dL, in contrast to the previous target of <100mg/dL. In order to achieve that goal, it is advised to consider adding ezetimibe or a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor to maximally tolerated statin therapy. For people with diabetes 40 to 75 years of age who have established CVD, treatment with high-intensity statin therapy is recommended with the target of ≥50% reduction from baseline and a target LDL-C level of ≤55mg/dL, in contrast to the previous target of <70mg/dL, and a stronger recommendation for ezetimibe or a PCSK9 inhibitor added to maximally tolerated statins. For those with diabetes older than 75 years of age and already on statins, they should continue

taking them. For those not already on a statin, it may be reasonable to initiate moderate-intensity statin therapy after discussion of the benefits and risks.

News:

- **August 2022:** The U.S. Preventive Services Task Force (USPSTF) commissioned a review of the evidence on the benefits and harms of statins for reducing CVD-related morbidity or mortality or all-cause mortality. The USPSTF concluded with moderate certainty that statin use for the prevention of CVD events and all-cause mortality in adults 40 to 75 years of age with no history of CVD, who have 1 or more CVD risk factors, and an estimated 10-year CVD event risk of ≥10% has at least a moderate net benefit. For those with an estimated 10-year CVD event risk of 7.5% to <10%, statin use has at least a small net benefit. The USPSTF recommends that clinicians prescribe a statin for the primary prevention of CVD for adults 40 to 75 years of age who have 1 or more CVD risk factors and an estimated 10-year CVD risk of ≥10%, and for those adults with a 7.5% to<10% risk, they selectively offer a statin. The USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of initiating a statin for the primary prevention of CVD events and mortality in adults 75 years of age or older. These recommendations are consistent with the 2016 USPSTF recommendations.
- **November 2022:** Regeneron Pharmaceuticals announced the U.S. Food and Drug Administration (FDA) has accepted the supplemental Biologics License Application (sBLA) for Priority Review of Evkeeza® (evinacumab-dgnb) as an adjunct to other lipid-lowering therapies to treat children 5 to 11 years of age with homozygous familial hypercholesterolemia (HoFH). The sBLA is supported by data from a 3-part trial evaluating Evkeeza® in children 5 to 11 years of age with HoFH. Efficacy was assessed in 14 children enrolled in part B of the trial. Despite treatment with other lipid-lowering therapies, these children entered the trial with an average LDL-C level of 264mg/dL, more than twice the target of <110mg/dL for pediatric patients with HoFH. The trial met its primary endpoint, showing children who added Evkeeza® to other lipid-lowering therapies reduced their LDL-C by 48% at week 24 on average. Furthermore, 79% (n=11) saw their LDL-C reduced by at least half at 24 weeks following Evkeeza® treatment, with an average absolute reduction in LDL-C from baseline of 132mg/dL. Among 20 children evaluated for long-term safety across parts A, B, and C of the trial, the most common adverse events occurring in ≥15% of patients included COVID-19, pyrexia, headache, throat pain, upper abdominal pain, diarrhea, vomiting, fatigue, nasopharyngitis, rhinitis, and cough. Most reported adverse effects were mild or moderate, and none led to

study discontinuation. The safety profile of Evkeeza® observed in these patients was generally consistent to those seen in adults and pediatric patients 12 years of age and older. The Prescription Drug User Fee Act (PDUFA) date is March 30, 2023.

- **December 2022:** Esperion Therapeutics announced that the landmark "Cholesterol Lowering via Bempedoic Acid, an Adenosine Triphosphate Citrate Lyase (ACL) Inhibiting Regimen" (CLEAR) Outcomes trial met its primary endpoint, demonstrating statistically significant risk reduction in major adverse cardiovascular events (MACE) in patients treated with 180mg/day of bempedoic acid compared to placebo. This makes bempedoic acid the first ATP-citrate lyase inhibitor and first oral non-statin to meet this endpoint. CLEAR Outcomes is a Phase 3, event-driven, randomized, multicenter, double-blind, placebo-controlled trial designed to evaluate whether treatment with bempedoic acid reduces the risk of CV events in patients with or who are at high risk for CVD with documented statin intolerance and elevated fasting LDL-C levels ≥100mg/dL (2.6mmol/L). The study included over 14,000 patients at over 1,200 sites in 32 countries, however results have not been shared at this time. They anticipate submitting to regulatory authorities in 2023.

Pipeline

- **Lerodalcibep (LIB003):** Lerodalcibep is being developed as adjunct therapy for patients who are using dietary modifications, are on maximally tolerated statin therapy, and require additional LDL-C reduction. Lerodalcibep, a small volume, once monthly subcutaneous (sub-Q) injection, consists of a PCSK9-binding domain and human serum albumin (HSA) as the pharmacokinetic (PK) extender. In a Phase 2 trial of 12 weeks, lerodalcibep was shown to be safe and highly effective in statin treated patients, reducing LDL-C >75% and continuously suppressing PCSK9 >80% with monthly sub-Q dosing of 300mg. In a 52-week Phase 2b study, lerodalcibep maintained consistent LDL-C reductions, with good tolerability and safety. A large, comprehensive global Phase 3 program in over 2,500 patients is underway in patients with CVD, high CVD risk, heterozygous familial hypercholesterolemia (HeFH), and HoFH.

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. 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. An 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 colesevelam 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.

