OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday, January 10, 2024

No live meeting scheduled for January.
January 2024 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 10, 2024

DATE: January 3, 2024

NOTE: **No live January meeting. January 2024 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/Annual Eye Exam in Members with Glaucoma – Appendix B

Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Atorvaliq® (Atorvastatin Oral Suspension) – Appendix C

Annual Review of Bladder Control Medications and 30-Day Notice to Prior Authorize Oxybutynin 2.5mg Tablet – Appendix D

Annual Review of Gastrointestinal (GI) Cancer Medications – Appendix E

Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize iDose® TR (Travoprost Intracameral Implant) – Appendix F

Annual Review of Hyperphosphatemia Medications and 30-Day Notice to Prior Authorize Xphozah® (Tenapanor) – Appendix G

Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Iwilfin™ (Eflornithine), Kepivance® (Palifermin), Loqtorzi™ (Toripalimab-tpzi), and Omisirge® (Omidubicel-onlv) – Appendix H

Annual Review of Non-Malignant Solid Tumor Medications and 30-Day Notice to Prior Authorize Ogsiveo™ (Nirogacestat) – Appendix I

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

Future Business

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Packet Meeting – January 10, 2024

NOTE: ***No live January meeting. January 2024 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 13, 2023 DUR Board Meeting Minutes
   B. December 13, 2023 DUR Board Recommendations Memorandum

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

2. **Update on Medication Coverage Authorization Unit/Annual Eye Exam in Members with Glaucoma – See Appendix B**
   A. Pharmacy Help Desk Activity for December 2023
   B. Medication Coverage Activity for December 2023
   C. Annual Eye Exam in Members with Glaucoma

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

3. **Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Atorvaliq® (Atorvastatin Oral Suspension) – See Appendix C**
   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. Morgan, Dr. Muchmore, Chairman:

4. **Annual Review of Bladder Control Medications and 30-Day Notice to Prior Authorize Oxybutynin 2.5mg Tablet – See Appendix D**
   A. Current Prior Authorization Criteria
   B. Utilization of Bladder Control Medications
   C. Prior Authorization of Bladder Control Medications
   D. Market News and Updates
   E. Oxybutynin Cost Comparison
   F. College of Pharmacy Recommendations
   G. Utilization Details of Bladder Control Medications

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

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

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

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

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

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

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

8. **Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Iwilfin™ (Eflornithine), Kepivance® (Palifermin), Loqtorzi™ (Toripalimab-tpzi), and Omisirge® (Omidubicel-onlv) – See Appendix H**
   A. Current Prior Authorization Criteria
   B. Utilization of Miscellaneous Cancer Medications
   C. Prior Authorization of Miscellaneous Cancer Medications
   D. Market News and Updates
   E. Product Summaries
   F. College of Pharmacy Recommendations
   G. Utilization Details of Miscellaneous Cancer Medications

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

9. **Annual Review of Non-Malignant Solid Tumor Medications and 30-Day Notice to Prior Authorize Ogsiveo™ (Nirogacestat) – See Appendix I**
   A. Current Prior Authorization Criteria
   B. Utilization of Non-Malignant Solid Tumor Medications
   C. Prior Authorization of Non-Malignant Solid Tumor Medications
   D. Market News and Updates
   E. Ogsiveo™ (Nirogacestat) Product Summary
   F. College of Pharmacy Recommendations
   G. Utilization Details of Non-Malignant Solid Tumor Medications

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

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

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

11. **Future Business* (Upcoming Product and Class Reviews)**
    A. Anti-Migraine Medications
    B. Antiviral Medications
    C. Leukemia Medications
    D. Topical Acne, Psoriasis, and Rosacea Products

    *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 13, 2023

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

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Mattie Morgan, Pharm.D.; Pharmacy Resident	X	
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor	X	
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Tad Autry Pharm.D., BCPS, BCOP		X
Emily Borders, Pharm.D., BCOP	X	
Brooke Daugherty, Pharm. D., BCOP		X
Graduate Students: Rykr Carpenter, Pharm.D.		X
Matthew Dickson, Pharm.D.		X
Michael Nguyen, Pharm.D.		X
Corby Thompson, Pharm.D.		X
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director	X	
Ellen Buettner; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	
Josh Holloway, J.D.; Deputy General Counsel	X	
Traylor Rains; State Medicaid Director		X

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

OTHERS PRESENT:	
Dan O'Donnell, Axsome	Jamie Tobitt, Apellis
Daphne Ni, Biogen	Cheng Yuet, Amgen
Bob Atkins, Biogen	Carmen Hinton, EBSI
Nick Bianchini, Axsome	Bryan Steffan, Boehringer
Janie Huff, Madrigal	Kristin Winters, Centene
Richie Crawford, Otsuka	Mark Kaiser, Otsuka
David Prather, Novo Nordisk	Dave Poskey, UCB
Nima Nabavi, Amgen	Steve George, Boehringer
Irene Chung, Aetna	Brandy Barrett, Aetna
John King, AbbVie	Shellie Keast, Mercer
Rhonda Clark, Indivior	Melissa Abbott, Eisai
Rusty Hailey, Intra-Cellular Therapies	Dana Mennen, Apellis
Peter Lee, OMES	Frank Alvarado, Johnson & Johnson
Phil Lohec, Viatris	Artia Solutions
Jen Tamburo, Astra Zeneca	John Omick, Travere

PRESENT FOR PUBLIC COMMENT:	
Jamie Tobitt, Apellis	Daphne Ni, Biogen
Nick Bianchini, Axsome	

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. 14 JAMIE TOBITT

2B: AGENDA ITEM NO. 15 DAPHNE NI

2C: AGENDA ITEM NO. 15 NICHOLAS BIANCHINI

ACTION: NONE REQUIRED

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

3A: NOVEMBER 8, 2023 DUR MINUTES

Materials included in agenda packet; presented by Dr. Muchmore

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

ACTION: MOTION CARRIED

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

4A: PHARMACY HELPDESK ACTIVITY FOR NOVEMBER 2023

4B: MEDICATION COVERAGE ACTIVITY FOR NOVEMBER 2023

4C: ACADEMIC DETAILING PROGRAM UPDATE

Materials included in agenda packet; presented by Dr. Morgan, Dr. Travers
ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO UPDATE THE MAINTENANCE DRUG LIST
5A: INTRODUCTION
5B: SOONERCARE MAINTENANCE DRUG LIST
5C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. West moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE SYMBICORT AEROSPHERE® (BUDESONIDE/FORMOTEROL) AND UPDATE THE APPROVAL CRITERIA FOR THE ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) MAINTENANCE MEDICATIONS
6A: MARKET NEWS AND UPDATES
6B: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Muñoz moved to approve; seconded by Dr. Haymore
ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE SOHONOS™ (PALOVAROTENE)
7A: MARKET NEWS AND UPDATES
7B: SOHONOS™ (PALOVAROTENE) PRODUCT SUMMARY
7C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. West moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE MIEBO™ (PERFLUOROHEXYLOCTANE OPHTHALMIC SOLUTION) AND VEVYE® (CYCLOSPORINE OPHTHALMIC SOLUTION)
8A: MARKET NEWS AND UPDATES
8B: PRODUCT SUMMARIES
8C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Morgan
Dr. West moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE VEOZAH™ (FEZOLINETANT) AND UPDATE THE APPROVAL CRITERIA FOR VASOMOTOR SYMPTOM (VMS) MEDICATIONS
9A: MARKET NEWS AND UPDATES
9B: VEOZAH™ (FEZOLINETANT) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Moss
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 10: VOTE TO PRIOR AUTHORIZE ELREXFIO™ (ELRANATAMAB-BCMM) AND TALVEY™ (TALQUETAMAB-TGVS) AND UPDATE THE APPROVAL CRITERIA FOR THE MULTIPLE MYELOMA MEDICATIONS
10A: MARKET NEWS AND UPDATES
10B: PRODUCT SUMMARIES

10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Patatanian moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