Utilization Details of Antihyperlipidemics: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
STATIN MEDICATIONS AND EZETIMIBE						
TIER-1 UTILIZATION						
ATORVASTATIN TAB 40MG	28,249	10,166	$363,349.50	$12.86	2.78	19.41%
ATORVASTATIN TAB 20MG	21,760	8,250	$274,030.75	$12.59	2.64	14.64%
ATORVASTATIN TAB 10MG	11,717	4,257	$135,489.39	$11.56	2.75	7.24%
ATORVASTATIN TAB 80MG	9,211	3,257	$145,449.13	$15.79	2.83	7.77%
ROSUVASTATIN TAB 20MG	4,522	1,800	$63,815.66	$14.11	2.51	3.41%
SIMVASTATIN TAB 20MG	4,329	1,425	$46,273.17	$10.69	3.04	2.47%
ROSUVASTATIN TAB 10MG	4,297	1,652	$55,822.50	$12.99	2.60	2.98%
PRAVASTATIN TAB 40MG	3,239	1,060	$48,890.56	$15.09	3.06	2.61%
SIMVASTATIN TAB 40MG	3,156	979	$36,501.81	$11.57	3.22	1.95%
ROSUVASTATIN TAB 40MG	3,025	1,142	$52,827.41	$17.46	2.65	2.82%
EZETIMIBE TAB 10MG	2,845	1,020	$47,191.77	$16.59	2.79	2.52%
PRAVASTATIN TAB 20MG	2,268	771	$29,238.09	$12.89	2.94	1.56%
SIMVASTATIN TAB 10MG	1,783	588	$18,919.28	$10.61	3.03	1.01%
ROSUVASTATIN TAB 5MG	1,568	651	$20,325.79	$12.96	2.41	1.09%
LOVASTATIN TAB 20MG	1,562	534	$19,039.65	$12.19	2.93	1.02%
PRAVASTATIN TAB 10MG	983	362	$13,821.67	$14.06	2.72	0.74%
LOVASTATIN TAB 40MG	840	282	$10,652.19	$12.68	2.98	0.57%
PRAVASTATIN TAB 80MG	567	187	$10,810.07	$19.07	3.03	0.58%
LOVASTATIN TAB 10MG	361	133	$4,437.02	$12.29	2.71	0.24%
SIMVASTATIN TAB 80MG	257	100	$3,684.65	$14.34	2.57	0.20%
SIMVASTATIN TAB 5MG	120	45	$1,391.19	$11.59	2.67	0.07%
TIER-1 SUBTOTAL	**106,659**	**38,661**	**$1,401,961.25**	**$13.14**	**2.76**	**74.90%**
SPECIAL PA UTILIZATION						
LIVALO TAB 4MG	25	7	$17,040.07	$681.60	3.57	0.91%
EZETIM/SIMVA TAB 10-40MG	8	2	$706.44	$88.31	4	0.04%
LIVALO TAB 2MG	6	3	$5,579.23	$929.87	2	0.30%
VYTORIN TAB 10-80MG	3	1	$3,199.47	$1,066.49	3	0.17%
EZETIM/SIMVA TAB 10-80MG	2	1	$157.87	$78.94	2	0.01%
EZETIM/SIMVA TAB 10-10MG	1	1	$118.10	$118.10	1	0.01%
LIVALO TAB 1MG	1	1	$925.61	$925.61	1	0.05%
TIER-2 SUBTOTAL	**46**	**16**	**$27,726.79**	**$602.76**	**2.88**	**1.49%**
STATINS AND EZETIMIBE TOTAL	**106,705**	**38,677**	**$1,429,688.04**	**$13.40**	**2.76**	**76.39%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FIBRIC ACID DERIVATIVE MEDICATIONS						
TIER-1 UTILIZATION						
FENOFIBRATE TAB 145MG	2,753	858	$48,317.09	$17.55	3.21	2.58%
GEMFIBROZIL TAB 600MG	1,978	612	$33,490.78	$16.93	3.23	1.79%
FENOFIBRATE TAB 160MG	1,621	492	$32,183.90	$19.85	3.29	1.72%
FENOFIBRATE TAB 48MG	731	240	$11,274.45	$15.42	3.05	0.60%
FENOFIBRATE TAB 54MG	603	195	$10,222.94	$16.95	3.09	0.55%
FENOFIBRATE CAP 134MG	358	116	$7,011.64	$19.59	3.09	0.37%
FENOFIBRIC CAP 45MG DR	149	29	$2,812.79	$18.88	5.14	0.15%
FENOFIBRATE CAP 67MG	71	23	$1,149.54	$16.19	3.09	0.06%
TIER-1 SUBTOTAL	**8,264**	**2,565**	**$146,463.13**	**$17.72**	**3.22**	**7.82%**
TIER-2 UTILIZATION						
FENOFIBRIC CAP 135MG DR	163	32	$7,968.03	$48.88	5.09	0.43%
FENOFIBRATE CAP 200MG	67	20	$1,589.55	$23.72	3.35	0.08%
FENOFIBRATE TAB 120MG	12	6	$10,612.33	$884.36	2	0.57%
FENOFIBRATE CAP 150MG	9	4	$3,843.48	$427.05	2.25	0.21%
FENOFIBRATE CAP 50MG	9	3	$983.04	$109.23	3	0.05%
FENOFIBRATE CAP 130MG	8	2	$995.34	$124.42	4	0.05%
FENOFIBRATE TAB 40MG	8	2	$4,067.81	$508.48	4	0.22%
TIER-2 SUBTOTAL	**276**	**69**	**$30,059.58**	**$108.91**	**4**	**1.61%**
FIBRIC ACID DERIVATIVE TOTAL	**8,540**	**2,634**	**$176,522.71**	**$20.67**	**3.24**	**9.43%**
OMEGA-3 FATTY ACID MEDICATIONS						
OMEGA-3-ACID CAP 1GM	1,505	535	$53,376.26	$35.47	2.81	2.85%
ICOSAPENT CAP 1GM	155	41	$37,921.46	$244.65	3.78	2.03%
VASCEPA CAP 1GM	119	29	$37,019.25	$311.09	4.10	1.98%
LOVAZA CAP 1GM	5	2	$60.80	$12.16	2.50	0.00%
OMEGA-3 FATTY ACIDS TOTAL	**1,784**	**607**	**$128,377.77**	**$71.96**	**2.94**	**6.86%**
COLESEVELAM MEDICATIONS						
COLESEVELAM TAB 625MG	382	119	$23,517.80	$61.56	3.21	1.26%
COLESEVELAM PAK 3.75GM	36	22	$32,389.22	$899.70	1.64	1.73%
COLESEVELAM MEDICATIONS TOTAL	**418**	**141**	**$55,907.02**	**$133.75**	**2.96**	**2.99%**
PCSK9 INHIBITORS						
REPATHA SURE INJ 140MG/ML	91	24	$44,650.88	$490.67	3.79	2.39%
PRALUENT INJ 75MG/ML	27	3	$12,352.54	$457.50	9	0.66%
REPATHA INJ 140MG/ML	23	7	$10,854.37	$471.93	3.29	0.58%
PRALUENT INJ 150MG/ML	23	5	$10,504.01	$456.70	4.60	0.56%
REPATHA PUSH INJ 420MG/3.5ML	5	2	$2,716.20	$543.24	2.50	0.15%
PCSK9 INHIBITORS TOTAL	**169**	**41**	**$81,078.00**	**$479.75**	**4.12**	**4.34%**
TOTAL	**117,616**	**36,373***	**$1,871,573.54**	**$15.91**	**2.79**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; EZETIM/SIMVA = ezetimibe/simvastatin; INJ = injection; PA = prior authorization; PAK = packet; PUSH = Pushtronex®; SURE = SureClick®; 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 12/2022. Last accessed 12/19/2022.
[2] Tucker, M. ADA Advises New BP, Lipid Targets for People with Diabetes. *Medscape*. Available online at: https://www.medscape.com/viewarticle/985482#vp_2. Issued 12/13/2022. Last accessed 12/19/2022.
[3] U.S. Preventive Services Task Force. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: U.S. Preventive Services Task Force Recommendation Statement. *JAMA* 2022; 328(8):746-753. doi:10.1001/jama.2022.13044.
[4] Regeneron Pharmaceuticals Inc. Evkeeza® (evinacumab-dgnb) sBLA for Children with Ultra-rare Inherited Form of High Cholesterol Accepted for FDA Priority Review. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/evkeeza-evinacumab-dgnb-sbla-for-children-with-ultra-rare-inherited-form-of-high-cholesterol-accepted-for-fda-priority-review-301690183.html. Issued 11/30/2022. Last accessed 12/16/2022.
[5] Esperion Therapeutics Inc. Esperion Announces CLEAR Cardiovascular Outcomes Trial of Nexletol® (Bempedoic Acid) Meets Primary Endpoint. Available online at: https://www.esperion.com/news-releases/news-release-details/esperion-announces-clear-cardiovascular-outcomes-trial-nexletolr. Issued 12/07/2022. Last accessed 12/16/2022.
[6] Esperion Therapeutics, Inc. Pipeline. Available online at: https://www.esperion.com/science/pipeline. Last accessed 12/16/2022.
[7] Lib Therapeutics. Pipeline. Available online at: https://www.libtherapeutics.com/#pipeline. Last accessed 12/16/2022.

Appendix F

Fiscal Year 2022 Annual Review of Ophthalmic Vascular Endothelial Growth Factor (VEGF) Inhibitor Medications and 30-Day Notice to Prior Authorize Vabysmo™ (Faricimab-svoa)

Oklahoma Health Care Authority
January 2023

Current Prior Authorization Criteria

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) 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.

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) must be provided; and
7. A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.

Utilization of Ophthalmic VEGF Inhibitor Medications: Fiscal Year 2022

There was no SoonerCare utilization of Byooviz™ (ranibizumab-nuna) or Susvimo™ (ranibizumab) during fiscal year 2022.

Prior Authorization of Ophthalmic VEGF Inhibitor Medications

There were no prior authorization requests submitted for Byooviz™ (ranibizumab-nuna) or Susvimo™ (ranibizumab) during fiscal year 2022.

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 an 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. 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 Vabsymo™. 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 Vabsymo™ 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 Vabsymo™ 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%) was conjunctival hemorrhage in patients receiving Vabsymo™

Efficacy:

- nAMD: The safety and efficacy of Vabsymo™ 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 Vabsymo™ 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:

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 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® with the following 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 with the following 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 must be provided; and
7. A quantity limit of one 100mg/0.1mL single-dose vial per 180 days will apply.

Utilization Details of Ophthalmic VEGF Inhibitor Medications: Fiscal Year 2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
AFLIBERCEPT INJ (J0178)	353	110*	$739,206.38	$2,094.07	3.21	94.94%
RANIBIZUMAB INJ (J2778)	29	12*	$39,407.50	$1,358.88	2.42	5.06%
TOTAL	**382⁺**	**122***	**$778,613.88**	**$2,038.26**	**3.13**	**100%**

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

[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 12/19/2022.
[2] Coherus BioSciences, Inc. FDA Approves Coherus' Cimerli™ (Ranibizumab-eqrn), as the First and Only Interchangeable Biosimilar to Lucentis® for All Five Indications, with 12 Months of Interchangeability Exclusivity. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2022/08/02/2490955/0/en/FDA-Approves-Coherus-CIMERLI-ranibizumab-eqrn-as-the-First-and-Only-Interchangeable-Biosimilar-to-Lucentis-for-All-Five-Indications-with-12-Months-of-Interchangeability-Exclusivity.html. Issued 08/02/2022. Last accessed 12/15/2022.
[3] Cimerli™ (Ranibizumab-eqrn) Injection Prescribing Information. Coherus Biosciences. Available online at: https://www.cimerli.com/pdf/prescribing-information.pdf. Last revised 08/2022. Last accessed 12/15/2022.
[4] Holz FG, Oleksy P, Ricci F, et al. Efficacy and Safety of Biosimilar FYB201 Compared with Ranibizumab in Neovascular Age-Related Macular Degeneration. *Ophthalmology* 2022; 129:54-63.
[5] Vabysmo™ (Faricimab-svoa) Injection Prescribing Information. Genentech. Available online at: https://www.gene.com/download/pdf/vabysmo_prescribing.pdf. Last revised 01/2022. Last accessed 12/15/2022.

Appendix G

Fiscal Year 2022 Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize Omlonti® (Omidenepag Isopropyl)

Oklahoma Health Care Authority
January 2023

Current Prior Authorization Criteria

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%)		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
Beta-Blockers		
brimonidine/timolol (Combigan® 0.2%/0.5%)	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%)		

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)		
Cholinergic Agonists/Cholinesterase Inhibitors		
echothiophate iodide (Phospholine Iodide® 0.125%)	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®)		
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 Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have documented, recent (within the last 120 days) trials with at least 3 Tier-1 medications for a minimum of 4 weeks duration each. Tier-1 trials may be from any pharmacologic class; or
3. Approvals may be granted if there is a documented adverse effect, drug interaction, or contraindication to all Tier-1 medications; or
4. Approvals may be granted if there is a unique FDA approved indication not covered by all Tier-1 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.

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.

Durysta® (Bimatoprost Implant) Approval Criteria:

1. An FDA approved indication to reduce intraocular pressure (IOP) in members with open-angle glaucoma (OAG) or ocular hypertension (OHT); and
2. Member must be 18 years of age or older; and
3. Durysta® must be prescribed by, or in consultation with, an ophthalmologist; and
4. A patient-specific, clinically significant reason why the member requires Durysta® and cannot utilize ophthalmic preparations, such as solution or suspension, to treat OAG or OHT must be provided; and
5. The affected eye has not received prior treatment with Durysta®; and
6. Member has no contraindications to Durysta®; and
7. A quantity limit of (1) Durysta® 10mcg implant per eye per lifetime will apply.

Utilization of Glaucoma Medications: Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

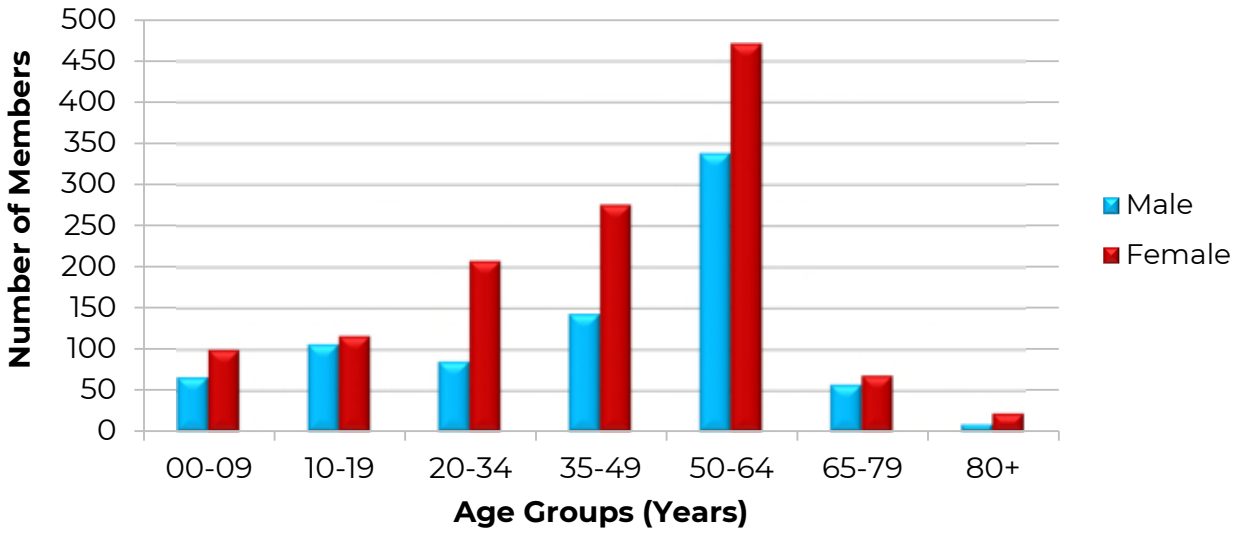
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1,413	6,650	$575,148.87	$86.49	$2.24	109,795	256,661
2022	2,062	8,681	$659,397.22	$75.96	$1.85	141,702	355,771
% Change	**45.9%**	**30.5%**	**14.6%**	**-12.2%**	**-17.4%**	**29.1%**	**38.6%**
Change	**649**	**2,031**	**$84,248.35**	**-$10.53**	**-$0.39**	**31,907**	**99,110**