AGENDA ITEM NO. 11: ANNUAL REVIEW OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
11A: CURRENT PRIOR AUTHORIZATION CRITERIA
11B: UTILIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
11C: PRIOR AUTHORIZATION OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
11D: MARKET NEWS AND UPDATES
11E: COLLEGE OF PHARMACY RECOMMENDATIONS
11F: UTILIZATION DETAILS OF ANTICOAGULANTS AND PLATELET AGGREGATION INHIBITORS
Materials included in agenda packet; presented by Dr. O'Halloran
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: ANNUAL REVIEW OF CONSTIPATION AND DIARRHEA MEDICATIONS
12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
12C: PRIOR AUTHORIZATION OF CONSTIPATION AND DIARRHEA MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF CONSTIPATION AND DIARRHEA MEDICATIONS
Materials included in agenda packet; presented by Dr. Morgan
Dr. Muñoz moved to approve; seconded by Dr. West
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF SKIN CANCER MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE HEPZATO KIT™ (MEPHALAN) AND ZYNYZ™ (RETIFANLIMAB-DLWR)
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF SKIN CANCER MEDICATIONS
13C: PRIOR AUTHORIZATION OF SKIN CANCER MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: PRODUCT SUMMARIES
13F: COLLEGE OF PHARMACY RECOMMENDATIONS
13G: 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

AGENDA ITEM NO. 14: ANNUAL REVIEW OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE RYSTIGGO® (ROZANOLIXIZUMAB-NOLI), VYVGART® HYTRULO (EFGARTIGIMOD ALFA/HYALURONIDASE-QVFC), AND ZILBRYSQ® (ZILUCOPLAN)
14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
14C: PRIOR AUTHORIZATION OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS

14D: MARKET NEWS AND UPDATES
14E: PRODUCT SUMMARIES
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF COMPLEMENT INHIBITORS AND MISCELLANEOUS IMMUNOMODULATORY AGENTS
Materials included in agenda packet; presented by Dr. Moss
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 15: ANNUAL REVIEW OF ANTIDEPRESSANTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE EXXUA™ (GEPIRONE) AND ZURZUVAE™ (ZURANOLONE)
15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTIDEPRESSANTS
15C: PRIOR AUTHORIZATION OF ANTIDEPRESSANTS
15D: MARKET NEWS AND UPDATES
15E: PRODUCT SUMMARIES
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ANTIDEPRESSANTS
Materials included in agenda packet; presented by Dr. O'Halloran
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 16: ANNUAL REVIEW OF LYSOSOMAL STORAGE DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ELFABRIO® (PEGUNIGALSIDASE ALFA-IWXJ), OPFOLDA™ (MIGLUSTAT), AND POMBILITI™ (CIPAGLUCOSIDASE ALFA-ATGA)
16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF LYSOSOMAL STORAGE DISEASE MEDICATIONS
16C: PRIOR AUTHORIZATION OF LYSOSOMAL STORAGE DISEASE MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: PRODUCT SUMMARIES
16F: COLLEGE OF PHARMACY RECOMMENDATIONS
16G: UTILIZATION DETAILS OF LYSOSOMAL STORAGE DISEASE MEDICATIONS
Materials included in agenda packet; presented by Dr. Wilson
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN FEBRUARY

AGENDA ITEM NO. 17: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Materials included in agenda packet; presented by Dr. Morgan
ACTION: NONE REQUIRED

AGENDA ITEM NO. 18: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
18A: ANTIHYPERLIPIDEMICS
18B: BLADDER CONTROL MEDICATIONS
18C: GLAUCOMA MEDICATIONS
18D: NON-MALIGNANT SOLID TUMOR MEDICATIONS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: ADJOURNMENT
The meeting was adjourned at 6:04pm.

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

Memorandum

Date: December 15, 2023

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

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

Subject: DUR Board Recommendations from Meeting on December 13, 2023

Recommendation 1: Academic Detailing Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Update the Maintenance Drug List

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the addition of non-controlled attention-deficit/hyperactivity disorder (ADHD) medications to the SoonerCare maintenance drug list* (changes shown in red):

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

- Non-Controlled Attention-Deficit/Hyperactivity Disorder (ADHD) Medications
- Parkinson's Medications
- Thyroid Medications

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

Recommendation 3: Vote to Prior Authorize Symbicort Aerosphere® (Budesonide/Formoterol) 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 following changes to the Tezspire® (tezepelumab-ekko) and Xolair® (omalizumab) approval criteria based on the new FDA approved label expansions and to be in line with the current Global Initiative for Asthma (GINA) guidelines (changes shown in red):

Tezspire® (Tezepelumab-ekko) Approval Criteria:

1. An FDA approved diagnosis of add-on maintenance treatment for severe asthma; and
2. Member must be 12 years of age or older; and
3. Member must have experienced ≥2 asthma exacerbations requiring oral or injectable corticosteroids or resulted in hospitalization in the last 12 months; and
4. Member must have failed a medium-to-high dose inhaled corticosteroid (ICS) used compliantly ~~for at least the past 12~~ within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
5. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
6. For authorization of Tezspire® vial or pre-filled syringe, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis; and
7. For authorization of Tezspire® pre-filled pen, prescriber must verify that the injection will be administered by a health care provider prepared to manage anaphylaxis or the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Tezspire®; and
8. Tezspire® must be prescribed by an allergist, pulmonologist, or pulmonary specialist, or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12

months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. A quantity limit of 1.91mL (1 single-dose glass vial or single-dose pre-filled syringe) per 28 days will apply.

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

1. Diagnosis of severe persistent asthma [as per National Asthma Education and Prevention Program (NAEPP) guidelines]; and
2. Member must be between 6 and 75 years of age; and
3. Member must have a positive skin test to at least 1 perennial aeroallergen (positive perennial aeroallergens must be listed on the prior authorization request); and
4. Member must have a pretreatment serum IgE level between 30 and 1,300 IU/mL (depending on member age); and
5. Member's weight must be between 20kg and 150kg; and
6. Member must have been on medium-to-high dose inhaled corticosteroids (ICS) (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose) ~~for at minimum the past 12~~ within the last 3-6 consecutive months; and
7. Prescribed Xolair® dose must be an FDA approved regimen per package labeling; and
8. For authorization of Xolair® vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
9. For authorization of Xolair® prefilled autoinjector or prefilled syringe, prescriber must verify the following:
    a. Member has no prior history of anaphylaxis; and
    b. Member must have had at least 3 doses of Xolair® under the guidance of a health care provider with no hypersensitivity reactions; and
    c. Member has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Xolair®; and
10. Xolair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
11. Member must have been in the emergency room (ER) or hospitalized, due to an asthma exacerbation, twice in the past 12 months (date of visits must be listed on the prior authorization request), or member must have been determined to be dependent on systemic corticosteroids to prevent serious exacerbations; and

12. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval.

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

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

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

1. An FDA approved indication for add-on maintenance treatment of nasal polyps in adult members with inadequate response to nasal corticosteroids; and
2. Member must be 18 years of age or older; and
3. Member must have a trial of intranasal corticosteroids for at minimum the past 4 weeks; and
4. Prescriber must verify member will continue to receive intranasal corticosteroid therapy, unless contraindicated; and
5. Member has symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/

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

The College of Pharmacy also recommends the following changes to all other asthma-indicated monoclonal antibodies (Cinqair®, Dupixent®, Fasenra®, and Nucala®) to be more consistent with current GINA guidelines (changes shown in red):

Cinqair® (Reslizumab) Approval Criteria:

1. An FDA approved indication of add-on maintenance treatment of members with severe asthma with an eosinophilic phenotype; and
2. Member must be 18 years of age or older; and
3. Member must have a blood eosinophil count ≥400cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high

dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly ~~for at least the past 12~~ within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. Cinqair® must be administered in a health care setting by a health care professional prepared to manage anaphylaxis; and
8. Cinqair® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. Member's weight should be provided on prior authorization requests. Weights should have been taken within the last 4 weeks to provide accurate weight-based dosing.