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

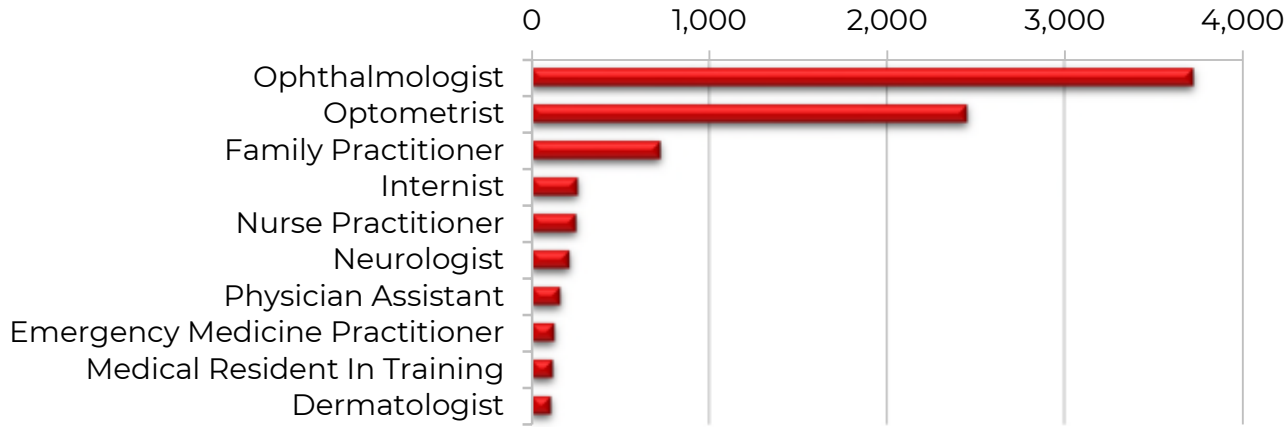
- There were no medical claims for Durysta® (bimatoprost implant) during fiscal year 2022.

- The glaucoma 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 glaucoma medications: $490,071.78[Δ]

Demographics of Members Utilizing Glaucoma Medications



Top Prescriber Specialties of Glaucoma Medications by Number of Claims



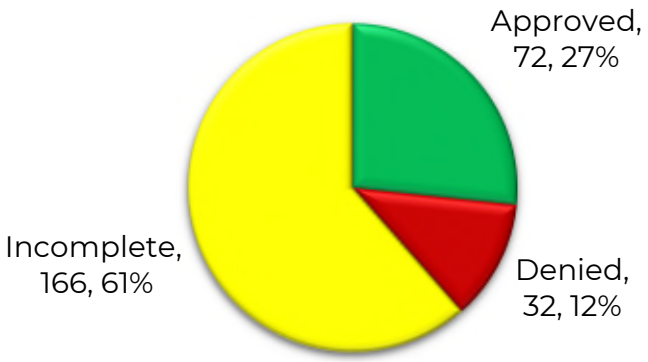
Prior Authorization of Glaucoma Medications

There were 270 prior authorization requests submitted for glaucoma medications during fiscal year 2022. Computer edits are in place to detect

[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.

lower tiered medications in a 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]

Anticipated Patent Expiration(s):

- Alphagan® P (brimonidine 0.1%): March 2024
- Vyzulta® (latanoprostene bunod 0.024%): October 2025
- Lumigan® (bimatoprost 0.01%): June 2027
- Zioptan® (tafluprost 0.0015%): May 2029
- Xelpros® (latanoprost 0.005%): September 2029
- Simbrinza® (brinzolamide/brimonidine 0.2%/1%): October 2030
- Rhopressa® (netarsudil 0.02%): March 2034
- Rocklatan® (netarsudil/latanoprost 0.02%/0.005%): March 2034
- Omlonti® (omidenepag isopropyl 0.002%): June 2035

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.

Pipeline:

- **PDP-716 (Brimonidine Tartrate 0.35%):** PDP-716 is a novel, once daily, ophthalmic suspension of brimonidine tartrate 0.35%. PDP-716 is developed using Sun Pharma Advanced Research Company's (SPARC's) proprietary TearAct™ technology. In May 2021, SPARC

reported positive results from a Phase 3 trial for PDP-716 for the treatment of OAG and OHT. The trial met its primary endpoint, demonstrating that PDP-716 dosed once daily is equivalent to Alphagan® P 0.1% dosed 3 times daily. In December 2022, Visiox Pharma announced the FDA accepted the New Drug Application (NDA) for PDP-716 for the treatment of glaucoma, including OAG and OHT. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 4, 2023. PDP-716 and the TearAct™ delivery technology were licensed by Visiox from SPARC.

- **iDose TR (G2TR Travoprost):** iDose TR is an intraocular implant containing travoprost. Two Phase 3 studies evaluated 2 models of the iDose TR implant (a fast release and a slow release version) versus twice daily timolol maleate 0.5% solution. Topline results from both trials, shared in September 2022, showed both versions of iDose TR reached the primary endpoint of non-inferiority to the comparator arm after 3 months. The results demonstrated favorable tolerability and safety profiles. Glaukos, the makers of iDose TR, plans to move forward with an NDA submission to the FDA for the slow release iDose TR model, with an expected FDA review and decision completed by the end of 2023.

Omlonti® (Omidenepag Isopropyl) Product Summary[8]

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 subjects 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 studies, but not in the SPECTRUM 3 study. However, in its review, the FDA noted that the SPECTRUM 4 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 category of the glaucoma medications PBPA category; 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 of the glaucoma medications PBPA category.

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%)		

Glaucoma Medications*		
Tier-1	**Tier-2**	**Special PA**
dorzolamide/timolol (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.

Utilization Details of Glaucoma Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
LATANOPROST SOL 0.005%	2,754	828	$44,084.79	3.33	$16.01	6.69%
TIMOLOL MAL SOL 0.5% OP	931	420	$16,658.30	2.22	$17.89	2.53%
DORZOL/TIMOL SOL 22.3-6.8MG/ML	877	308	$20,633.95	2.85	$23.53	3.13%
BRIMONIDINE SOL 0.2% OP	726	341	$11,620.12	2.13	$16.01	1.76%
ACETAZOLAMIDE TAB 250MG	572	180	$17,619.48	3.18	$30.80	2.67%
COMBIGAN SOL 0.2/0.5%	430	128	$124,549.04	3.36	$289.65	18.89%
ACETAZOLAMIDE CAP 500MG ER	425	151	$15,634.98	2.81	$36.79	2.37%
TRAVATAN Z DRO 0.004%	390	109	$106,092.99	3.58	$272.03	16.09%
DORZOLAMIDE SOL 2% OP	315	118	$7,646.36	5.67	$24.27	1.16%
LUMIGAN SOL 0.01%	217	65	$81,198.92	3.34	$374.19	12.31%
ALPHAGAN-P SOL 0.1%	205	69	$55,105.01	2.97	$268.80	8.36%
SIMBRINZA SUS 1-0.2%	148	51	$28,885.75	2.90	$195.17	4.38%
RHOPRESSA SOL 0.02%	106	37	$36,302.58	2.86	$342.48	5.51%
TIMOLOL MAL SOL 0.25% OP	90	37	$1,272.01	2.43	$14.13	0.19%
ACETAZOLAMIDE TAB 125MG	81	34	$1,875.10	2.38	$23.15	0.28%
BRIMO/TIMOL SOL 0.2/0.5%	73	42	$21,671.32	1.74	$296.87	3.29%
ROCKLATAN DRO 0.02%/0.005%	66	16	$20,869.91	4.13	$316.21	3.16%
BRINZOLAMIDE SUS 1%	29	13	$7,357.39	2.23	$253.70	1.12%
AZOPT SUS 1% OP	19	8	$6,635.91	2.38	$349.26	1.01%
ZIOPTAN DRO 0.0015%	11	3	$2,902.11	3.67	$263.83	0.44%
TRAVOPROST DRO 0.004%	1	1	$86.57	1	$86.57	0.01%
SUBTOTAL	**8,466**	**2,959**	**$628,702.59**	**2.86**	**$74.26**	**95.35%**
TIER-2 PRODUCTS						
TIMOLOL GEL SOL 0.5% OP	66	31	$4,372.00	2.13	$66.24	0.66%
DORZOL/TIMOL SOL 2%-0.5% PF	43	6	$5,371.83	7.17	$124.93	0.81%
BIMATOPROST SOL 0.03%	17	4	$1,825.79	4.25	$107.40	0.28%
PILOCARPINE SOL 4% OP	4	1	$289.89	4	$72.47	0.04%
PILOCARPINE SOL 1% OP	3	3	$195.52	1	$65.17	0.03%
SUBTOTAL	**133**	**45**	**$12,055.03**	**2.96**	**$90.64**	**1.82%**
SPECIAL PA PRODUCTS						
VYZULTA SOL 0.024%	33	4	$7,508.05	8.25	$227.52	1.14%
BRIMONIDINE SOL 0.15%	22	2	$4,507.86	11	$204.90	0.68%
TIMOLOL MAL SOL 0.5%	17	10	$3,549.31	1.70	$208.78	0.54%
METHAZOLAMIDE TAB 50MG	10	3	$3,074.38	3.33	$307.44	0.47%
SUBTOTAL	**82**	**19**	**$18,639.60**	**4.32**	**$227.31**	**2.83%**
TOTAL	**8,681**	**2,062***	**$659,397.22**	**2.87**	**$75.96**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BRIMO = brimonidine; CAP = capsule; DORZOL= dorzolamide; DRO = drop; ER = extended-release; MAL = maleate; OP = ophthalmic; PA = prior authorization; PF = preservative free; SOL = solution; SUS = suspension; TAB = tablet; TIMOL = timolol
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

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[5] Glaukos Corporation. Glaukos Announces Positive Topline Outcomes for Both Phase 3 Pivotal Trials of iDose TR, Achieving Primary Efficacy Endpoints and Demonstrating Favorable Tolerability and Safety Profiles. Available online at: https://investors.glaukos.com/investors/news/news-details/2022/Glaukos-Announces-Positive-Topline-Outcomes-for-Both-Phase-3-Pivotal-Trials-of-iDose-TR-Achieving-Primary-Efficacy-Endpoints-and-Demonstrating-Favorable-Tolerability-and-Safety-Profiles/default.aspx. Issued 09/07/2022. Last accessed 12/21/2022.
[6] Randomized Study Comparing Two Models of a Travoprost® Intraocular Implant to Timolol Maleate Ophthalmic Solution, 0.5%. *Clinicaltrials.gov*. Available online at: https://clinicaltrials.gov/ct2/show/NCT03519386. Last revised 04/30/2021. Last accessed 12/21/2022.
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Appendix H

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

Oklahoma Health Care Authority
January 2023

Introduction[1,2]

Tuberous sclerosis complex (TSC) is an autosomal dominant genetic rare disease that causes benign tumors to grow throughout the body. TSC affects 1 in 6,000 newborns in the United States, and approximately 40,000 to 80,000 people in the United States have TSC. Facial angiofibromas associated with TSC are facial skin lesions caused by aberrant activation of the mechanistic target of rapamycin (mTOR) pathway, and they are pinkish or reddish benign tumors that are typically located on the cheeks, nose, and chin. Without treatment, they may cause significant disfiguration, bleeding, pruritus, and erythema. Facial angiofibromas are seen in approximately 75-80% of patients with TSC. In April 2022, the U.S. Food and Drug Administration (FDA) approved the first topical treatment indicated for facial angiofibroma associated with TSC, Hyftor™ (sirolimus topical gel).

Market News and Updates[3,4]

Anticipated Exclusivity Expiration(s):

- Hyftor™ (sirolimus topical gel): March 2025

New FDA Approval(s):

- **March 2022:** The FDA approved Hyftor™ (sirolimus topical gel), an mTOR inhibitor immunosuppressant, for the treatment of facial angiofibroma associated with TSC in adults and children 6 years of age or older.

Hyftor™ (Sirolimus Topical Gel) Product Summary[5]

- **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 listed 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. 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.

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[1] National Organization for Rare Disorders (NORD). Tuberous Sclerosis. Available online at: https://rarediseases.org/rare-diseases/tuberous-sclerosis/. Last revised 2019. Last accessed 12/22/2022.
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[5] 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 12/22/2022.

Appendix I

Fiscal Year 2022 Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Pedmark® (Sodium Thiosulfate) and Vijoice® (Alpelisib)

Oklahoma Health Care Authority
January 2023

Current Prior Authorization Criteria

Azedra® (Iobenguane I-131) Approval Criteria [Pheochromocytoma or Paraganglioma (PPGL) Diagnosis]:

1. Adult and pediatric members 12 years of age and older; and
2. Iobenguane scan positive; and
3. Unresectable, locally advanced or metastatic pheochromocytoma or PPGL requiring systemic anticancer therapy.

Bynfezia Pen™ (Octreotide) Approval Criteria [Acromegaly Diagnosis]:

1. Diagnosis of acromegaly; and
2. Documentation of inadequate response to or inability to treat with surgical resection, pituitary irradiation, and bromocriptine mesylate or cabergoline at maximally tolerated doses; and
3. A patient-specific, clinically significant reason why the member cannot use other available short-acting injectable formulations of octreotide must be provided.

Bynfezia Pen™ (Octreotide) Approval Criteria [Metastatic Carcinoid Tumor or Vasoactive Intestinal Peptide-Secreting Tumors (VIPoma) Diagnosis]:

1. Diagnosis of advanced metastatic carcinoid tumor or VIPoma; and
2. Presence of severe diarrhea or flushing; and
3. A patient-specific, clinically significant reason why the member cannot use other available short-acting injectable formulations of octreotide must be provided.

Danyelza® (Naxitamab-gqgk) Approval Criteria [Neuroblastoma Diagnosis]:

1. Diagnosis of relapsed or refractory high-risk neuroblastoma in adult and pediatric members 1 year of age and older; and
2. Disease in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy (i.e., no progressive disease following most recent therapy); and
3. Must be given in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) according to package labeling (GM-CSF

dosed at 250mcg/m^2/day daily starting 5 days prior to Danyelza® therapy and 500mcg/m^2/day daily on days 1 to 5 of Danyelza® therapy); and
4. Prescriber must agree to provide the member appropriate premedication for pain management and neuropathic pain (e.g., oral opioids, gabapentin); and
5. Prescriber must agree to provide the member appropriate premedication for infusion-related reactions and nausea/vomiting including an intravenous (IV) corticosteroid, a histamine 1 (H_1) antagonist, an H_2 antagonist, acetaminophen, and an antiemetic.

Koselugo® (Selumetinib) Approval Criteria [Neurofibromatosis Type 1 (NF1) Diagnosis]:
1. Members must be 2 years of age or older; and
2. Diagnosis of NF1 with symptomatic, inoperable plexiform neurofibromas.

Lutathera® (Lutetium Lu-177 Dotatate) Approval Criteria [Gastroenteropancreatic Neuroendocrine Tumor (GEP-NET) Diagnosis]:
1. Diagnosis of progressive locoregional advanced disease or metastatic disease; and
2. Positive imaging of somatostatin receptor; and
3. Used as second-line or subsequent therapy following progression on octreotide or lanreotide; or
4. May be used first line for treatment of pheochromocytoma/ paraganglioma.

Rezurock® (Belumosudil) Approval Criteria [Graft-Versus-Host Disease (GVHD) Diagnosis]:
1. Diagnosis of chronic GVHD; and
2. Failure of at least 2 prior lines of systemic therapy; and
3. Member must be 12 years of age or older.