Dupixent® (Dupilumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with moderate-to-severe eosinophilic phenotype asthma or oral corticosteroid-dependent asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly ~~for at least the past 12~~ within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. Prescriber must verify the member has been counseled on proper administration and storage of Dupixent®; and

8. Dupixent® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
9. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
10. Quantities approved must not exceed FDA recommended dosing requirements.

Fasenra® (Benralizumab Injection) Approval Criteria:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 12 years of age or older; and
3. Member must have a blood eosinophil count of ≥150cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly ~~for at least the past 12~~ within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. For authorization of Fasenra® prefilled syringe, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Fasenra® prefilled autoinjector pen, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Fasenra®; and
9. Fasenra® must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
11. A quantity limit of 1 prefilled syringe or prefilled autoinjector pen per 56 days will apply.

Nucala® (Mepolizumab Injection) Approval Criteria [Eosinophilic Phenotype Asthma Diagnosis]:

1. An FDA approved indication for add-on maintenance treatment of members with severe eosinophilic phenotype asthma; and
2. Member must be 6 years of age or older; and
3. Member must have a blood eosinophil count of ≥150 cells/mcL (can apply to either a recent level or in history prior to oral corticosteroid use); and
4. Member must have had at least 2 asthma exacerbations requiring systemic corticosteroids within the last 12 months or require daily systemic corticosteroids despite compliant use of medium-to-high dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication; and
5. Member must have failed a medium-to-high dose ICS used compliantly ~~for at least the past 12~~ within the last 3-6 consecutive months (for ICS/LABA combination products, the ICS component would meet criteria at an equivalent medium-to-high dose); and
6. Member must have failed at least 1 other asthma controller medication used in addition to the medium-to-high dose ICS compliantly for at least the past 3 months; and
7. For authorization of Nucala vial, prescriber must verify the injection will be administered in a health care setting by a health care professional prepared to manage anaphylaxis; or
8. For authorization of Nucala prefilled autoinjector or prefilled syringe, prescriber must verify the member or caregiver has been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala; and
9. Nucala must be prescribed by an allergist, pulmonologist, or pulmonary specialist or the member must have been evaluated by an allergist, pulmonologist, or pulmonary specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is an allergist, pulmonologist, or pulmonary specialist); and
10. Initial approvals will be for the duration of 6 months after which time compliance will be evaluated for continued approval; and
11. A quantity limit of 1 vial, prefilled autoinjector, or prefilled syringe per 28 days will apply.

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

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

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

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

Tier-1 products indicated for the member's age are covered with no prior authorization required.
Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Unique criteria apply to each Tier-2 product.
βDoes not include Breyna™; authorization of Breyna™ requires a reason why the member cannot use the brand formulation (Symbicort®).
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.

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

~~1. An FDA approved diagnosis of asthma; and~~

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

~~Asmanex® HFA (Mometasone Furoate) 50mcg and~~ QVAR® RediHaler® (Beclomethasone Dipropionate) Approval Criteria:

1. An FDA approved diagnosis of asthma; and
2. Member must be at the age indicated for the requested product:
   ~~a. Asmanex® HFA 50mcg: Member must be between 5 and 11 years of age; or~~
   b. QVAR® RediHaler®: Member must be 4 years of age or older; and
3. A trial of all available Tier-1 inhaled corticosteroids or a patient-specific, clinically significant reason why they are not appropriate for the member must be provided.

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

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD) or chronic bronchitis and/or emphysema associated with COPD; and
   a. For a diagnosis of COPD or chronic bronchitis and/or emphysema associated with COPD, trials of Advair® and Symbicort®, consisting of at least 30 days each within the last 90 days that did not adequately control COPD symptoms; or
2. An FDA approved diagnosis of asthma in patients 5 ~~18~~ years of age and older; and
   a. For a diagnosis of asthma, trials of Advair®, Dulera®, and Symbicort® consisting of at least 30 days each within the last 120 days that did not adequately control asthma symptoms; and
3. Requests for generic fluticasone furoate/vilanterol will require a patient-specific, clinically significant reason why brand name Breo® Ellipta® cannot be used.

Breyna™ (Budesonide/Formoterol Fumarate) Approval Criteria:

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

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

1. An FDA approved diagnosis of chronic obstructive pulmonary disease (COPD); and
2. A patient-specific, clinically significant reason why the member cannot use brand name Symbicort® and Advair® must be provided.

Long-Acting Beta$_2$ Agonists (LABA) and Long-Acting Muscarinic Antagonists (LAMA)	
Tier-1	**Tier-2**
Long-Acting Beta$_2$ Agonists* (LABA)	
salmeterol inhalation powder (Serevent®)	arformoterol nebulizer solution (Brovana®)
	formoterol nebulizer solution (Perforomist®)
	olodaterol inhalation spray (Striverdi® Respimat®)
Long-Acting Muscarinic Antagonists (LAMA)	
aclidinium inhalation powder (Tudorza® PressAir®)	~~**aclidinium inhalation powder (Tudorza® PressAir®)**~~
tiotropium inhalation powder (Spiriva® HandiHaler®) **– Brand Preferred**	~~**glycopyrrolate inhalation solution (Lonhala® Magnair®)**~~
tiotropium soft mist inhaler (Spiriva® Respimat®)	revefenacin inhalation solution (Yupelri®)
umeclidinium inhalation powder (Incruse® Ellipta®)	~~**umeclidinium inhalation powder (Incruse® Ellipta®)**~~

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

Recommendation 4: Vote to Prior Authorize Sohonos™ (Palovarotene)

MOTION CARRIED by unanimous approval.

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

Sohonos™ (Palovarotene) Approval Criteria:

1. An FDA approved diagnosis of fibrodysplasia ossificans progressiva (FOP); and
   a. Diagnosis must be confirmed by genetic testing identifying a pathogenic R206H mutation in the *ACVR1* gene (results of genetic testing must be submitted); and
2. Member must be:
   a. 8 years of age or older for female members; or
   b. 10 years of age or older for male members; and
3. For members younger than 14 years of age, member's recent weight (taken within the past 3 weeks) must be provided in order to ensure appropriate dosing in accordance with package labeling; and
4. Must be prescribed by a geneticist or other specialist with expertise in the treatment of FOP; and

5. Female members of reproductive potential must not be pregnant and must have a negative pregnancy test within 1 week prior to therapy initiation; and
6. Prescriber must verify female members of reproductive potential are not breastfeeding and will use effective contraception at least 1 month prior to initiating treatment with Sohonos™ and for 1 month after the last dose of Sohonos™; and
7. Prescriber must verify the member does not have severe renal impairment (creatinine clearance <30mL/min) or moderate or severe hepatic impairment (Child-Pugh B or C); and
8. Member must not be taking any of the following medications concomitantly with Sohonos™:
    a. Strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); or
    b. Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone); or
    c. Vitamin A at doses higher than the recommended daily allowance (RDA); or
    d. Other oral retinoids (e.g., acitretin, isotretinoin, tretinoin); or
    e. Tetracyclines (e.g., doxycycline, minocycline, tetracycline); and
9. If concurrent use with a moderate CYP3A4 inhibitor (e.g., ciprofloxacin, diltiazem, erythromycin, imatinib, fluconazole, fluvoxamine, verapamil) is required, prescriber must agree to reduce the Sohonos™ dose as recommended in the package labeling; and
10. Prescriber must verify the member or member's caregiver has been counseled on all warnings and precautions related to Sohonos™, including the risks of embryo-fetal toxicity, premature epiphyseal closure, metabolic bone disorders, psychiatric disorders, and night blindness; and
11. The request must specify if it is for a chronic daily dose or a flare-up dose; and
12. Chronic Daily Dose Approvals: Initial approvals will be for the duration of 6 months for the appropriate dose based on member age or weight. For additional approval consideration after 6 months, the prescriber must verify the member is tolerating and responding well to the medication. Subsequent approvals will be for the duration of 1 year; and
13. Flare-Up Dose Approvals: Initial approvals will be for the duration of 12 weeks for the appropriate doses based on member age or weight. After 12 weeks, flare-up dosing may be approved in additional 4-week increments if the prescriber documents the flare-up symptoms have not resolved at the end of the 12-week period; and
14. Member will not be approved for the chronic daily dose and flare-up dosing at the same time.