Turalio® (Pexidartinib) Approval Criteria [Soft Tissue Sarcoma – Pigmented Villonodular Synovitis (PVNS)/Tenosynovial Giant Cell Tumor (TGCT) Diagnosis]:
1. Member must not be a candidate for surgery; and
2. As a single agent.

Vitrakvi® (Larotrectinib) Approval Criteria [Solid Tumors with Neurotrophic Receptor Tyrosine Kinase (*NTRK*) Gene Fusion Diagnosis]:
1. Diagnosis of a solid tumor with a *NTRK* gene fusion without a known acquired resistance mutation; and
2. Disease is metastatic or surgical resection (or radioactive iodine refractory if thyroid carcinoma) is contraindicated; and

3. Documentation of no satisfactory alternative treatments or progression following acceptable alternative treatments.

Utilization of Miscellaneous Cancer 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	13	102	$1,247,053.58	$12,226.02	$427.95	10,683	2,914
2022	15	128	$1,561,155.69	$12,196.53	$409.97	13,944	3,808
% Change	**15.4%**	**25.5%**	**25.2%**	**-0.2%**	**-4.2%**	**30.5%**	**30.7%**
Change	**2**	**26**	**$314,102.11**	**-$29.49**	**-$17.98**	**3,261**	**894**

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	4	8	$351,788.00	$43,973.50	2

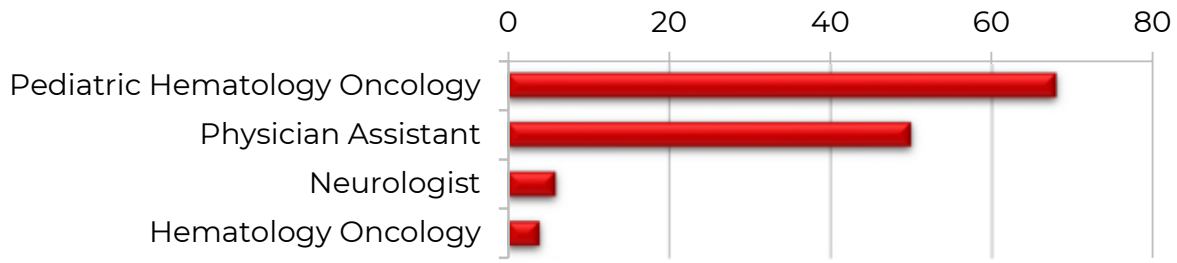
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

- The medical claims utilization data provided is for Lutathera® (lutetium Lu-177 dotatate). There was no SoonerCare medical claims utilization of Azedra® (iobenguane I-131) or Danyelza® (naxitamab-gqgk) in fiscal year 2022.

Demographics of Members Utilizing Miscellaneous Cancer Medications: Pharmacy Claims

- Due to the limited number of members utilizing miscellaneous cancer medications during fiscal year 2022, detailed demographic information could not be provided.

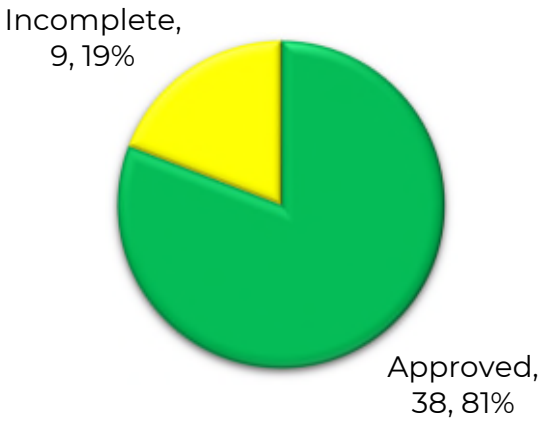
Top Prescriber Specialties of Utilizing Miscellaneous Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Miscellaneous Cancer Medications

There were 47 prior authorization requests submitted for miscellaneous cancer 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]

Anticipated Patent or Exclusivity Expiration(s):

- Azedra® (iobenguane I-131): July 2025
- Koselugo® (selumetinib): December 2026
- Vijoice® (alpelisib): September 2030
- Rezurock® (belumosudil): April 2035
- Vitrakvi® (larotrectinib): August 2036
- Lutathera® (lutetium Lu-177 dotatate): July 2038
- Turalio® (pexidartinib): July 2038
- Pedmark® (sodium thiosulfate): July 2039

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[4]

- **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[5]

- **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 $69,64260 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 listed in red:

Pedmark® (Sodium Thiosulfate) Approval Criteria [Reduction in Ototoxicity Risk Associated with Cisplatin for Solid Tumors 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.

Utilization Details of Miscellaneous Cancer Medications: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SELUMETINIB PRODUCTS						
KOSELUGO CAP 10MG	66	10	$787,026.35	$11,924.64	6.6	50.41%
KOSELUGO CAP 25MG	58	8	$767,199.90	$13,227.58	7.3	49.14%
SUBTOTAL	**124**	**14***	**$1,554,226.25**	**$12,534.08**	**8.9**	**99.56%**
BELUMOSUDIL PRODUCTS						
REZUROCK TAB 200MG	4	1	$6,929.44	$1,732.36	4	0.44%
SUBTOTAL	**4**	**1***	**$6,929.44**	**$1,732.36**	**4**	**0.44%**
TOTAL	**128**	**15***	**$1,561,155.69**	**$12,196.53**	**8.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; 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
A9513 LUTETIUM LU-177 DOTATATE INJ	8	4	$351,788.00	$43,973.50	2
TOTAL	**8⁺**	**4***	**$351,788.00**	**$43,973.50**	**2**

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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[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 12/2022. Last accessed 12/21/2022.
[2] 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 12/21/2022.
[3] 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 12/21/2022.
[4] 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 12/21/2022.
[5] 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 12/21/2022.

Appendix J

Fiscal Year 2022 Annual Review of Gastrointestinal (GI) Cancer Medications and 30-Day Notice to Prior Authorize Lytgobi® (Futibatinib)

Oklahoma Health Care Authority
January 2023

Current Prior Authorization Criteria

Ayvakit™ (Avapritinib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of unresectable or metastatic GIST in adult members; and
2. Member has a *PDGFRA* exon 18 mutation (including *PDGFRA* D842V mutations).

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.

Pemazyre® (Pemigatinib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; and
2. Must have failed 1 or more prior therapies; and
3. Disease is positive for a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other FGFR rearrangement.

Qinlock® (Ripretinib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of advanced GIST; and
2. Previously received ≥3 kinase inhibitors, including imatinib; and
3. As a single agent.

Truseltiq® (Infigratinib) Approval Criteria [Cholangiocarcinoma Diagnosis]:

1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma; and
2. Presence of fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement; and
3. Disease has progressed on at least 1 prior systemic therapy; and
4. As a single agent.

Utilization of GI Cancer Medications: Fiscal Year 2022

There was no SoonerCare utilization of GI cancer medications during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of GI Cancer Medications

There were no prior authorization requests submitted for GI cancer medications during fiscal year 2022 (07/01/2021 to 06/30/2022).

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

Anticipated Patent or Exclusivity Expiration(s):

- Ayvakit™ (avapritinib): October 2034
- Truseltiq® (infigratinib): December 2034
- Lytgobi® (futibatinib): March 2036
- Pemazyre® (pemigatinib): May 2039
- Qinlock® (Ripretinib): December 2040

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[5]

- **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 listed 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). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2022. Last accessed 12/22/2022.
[2] U.S. 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 12/22/2022.
[3] 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 12/22/2022.
[4] 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 12/22/2022.
[5] 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 12/22/2022.