Recommendation 5: Vote to Prior Authorize Miebo™ (Perfluorohexyloctane Ophthalmic Solution) and Vevye® (Cyclosporine Ophthalmic Solution)

MOTION CARRIED by unanimous approval.

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

Miebo™ (Perfluorohexyloctane) Approval Criteria:

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

Vevye® (Cyclosporine 0.1% Solution) Approval Criteria:

1. An FDA approved diagnosis of dry eye disease (DED); and
2. Member must be 18 years of age or older; and
3. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
4. Member must have trials with at least 3 over-the-counter (OTC) products for 3 days in the last 30 days that failed to relieve signs and symptoms of dry eyes; and
5. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without prior authorization, and Xiidra® (lifitegrast ophthalmic solution) must be provided; and
6. A quantity limit of 2mL per 50 days will apply.

Recommendation 6: Vote to Prior Authorize Veozah™ (Fezolinetant) and Update the Approval Criteria for the Vasomotor Symptom (VMS) Medications

MOTION CARRIED by unanimous approval.

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

Veozah™ (Fezolinetant) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe vasomotor symptoms (VMS) due to menopause; and
2. Member must not use CYP1A2 inhibitors (e.g., cimetidine, ciprofloxacin, ethinyl estradiol, fluvoxamine, mexiletine) concomitantly with Veozah™; and
3. Member must not have a history of severe renal impairment, end-stage renal disease, or cirrhosis; and
4. Prescriber must verify baseline renal function and member must have an estimated glomerular filtration rate (eGFR) ≥30mL/min/1.73m^2; and
5. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored prior to the initiation of Veozah™, every 3 months for the first 9 months of treatment, and as clinically indicated thereafter; and
6. A patient-specific, clinically significant reason why the member cannot use menopausal hormone therapy must be provided; and
7. A patient-specific, clinically significant reason why the member cannot use other guideline supported non-hormonal therapy for VMS (e.g., gabapentin, paroxetine, venlafaxine) must be provided; and
8. A quantity limit of 30 tablets per 30 days will apply.

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

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

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

Recommendation 7: Vote to Prior Authorize Elrexfio™ (Elranatamab-bcmm) and Talvey™ (Talquetamab-tgvs) and Update the Approval Criteria for the Multiple Myeloma Medications

MOTION CARRIED by unanimous approval.

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

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

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

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

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

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

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

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

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

~~1. Diagnosis of relapsed or refractory multiple myeloma (RRMM); and~~
~~2. Member has received at least 4 prior lines of therapy (including being refractory to at least 1 proteasome inhibitor, 1 immunomodulatory agent, and 1 CD-38 directed monoclonal antibody); and~~

~~Members who are new to treatment with Pepaxto® will generally not be approved.~~

Recommendation 8: Annual Review of Anticoagulants and Platelet Aggregation Inhibitors

MOTION CARRIED by unanimous approval.

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

Pradaxa® (Dabigatran) Approval Criteria:

1. Pradaxa (dabigatran) capsules require the following:
    a. An FDA approved indication of 1 of the following:
        i. Non-valvular atrial fibrillation; or
        ii. Treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) after treatment with a parenteral anticoagulant for 5 to 10 days; or
        iii. To reduce the risk of recurrent DVT or PE in members who have been previously treated; or
        iv. For the prophylaxis of DVT and PE in members who have undergone hip replacement surgery; or
        v. Treatment of venous thromboembolic events (VTE) in pediatric members 8 to 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days; or
        vi. To reduce the risk of recurrent VTE in pediatric members 8 to 18 years of age who have been previously treated; and
    b. A patient-specific, clinically significant reason why the member cannot use Eliquis® (apixaban) and Xarelto® (rivaroxaban) must be provided; and
    c. Requests for generic dabigatran capsules will require a patient-specific, clinically significant reason why brand name Pradaxa® cannot be used.
2. Pradaxa (dabigatran) oral pellets require the following:
    a. An FDA approved indication of 1 of the following:
        i. Treatment of VTE in members who have been treated with a parenteral anticoagulant for at least 5 days; or
        ii. To reduce the risk of recurrent VTE in members who have been previously treated; and
    b. Member must be 3 months of age or older; and
    c. Members older than 7 ~~10~~ years of age require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
    d. A patient-specific, clinically significant reason why the member cannot use Xarelto® (rivaroxaban) oral suspension must be provided.

Recommendation 9: Annual Review of Constipation and Diarrhea Medications

MOTION CARRIED by unanimous approval.

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

Linzess® (Linaclotide) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Chronic idiopathic constipation (CIC) in members 18 years of age or older; or
   b. Irritable bowel syndrome with constipation (IBS-C) in members 18 years of age or older; or
   c. Functional constipation in members 6 to 17 years of age; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
   a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
   b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents the member is responding well to treatment; and
7. A quantity limit of 30 capsules per 30 days will apply.

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

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

1. An FDA approved diagnosis of CIC in members 18 years of age or older, or IBS-C in female members 18 years of age or older; and
2. Documentation that constipation-causing therapies for other disease states have been discontinued (excluding opioid pain medications for cancer patients); and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. A patient-specific, clinically significant reason why the member cannot use Linzess® (linaclotide) or Trulance® (plecanatide) must be provided; and
7. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
8. A quantity limit of 60 capsules per 30 days will apply.

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

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy, except methadone, including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
3. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or

   b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
4. Member must not have known or suspected gastrointestinal obstruction; and
5. Documentation of hydration attempts and trials of at least 3 different types of products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
   a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if the prescriber documents member is responding well to treatment; and
7. Amitiza® must be discontinued if treatment with the opioid pain medication is also discontinued; and
8. A quantity limit of 60 capsules per 30 days will apply.

Ibsrela® (Tenapanor) Approval Criteria:

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

8. A quantity limit of 60 tablets per 30 days will apply.

Motegrity® (Prucalopride) Approval Criteria:

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

Movantik® (Naloxegol) Approval Criteria:

1. An FDA approved diagnosis of opioid-induced constipation (OIC) in members 18 years of age or older with chronic, non-cancer pain who are currently on chronic opioid therapy including members with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Member must not have known or suspected gastrointestinal obstruction; and
3. Documentation of the underlying cause of chronic pain, or reason why member is on chronic opioid therapy; and
4. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):

a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and

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

Pizensy™ (Lactitol) Approval Criteria:

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

8. Use of the unit-dose packets will require a patient-specific, clinically significant reason why the member cannot use the multi-dose bottle; and
9. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
10. A quantity limit of 560 grams per 28 days will apply.

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

1. An FDA approved diagnosis of OIC in members 18 years of age or older with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; and
2. Documentation of the underlying cause of chronic pain, or reason why the member is on chronic opioid therapy; and
3. Member must have current use of opioid medications; and
4. Documented and updated colon screening for members ~~older than 50~~ 45 years of age or older using 1 of the following methods (results must be submitted):
    a. Recent colonoscopy (within the last 10 years or sooner depending on risk factors and/or previous screening results); or
    b. Recent negative Cologuard® test (within the last 3 years or sooner depending on risk factors and/or previous screening results); and
5. Documentation of hydration attempts and trials of at least 3 different products that failed to relieve constipation. Trials must be within the past 90 days. Products may be over-the-counter (OTC) or prescription (does not include fiber or stool softeners); and
    a. 1 of the 3 trials must be polyethylene glycol 3350 (PEG-3350); and
    b. Members with an oncology-related diagnosis are exempt from trial requirements; and
6. Member must not have known or suspected gastrointestinal obstruction; and
7. A patient-specific, clinically significant reason why the member cannot use Amitiza® (lubiprostone), Movantik® (naloxegol), or Symproic® (naldemedine) must be provided; and
8. A patient-specific, clinically significant reason why the member cannot use the tablet formulation of Relistor® must be provided; and
9. The 12mg single-use vials, syringes, or kits will be the preferred products. Criteria for consideration of 8mg single-use syringes:
    a. Weight range of 38kg to 62kg; and/or
    b. Caregiver unable to draw up dose from vial; and
10. Approval will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and

11. Relistor® must be discontinued if treatment with the opioid pain medication is also discontinued; and
12. A quantity limit of 30 units per month will apply.

Relistor® (Methylnaltrexone) Tablets Approval Criteria:

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

Symproic® (Naldemedine) Approval Criteria:

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

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

Trulance® (Plecanatide) Approval Criteria:

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

   b. Members with an oncology-related diagnosis are exempt from the trial requirements; and
6. Approvals will initially be for 12 weeks of therapy. Further approval may be granted if prescriber documents member is responding well to treatment; and
7. A quantity limit of 30 tablets per 30 days will apply.

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

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

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

Recommendation 10: Annual Review of Skin Cancer Medications and 30-Day Notice to Prior Authorize Hepzato Kit™ (Melphalan) and Zynyz™ (Retifanlimab-dlwr)

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

Recommendation 11: Annual Review of Complement Inhibitors and Miscellaneous Immunomodulatory Agents and 30-Day Notice to Prior Authorize Rystiggo® (Rozanolixizumab-noli), Vyvgart® Hytrulo (Efgartigimod Alfa/Hyaluronidase-qvfc), and Zilbrysq® (Zilucoplan)

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

Recommendation 12: Annual Review of Antidepressants and 30-Day Notice to Prior Authorize Exxua™ (Gepirone) and Zurzuvae™ (Zuranolone)

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

Recommendation 13: Annual Review of Lysosomal Storage Disease Medications and 30-Day Notice to Prior Authorize Elfabrio® (Pegunigalsidase Alfa-iwxj), Opfolda™ (Miglustat), and Pombiliti™ (Cipaglucosidase Alfa-atga)

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

Recommendation 14: U.S. Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) Updates

NO ACTION REQUIRED.

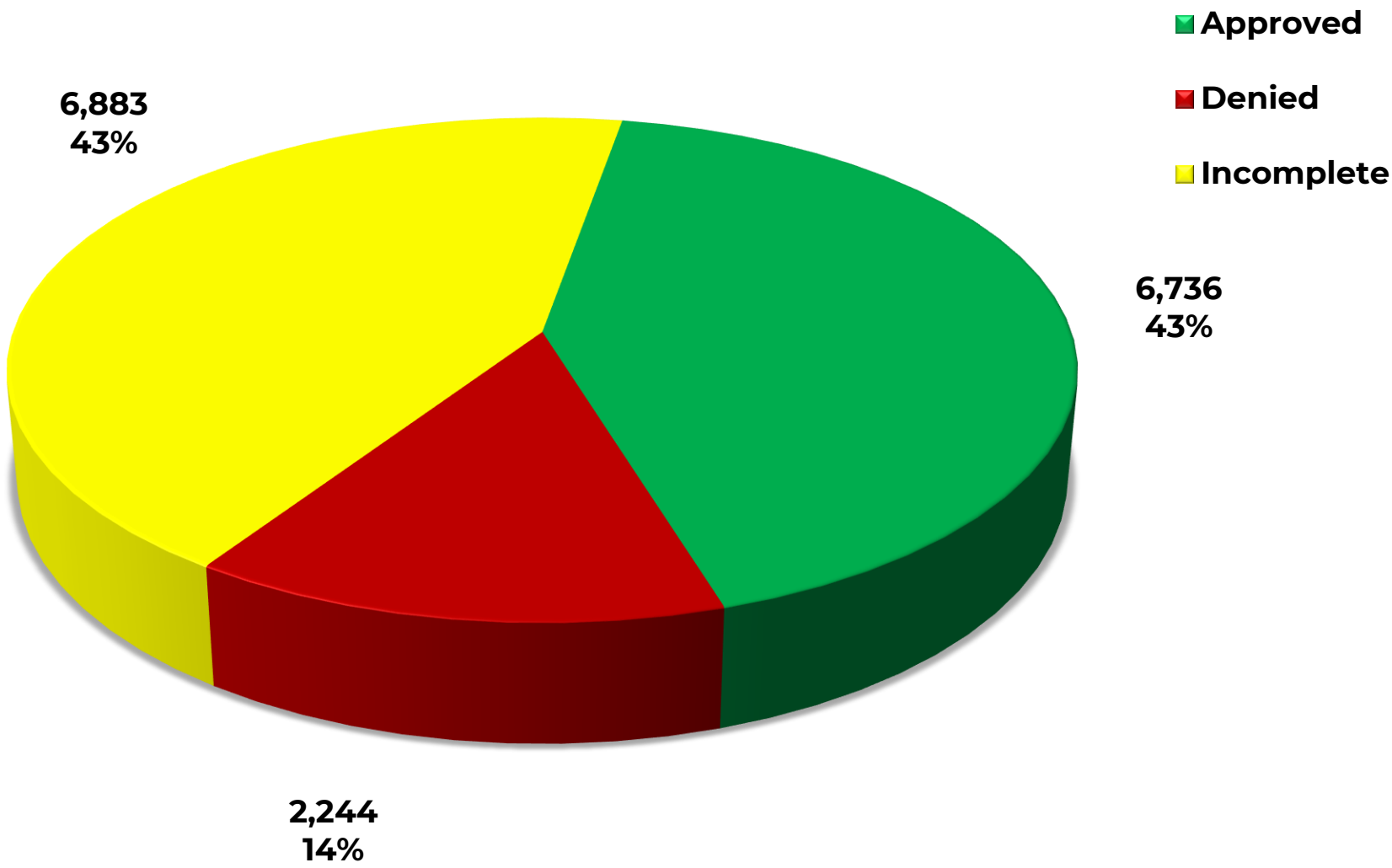
Recommendation 15: Future Business

No live DUR Board meeting scheduled for January 2024. January 2024 will be a packet-only meeting.

NO ACTION REQUIRED.

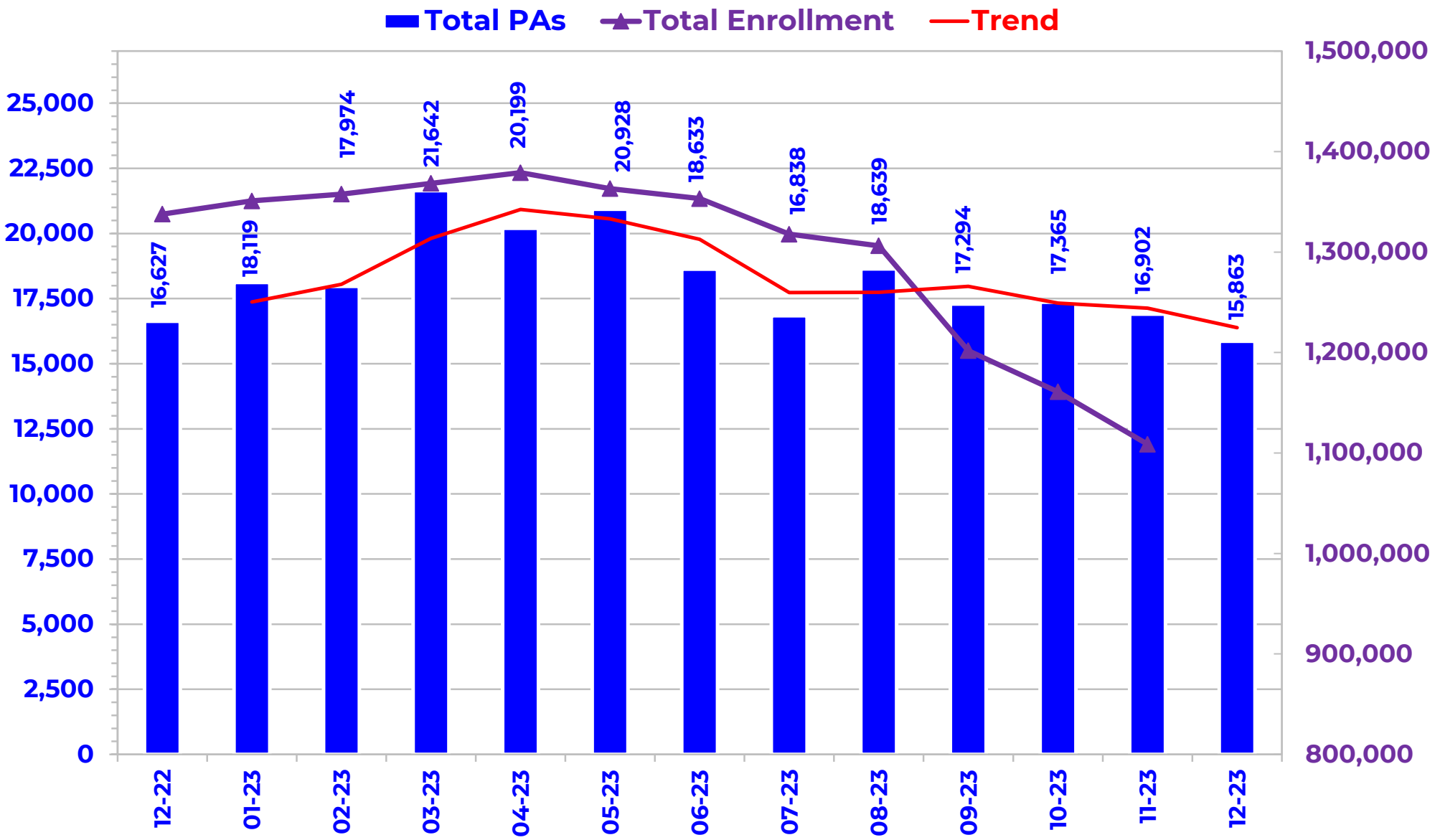
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: DECEMBER 2023