Appendix K

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: December 22, 2022

FDA Approves New HIV Drug for Adults with Limited Treatment Options

The FDA approved Sunlenca® (lenacapavir), a new type of antiretroviral medication for adult patients living with human immunodeficiency virus type 1 (HIV-1), whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations. After the starting dose is completed, Sunlenca® is administered as subcutaneous (sub-Q) injections once every 6 months, allowing convenient dosing for patients.

Sunlenca® is the first of a new class of drugs called capsid inhibitors to be FDA approved for treating HIV-1. Sunlenca® works by blocking the HIV-1 virus' protein shell, thereby interfering with multiple essential steps of the viral lifecycle. The starting dose is given as oral tablets and sub-Q injections, followed by maintenance injections every 6 months; Sunlenca® is given in combination with other antiretroviral(s).

The safety and efficacy of Sunlenca® were established through a multicenter clinical trial with 72 patients whose HIV infections were resistant to multiple classes of HIV medications. These patients had to have high levels of virus in their blood despite being on antiretroviral drugs. Patients were enrolled into 1 of 2 study groups. One group was randomized to receive either Sunlenca® or placebo in a double-blind fashion, and the other group received open-label Sunlenca®. The primary measure of efficacy was the proportion of patients in the randomized study group who achieved a certain level of reduction in virus during the initial 14 days compared to baseline. In this group, 87.5% of patients who received Sunlenca® achieved such a decrease in virus compared to 16.7% of patients who received a placebo. After 26 weeks of Sunlenca® plus other antiretroviral drugs, 81% of participants in the first group achieved HIV RNA suppression, where levels of HIV were low enough to be considered undetectable. After 52 weeks, 83% of participants continued to have HIV RNA suppression.

The most common adverse reactions with Sunlenca® were injection site reactions and nausea. Most injection site reactions were described as swelling, pain, or redness. Sunlenca® comes with certain warnings and precautions. Injection site reactions described as nodules or indurations may be persistent in some patients. Additional warnings and precautions include the risk of developing immune reconstitution syndrome, which is when the immune system overreacts after starting HIV treatment. Also, small (residual) amounts of Sunlenca® can remain in the body for up to a year or longer; low levels of drug caused by missing doses of Sunlenca® or failing to maintain a fully suppressive HIV treatment regimen after stopping Sunlenca® could lead to an increased risk of developing viral resistance. Residual amounts of Sunlenca® could also lead to potential drug interactions. Patients should not receive Sunlenca® if they also take certain drugs that cause reduced levels of Sunlenca®. This may result in losing virologic response and developing viral resistance.

FDA NEWS RELEASE

For Immediate Release: December 16, 2022

FDA Approves First Gene Therapy for the Treatment of High-Risk, Non-Muscle-Invasive Bladder Cancer

The FDA approved Adstiladrin® (nadofaragene firadenovec-vncg), a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle-invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

Bladder cancer, one of the more common forms of cancer, is a disease in which malignant cells form a tumor in the tissues of the bladder. These abnormal cells can invade and destroy normal body tissue. Over time, the abnormal cells can also metastasize through the body. Most newly diagnosed bladder cancers (75% to 80%) are classified as NMIBC – a type of cancer that has grown through the lining of the bladder but has not yet invaded the muscle layer. This type of cancer is associated with high rates of recurrence (between 30 to 80%) and the risk of progression to invasive and metastatic cancer.

The safety and effectiveness of Adstiladrin® were evaluated in a multicenter clinical study that included 157 patients with high-risk BCG-unresponsive NMIBC, 98 of whom had BCG-unresponsive CIS with or without papillary tumors and could be evaluated for response. Patients received Adstiladrin® once every 3 months for up to 12 months, or until unacceptable toxicity to therapy or recurrent high-grade NMIBC. Overall, 51% of enrolled patients using Adstiladrin® therapy achieved a complete response. The median duration of response was 9.7 months. Forty-six percent of responding patients remained in complete response for at least 1 year.

Adstiladrin® is administered once every 3 months into the bladder via a urinary catheter. The most common adverse reactions associated with Adstiladrin® included bladder discharge, fatigue, bladder spasm, urinary urgency, hematuria, chills, fever, and painful urination. Individuals who are immunosuppressed or immune-deficient should not come into contact with Adstiladrin®.

FDA NEWS RELEASE

For Immediate Release: December 16, 2022

Coronavirus (COVID-19) Update: FDA to Hold Advisory Committee Meeting to Discuss Future Vaccination Regimens Addressing COVID-19

On January 26, 2023, the FDA will hold a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to consider whether and how the composition for primary doses of the currently available COVID-19 vaccines should be modified and how and whether the composition and schedule for booster doses should be adjusted moving forward. Along with the independent experts of the advisory committee, representatives from the U.S. Centers for Disease Control and Prevention and the National Institutes of Health (NIH) will also participate in the meeting.

COVID-19 vaccines remain the best available protection against COVID-19, particularly the most devastating consequences of the disease, including hospitalization and death. Since the initial authorizations of these vaccines, the FDA has learned that protection wanes over time, especially as the virus rapidly mutates and new variants and subvariants emerge. Therefore, it is important to continue discussions about the optimal composition of COVID-19 vaccines for primary and booster vaccination, as well as the optimal interval for booster vaccination.

At the upcoming January meeting, the FDA is planning to examine the state of the pandemic, the evolution of variants and subvariants, and the available effectiveness, safety, and immunogenicity data with the current monovalent and bivalent vaccines. The FDA will also consider the potential composition of the current and next generation of COVID-19 vaccines for primary and booster immunization. There will also be presentations from manufacturers and the FDA summarizing the manufacturing considerations and timelines related to vaccine composition changes. Following the discussion and taking into account the advice provided by the VRBPAC at the meeting, the FDA will consider whether to recommend adjustments to the current authorizations and approvals, and the FDA will consider the most efficient and transparent process to use for selection of strains for inclusion in the primary and booster vaccines.

In June 2022, the FDA held a VRBPAC meeting to discuss whether a change in the vaccine strain composition of COVID-19 vaccines for booster doses was necessary for the 2022 fall and winter seasons given that the virus had mutated significantly, and the omicron variants were most prevalent. After an overwhelming majority of the committee voted in favor of including a SARS-CoV-2 omicron component in COVID-19 boosters, the FDA advised manufacturers that, based on the best available data, they should develop modified COVID-19 vaccines that included an omicron BA.4/5 spike protein component to the vaccine composition to create a 2 component (bivalent) booster vaccine. The agency did not advise manufacturers to change the compositions of vaccines used for primary vaccination because at the time the available clinical data did not support making such a recommendation.

FDA NEWS RELEASE

For Immediate Release: December 8, 2022

Coronavirus (COVID-19) Update: FDA Authorizes Updated (Bivalent) COVID-19 Vaccines for Children Down to 6 Months of Age

The FDA amended the emergency use authorizations (EUAs) of the updated (bivalent) Moderna and Pfizer-BioNTech COVID-19 vaccines to include use in children down to 6 months of age.

The monovalent Moderna COVID-19 Vaccine is authorized as a 2 dose primary series in individuals 6 months of age and older and as a third primary series dose for individuals 6 months of age and older who have been determined to have certain kinds of immunocompromise. With this authorization, the Moderna COVID-19 Vaccine, Bivalent is now authorized for administration in individuals 6 months through 5 years of age as a single booster dose at least 2 months after completion of primary vaccination with the monovalent Moderna COVID-19 Vaccine. The Moderna COVID-19 Vaccine, Bivalent is also authorized for use in individuals 6 years of age and older as a single booster dose at least 2 months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine. For the authorization of a single booster dose of the Moderna COVID-19 Vaccine, Bivalent for children 6 months through 5 years of age, the FDA relied on immune response data that it had previously evaluated from a clinical study in adults of a booster dose of Moderna's investigational bivalent COVID-19 vaccine that contained a component corresponding to the original strain of SARS-CoV-2 and a component corresponding to the omicron lineage BA.1.