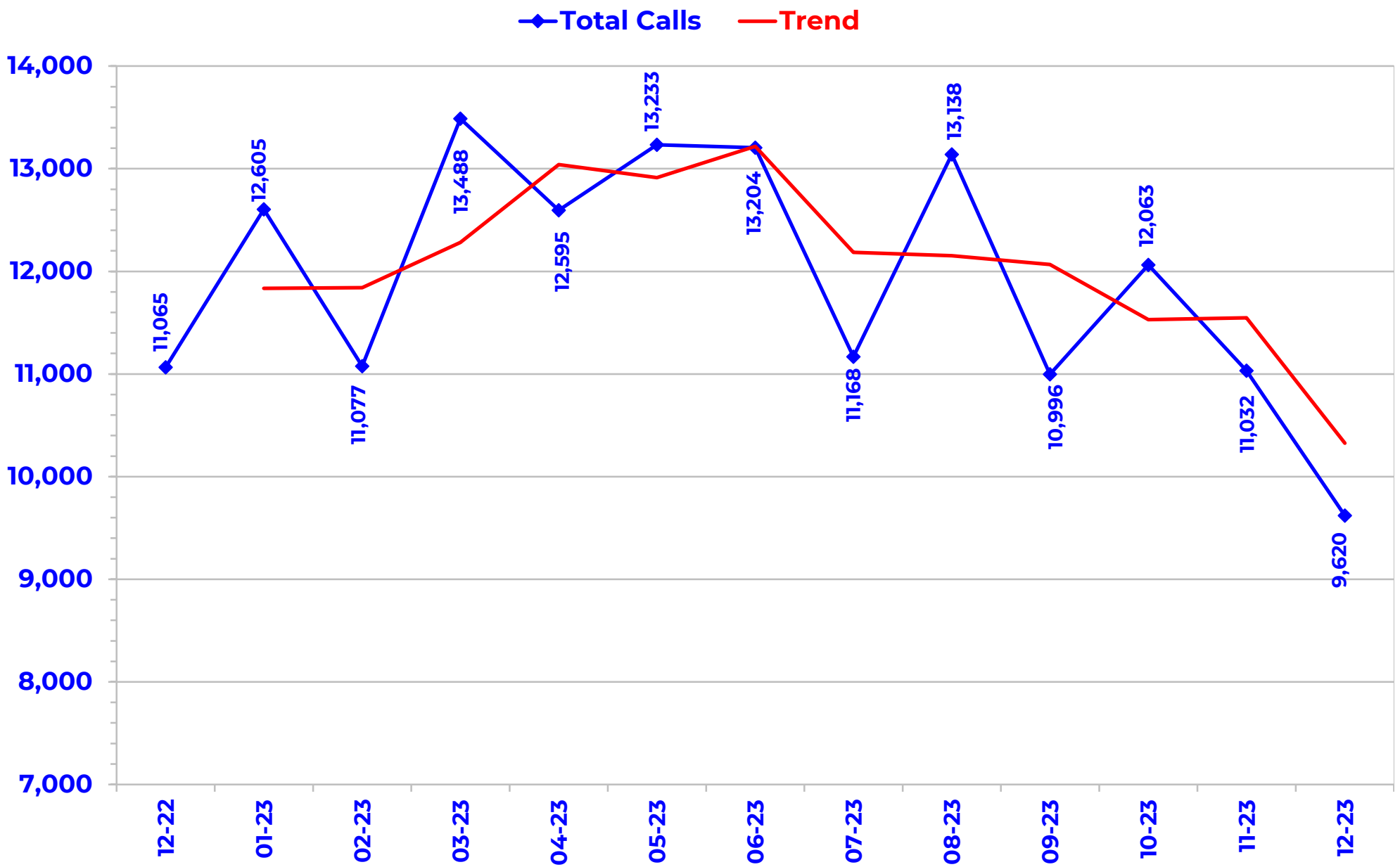
PA totals include approved/denied/incomplete/overrides

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: DECEMBER 2022 – DECEMBER 2023



Prior Authorization Activity

12/1/2023 Through 12/31/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	172	52	11	109	355
Analgesic - NonNarcotic	12	0	1	11	0
Analgesic, Narcotic	420	184	39	197	131
Antiasthma	118	39	24	55	260
Antibiotic	65	34	3	28	227
Anticonvulsant	250	134	13	103	304
Antidepressant	533	115	78	340	277
Antidiabetic	2,173	599	576	998	358
Antifungal	15	4	0	11	143
Antigout	12	2	0	10	268
Antihemophilic Factor	32	17	2	13	247
Antihistamine	49	16	12	21	343
Antimigraine	650	123	207	320	240
Antineoplastic	264	181	17	66	181
Antiobesity	25	0	23	2	0
Antiparasitic	26	5	4	17	84
Antiparkinsons	11	1	2	8	321
Antiulcers	45	6	4	35	147
Anxiolytic	31	5	2	24	312
Atypical Antipsychotics	652	247	58	347	357
Biologics	447	220	62	165	314
Bladder Control	84	19	16	49	314
Blood Thinners	37	3	7	27	360
Botox	59	36	16	7	357
Buprenorphine Medications	100	37	11	52	132
Calcium Channel Blockers	17	4	1	12	291
Cardiovascular	155	87	10	58	344
Chronic Obstructive Pulmonary Disease	298	57	58	183	351
Constipation/Diarrhea Medications	294	75	66	153	224
Contraceptive	63	16	14	33	290
Corticosteroid	10	0	1	9	0
Dermatological	612	193	175	244	237
Diabetic Supplies	444	183	49	212	187
Endocrine & Metabolic Drugs	73	16	16	41	248
Erythropoietin Stimulating Agents	36	14	4	18	111
Estrogen Derivative	11	2	2	7	361
Fibromyalgia	23	9	2	12	249
Fish Oils	24	2	5	17	358
Gastrointestinal Agents	183	57	29	97	204

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

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Genitourinary Agents	11	1	2	8	86
Glaucoma	42	6	8	28	198
Growth Hormones	104	71	8	25	143
Hematopoietic Agents	32	11	7	14	192
Hepatitis C	27	16	3	8	8
HFA Rescue Inhalers	22	1	1	20	361
Insomnia	114	10	23	81	214
Insulin	304	100	23	181	353
Miscellaneous Antibiotics	27	5	4	18	36
Multiple Sclerosis	74	33	10	31	264
Muscle Relaxant	84	16	14	54	158
Nasal Allergy	45	6	10	29	209
Neurological Agents	236	81	44	111	202
Neuromuscular Agents	19	5	5	9	361
NSAIDs	38	2	7	29	361
Ophthalmic	28	11	2	15	177
Ophthalmic Anti-infectives	21	7	1	13	9
Ophthalmic Corticosteroid	13	3	1	9	175
Osteoporosis	20	9	1	10	360
Other*	395	136	63	196	262
Otic Antibiotic	29	1	8	20	10
Pediculicide	26	15	1	10	17
Respiratory Agents	45	26	0	19	285
Statins	63	18	11	34	149
Stimulant	2,705	1,526	112	1,067	323
Synagis	72	44	14	14	17
Testosterone	199	49	46	104	310
Thyroid	20	7	0	13	333
Topical Antifungal	47	5	14	28	154
Topical Corticosteroids	57	1	21	35	361
Vaccine	16	3	7	6	76
Vitamin	97	17	53	27	195
Pharmacotherapy	134	117	1	16	314
Emergency PAs	0	0	0	0	
Total	**13,691**	**5,153**	**2,145**	**6,393**	

* 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	39	24	3	12	170
Compound	7	6	0	1	13
Dosage Change	398	374	1	23	17
High Dose	3	3	0	0	242
Ingredient Duplication	5	4	0	1	131
Lost/Broken Rx	101	90	5	6	17
MAT Override	318	250	10	58	82
NDC vs Age	315	207	31	77	267
NDC vs Sex	16	10	3	3	156
Nursing Home Issue	36	34	0	2	13
Opioid MME Limit	140	46	11	83	123
Opioid Quantity	28	21	0	7	168
Other	51	29	15	7	9
Quantity vs. Days Supply	583	400	15	168	245
STBS/STBSM	11	10	1	0	67
Step Therapy Exception	28	11	3	14	359
Stolen	12	10	1	1	14
Temporary Unlock	1	1	0	0	3
Third Brand Request	80	53	0	27	26
Overrides Total	**2,172**	**1,583**	**99**	**490**	
Total Regular PAs + Overrides	**15,863**	**6,736**	**2,244**	**6,883**	

Denial Reasons	
Unable to verify required trials.	5,796
Does not meet established criteria.	2,265
Lack required information to process request.	1,072
Other PA Activity	
Duplicate Requests	1,496
Letters	40,098
No Process	0
Changes to existing PAs	1,265
Helpdesk Initiated Prior Authorizations	960
PAs Missing Information	716

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

Glaucoma Educational Initiative

Oklahoma Health Care Authority
January 2024

Introduction[1,2,3,4]

Glaucoma is the second leading cause of permanent blindness in the United States and is caused by an increase in intraocular pressure (IOP) which can lead to damage of the optic nerve. It is estimated by the Centers for Disease Control and Prevention (CDC) that 3 million Americans have glaucoma. The most common type of glaucoma is primary open-angle glaucoma (POAG) which often has no early symptoms. The CDC estimates about 50% of people with POAG are unaware they have it. The National Eye Institute (NEI) recommends a dilated eye exam every 1 to 2 years for people who are at high risk of glaucoma which includes people older than 60 years of age, African Americans older than 40 years of age, people with a family history of glaucoma, and those who have diabetes or hypertension.

The treatment of glaucoma is dependent upon the specific type and severity; however, treatment cannot reverse any vision loss, but only prevent further damage. Glaucoma treatment includes medications (i.e., prostaglandins, alpha adrenergic agonists, beta blockers), glaucoma laser treatment, or incisional glaucoma surgeries. Glaucoma is a slowly progressive disease so patients should be educated about the importance of treatment and follow-up with their provider. Current treatment guidelines from the American Academy of Ophthalmology (AAO) for POAG recommend specific follow-up times for patients, which includes a comprehensive eye exam, depending on the severity of their disease and duration of control, with the longest follow-up period being 12 months.

Considering that vision loss with glaucoma is preventable with appropriate treatment and follow-up, during the annual review of the glaucoma medications, an analysis of recent SoonerCare data was done to identify members with POAG who are not receiving appropriate follow up or treatment for glaucoma.

SoonerCare Data

Two groups of members were identified during the time period of December 6, 2022, to December 6, 2023. The first group were members with a diagnosis of POAG in their medical claims history or ≥1 paid pharmacy claim for a glaucoma medication in their pharmacy claims history, and who have a comprehensive eye exam in their medical claims history during the past 12

months (see results in Figure 1). The second group of members were those with a diagnosis of POAG with ≥1 paid pharmacy claim for a glaucoma medication during the past 12 months (see results in Figure 2).

Figure 1: Comprehensive Eye Exam in Members with Glaucoma	
Total number of members with POAG or with ≥1 paid pharmacy claim for a glaucoma medication	4,425
Number of members with a comprehensive eye exam	1,308
Percentage of members with a comprehensive eye exam	29.56%

POAG = primary open-angle glaucoma

Figure 2: Members with a Diagnosis of POAG on Treatment	
Total number of members with a POAG diagnosis	2,565
Number of members with POAG with ≥1 paid pharmacy claim for a glaucoma medication	1,039
Percentage of members with POAG with ≥1 paid pharmacy claim for a glaucoma medication	40.51%

POAG = primary open-angle glaucoma

Conclusions

The results show that only 29.56% of members with a diagnosis of POAG or with ≥1 paid pharmacy claim for a glaucoma medication received a comprehensive eye exam in the previous 12 months. Additionally, only 40.51% of members with a diagnosis of POAG have ≥1 paid pharmacy claim for a glaucoma medication in the past year. It is important to note that the analysis is based on paid SoonerCare pharmacy claims and does not include whether a member received their medications or eye exams through a non-SoonerCare source (i.e., Indian Health Services, private insurance, free clinics). Additionally, the treatment of POAG may include laser therapy and/or surgery, which may delay the need for glaucoma medication; therefore, it may be appropriate for some members to not be utilizing a glaucoma medication. These results indicate a need for provider and member education regarding the importance of treatment and follow-up for glaucoma to help prevent disease progression and vision loss.

Recommendations

The College of Pharmacy recommends a provider educational mailing with the goal of increasing the appropriate utilization of glaucoma medications and annual comprehensive eye exams for members with glaucoma in the Oklahoma SoonerCare population.

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[4] Gedde S, Vinod K, Wright M, et al. American Academy of Ophthalmology (AAO) Primary Open-Angle Glaucoma Preferred Practice Pattern (PPP). *Ophthalmology* 2021; 128(1):PP71-P150. doi: 10.1016/j.ophtha.2020.10.022.

Appendix C

Fiscal Year 2023 Annual Review of Antihyperlipidemics and 30-Day Notice to Prior Authorize Atorvaliq® (Atorvastatin Oral Suspension)

Oklahoma Health Care Authority
January 2024

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. Documented evidence of definite HeFH in both parents; 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®) 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 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 formulation of colesevelam, which is available without prior authorization, must be provided; and
3. The following quantity limits will apply:
   a. 30 chewable bars per 30 days; and
   b. 30 packets for oral suspension per 30 days.