In addition, the FDA conducted an analysis of data from a clinical study that compared the immune response among 56 study participants 17 months through 5 years of age who received a single booster dose of monovalent Moderna COVID-19 Vaccine at

least 6 months after completion of a 2 dose primary series of the vaccine to the immune response among approximately 300 study participants 18 through 25 years of age who had received a 2 dose primary series of monovalent Moderna COVID-19 Vaccine in a previous study which determined the vaccine to be effective in preventing COVID-19. The immune response to the booster dose of monovalent Moderna COVID-19 Vaccine in the 17 months through 5 years age group was comparable to the immune response to the 2 dose primary series in the adult participants.

The safety of a single booster dose of the Moderna COVID-19 Vaccine, Bivalent for children 6 months through 5 years of age is supported by safety data from a clinical study which evaluated a booster dose of Moderna's investigational bivalent COVID-19 vaccine (original and omicron BA.1), safety data from clinical trials which evaluated primary and booster vaccination with the monovalent Moderna COVID-19 Vaccine, and post marketing safety data with the monovalent Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent. In 1 clinical study, the safety of a single booster dose of monovalent Moderna COVID-19 Vaccine was evaluated in 145 clinical study participants 6 months through 5 years of age who received a booster dose of monovalent Moderna COVID-19 Vaccine at least 6 months after completion of the monovalent Moderna COVID-19 Vaccine 2 dose primary series. The most commonly reported side effects after a booster dose of the monovalent Moderna COVID-19 Vaccine across this age group included pain, redness and swelling at the injection site, swelling/tenderness of the lymph nodes of the injected arm or thigh, and fever. In clinical study participants 17 months through 36 months of age, other commonly reported side effects included irritability/crying, sleepiness, and loss of appetite. In clinical trial participants 37 months through 5 years of age, other commonly reported side effects included fatigue, headache, muscle pain, joint pain, chills, and nausea/vomiting. The data accrued with the investigational Moderna bivalent COVID-19 vaccine (original and omicron BA.1) and with the monovalent Moderna COVID-19 Vaccine are relevant to the Moderna COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

With this authorization, children 6 months through 4 years of age who have not yet received the third dose of the 3 dose primary series with the monovalent Pfizer-BioNTech COVID-19 Vaccine will now receive the Pfizer-BioNTech COVID-19 Vaccine, Bivalent as the third dose of the primary series. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is also authorized for administration in individuals 5 years of age and older as a single booster dose at least 2 months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine, or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

The monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use as the third dose of the 3 dose primary series in children 6 months through 4 years of age. The monovalent Pfizer-BioNTech COVID-19 Vaccine remains authorized for administration as the first 2 doses of the 3 dose primary series in individuals 6 months through 4 years of age, as a 2 dose primary series for individuals 5 years of age and older, and as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise.

The authorization of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for administration as the third dose of a 3 dose primary series following 2 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age is supported by the FDA's previous analyses of the effectiveness of primary vaccination with the monovalent Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older and individuals 6 months through 4 years of age, and previous

analyses of immune response data in adults older than 55 years of age who had received a 2 dose primary series and one booster dose with the monovalent Pfizer-BioNTech COVID-19 Vaccine and a second booster dose with the investigational Pfizer-BioNTech bivalent COVID-19 vaccine (original and omicron BA.1).

The safety of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for administration as the third dose of a 3 dose primary series following 2 doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age is based on safety data from a clinical study which evaluated a booster dose of Pfizer-BioNTech's investigational bivalent COVID-19 vaccine (original and omicron BA.1) in individuals older than 55 years of age, safety data from clinical trials which evaluated primary vaccination in individuals 6 months of age and older with the monovalent Pfizer-BioNTech COVID-19 Vaccine, safety data from clinical trials which evaluated booster vaccination in individuals 5 years of age and older with the monovalent Pfizer-BioNTech COVID-19 Vaccine and post marketing safety data with the monovalent Pfizer-BioNTech COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. The data accrued with the investigational Pfizer-BioNTech bivalent COVID-19 vaccine (original and omicron BA.1) and with the monovalent Pfizer-BioNTech COVID-19 Vaccine are relevant to the Pfizer-BioNTech COVID 19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

FDA NEWS RELEASE

For Immediate Release: November 30, 2022

FDA Approves First Fecal Microbiota Product

The FDA approved Rebyota®, the first fecal microbiota product approved by the agency. Rebyota® is approved for the prevention of recurrence of *Clostridioides difficile* (*C. difficile*) infection (CDI) in individuals 18 years of age and older after completion of antibiotic treatment for recurrent CDI.

C. difficile is a bacterium that can cause CDI, a potentially life-threatening disease resulting in diarrhea and significant inflammation of the colon. In the United States, CDI is associated with 15,000-30,000 deaths annually. The intestinal tract contains millions of microorganisms, often referred to as the "gut flora," or "gut microbiome." Certain situations, such as taking antibiotics to treat an infection, may change the balance of microorganisms in the gut, allowing *C. difficile* to multiply and release toxins causing diarrhea, abdominal pain, and fever, and in some cases, organ failure and death. Other factors that can increase the risk for CDI include age older than 65 years, hospitalization, a weakened immune system, and a previous history of CDI. After recovering from CDI, individuals may get the infection again – often multiple times – a condition known as recurrent CDI. The risk of additional recurrences increases with each infection and treatment options for recurrent CDI are limited. The administration of fecal microbiota is thought to facilitate restoration of the gut flora to prevent further episodes of CDI.

Rebyota® is administered rectally as a single dose and is prepared from stool donated by qualified individuals. The donors and the donated stool are tested for a panel of transmissible pathogens, however, as Rebyota® is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. In addition, Rebyota® may contain food allergens; the potential for the product to cause adverse reactions due to food allergens is unknown.

The safety of Rebyota® was assessed from 2 randomized, double-blind, placebo-controlled clinical studies and from open-label clinical studies conducted in the United States and in Canada. The participants had a history of 1 or more recurrences of CDI. They received 1 or more doses of Rebyota® or placebo 24 to 72 hours after completion of antibiotic treatment for their CDI; participants' CDI was under control at the time of receipt of Rebyota® or placebo. Across these studies, 978 individuals 18 years of age and older received at least 1 dose of Rebyota®. In 1 study, among 180 Rebyota® recipients, when compared to 87 placebo recipients, the most common side effects after receiving 1 dose of Rebyota® were abdominal pain, diarrhea, abdominal bloating, gas, and nausea.

The effectiveness of Rebyota® was evaluated in an analysis of data from a randomized, double-blind, placebo-controlled, multicenter study. The analysis included 177 adults who received 1 dose of Rebyota® and 85 who received 1 dose of placebo in this study. It also incorporated success rates from a different placebo-controlled study in which 39 adults received 1 dose of Rebyota® and 1 of placebo and 43 adults received 2 doses of placebo. Success in preventing recurrent CDI was defined as the absence of CDI diarrhea within 8 weeks of administration of Rebyota® or placebo. In a statistical analysis that took into account both studies, the overall estimated rate of success in preventing recurrent CDI through 8 weeks was significantly higher in the Rebyota® group (70.6%) than in the placebo group (57.5%).

Current Drug Shortages Index (as of December 27, 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***