Utilization of Antihyperlipidemics: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	36,374	117,615	$1,871,560.78	$15.91	$0.26	7,532,442	7,214,736
2023	46,759	151,012	$2,371,633.17	$15.70	$0.24	10,193,525	9,818,694
% Change	**28.60%**	**28.40%**	**26.70%**	**-1.30%**	**-7.70%**	**35.30%**	**36.10%**
Change	**10,385**	**33,397**	**$500,072.39**	**-$0.21**	**-$0.02**	**2,661,083**	**2,603,958**

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

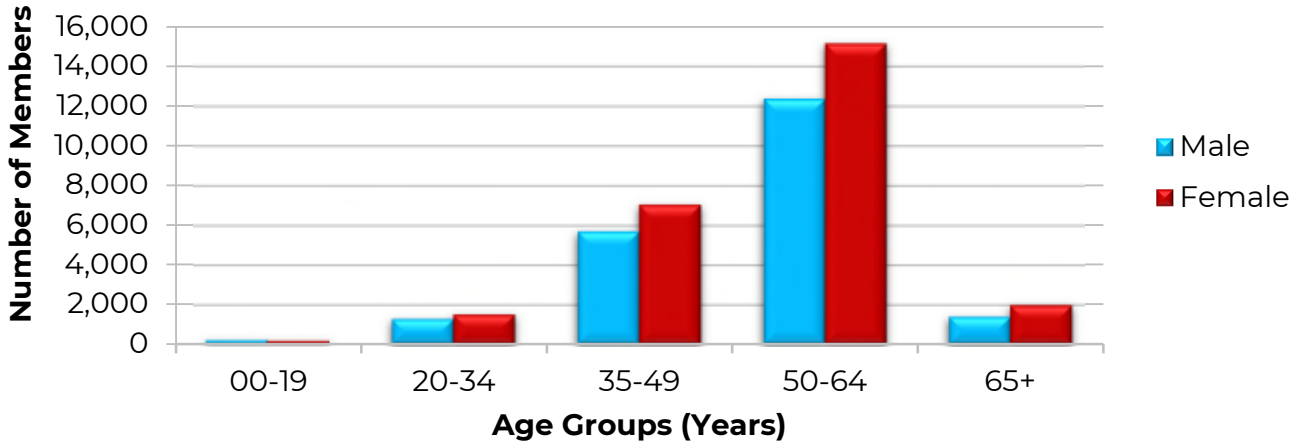
- Aggregate drug rebates collected during fiscal year 2023 for the antihyperlipidemics totaled $262,172.61.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Fiscal Year 2023 Utilization: Medical Claims

Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2023	3	3	$10,201.28	$3,400.43	1

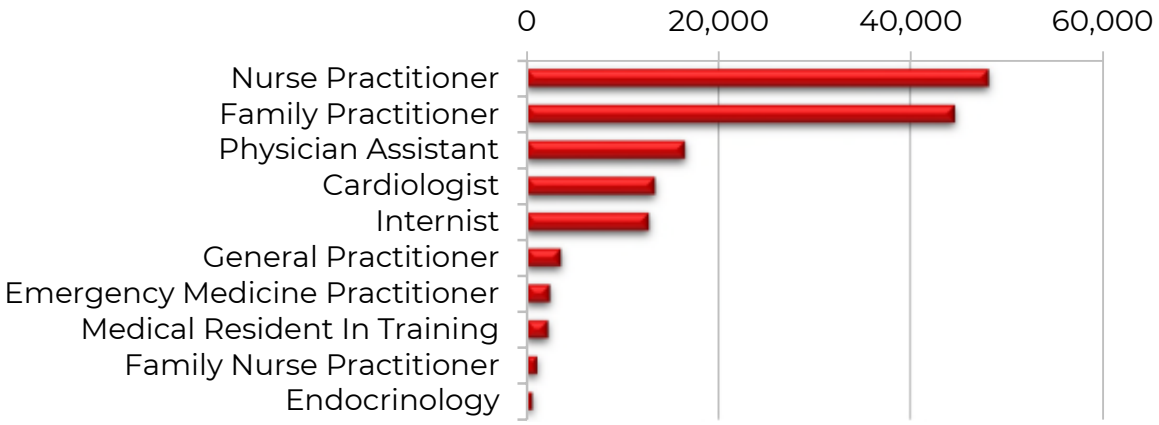
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: There were no paid medical claims during fiscal year 2022 (07/01/2021 to 06/30/2022) to allow for a fiscal year comparison.

Demographics of Members Utilizing Antihyperlipidemics



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

Top Prescriber Specialties of Antihyperlipidemics by Number of Claims



Prior Authorization of Antihyperlipidemics

There were 1,491 prior authorization requests submitted for antihyperlipidemics during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions

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

Anticipated Patent Expiration(s):

- Livalo® (pitavastatin calcium tablet): August 2024
- 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
- Vascepa® (icosapent ethyl capsule): June 2033
- Ezallor™ Sprinkle (rosuvastatin capsule): February 2036
- Leqvio® (inclisiran injection): August 2036
- Atorvaliq® (atorvastatin oral suspension): June 2037
- Nexletol® (bempedoic acid tablet): June 2040
- Nexlizet® (bempedoic acid/ezetimibe tablet): June 2040

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

- **March 2023:** The FDA approved an age expansion for Evkeeza® (evinacumab-dgnb) down to 5 years of age as an adjunct to other lipid-lowering therapies for homozygous familial hypercholesterolemia (HoFH). This makes Evkeeza® the first angiopoietin-like 3 (ANGPTL3) inhibitor treatment indicated for children as young as 5 years of age to control dangerously high levels of low-density lipoprotein cholesterol (LDL-C) caused by HoFH. Evkeeza® was initially FDA approved in February 2021 as an adjunct to other lipid-lowering therapies in those 12 years of age and older with HoFH.
- **July 2023:** The FDA approved a label update for Leqvio® (inclisiran) for the indication of primary hyperlipidemia as an adjunct to diet and statin therapy. Previously Leqvio® was approved only for patients with atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH). The update also included the removal of the previous limitations of use stating, "the effect of Leqvio® on cardiovascular (CV) morbidity and mortality has not been determined." Additionally, 4 adverse reactions (urinary tract infections, diarrhea, pain in extremities, and dyspnea) were removed due to the frequency of these events being equal to those in the placebo arm.
- **December 2023:** The FDA approved label updates for Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe) to include the diagnosis of primary hyperlipidemia. Similar to Leqvio®, the prior limitations of use stating "the effect of Nexlizet® or Nexletol® on CV morbidity and mortality has not been determined" has also been removed. Additionally, the labels have been updated and now state that Nexletol® and Nexlizet® are indicated for use as an adjunct to diet and statin therapy. The prior indication stated they must be used as an adjunct to diet and maximally tolerated statin therapy.

Guideline Update(s):

- **American Diabetes Association (ADA):** The ADA has released their annual Standards of Care in Diabetes for 2024. Some notable updates have been made to the *Cardiovascular Disease and Risk Management* section including the addition of a subsection *Intolerance to Statin Therapy* to expand on this scenario with some updates listed below:
    - For patients with diabetes and ASCVD who are intolerant to statin therapy, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor therapy (i.e., alirocumab, evolocumab, inclisiran) or bempedoic acid therapy should be considered as an alternative cholesterol-lowering therapy.
    - For patients with diabetes without established CV disease (CVD) who are intolerant to statin therapy and/or patients who cannot use or tolerate other evidence-based LDL-C lowering approaches

or for whom those other therapies are inadequately effective, bempedoic acid should be recommended.

- **American College of Cardiology (ACC):** The ACC released the 2022 Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-C lowering in the Management of ASCVD. The goal of this release was to offer guidance on the use of the newer nonstatin therapies and the situations in which they should be considered. Algorithms were created to separate patient groups based on their specific recommendations. Some key points are summarized below:
  - Adults with clinical ASCVD on statin therapy for secondary prevention who are at very high risk or adults who have a baseline LDL-C ≥190mg/dL who do not achieve a ≥50% LDL-C reduction or their LDL-C is ≥55mg/dL on maximally tolerated statins should be considered for either ezetimibe or PCSK9 inhibitor therapy. PCSK9 inhibitors may be preferred if the patient still requires >25% additional lowering of LDL-C. If additional therapy is needed despite maximally tolerated statins, ezetimibe, and a PCSK9 inhibitor, inclisiran in place of the PCSK9 inhibitor or bempedoic acid can also be considered.
  - Adults with possible statin-associated side effects are still recommended to show intolerance to at least 2 statins with 1 attempt at the lowest FDA-approved dose and a trial of alternative dosing. For those who have attempted this and still are intolerant of statins, the nonstatin recommendations depend on the patients' additional clinical factors.

News:

- **March 2023:** Results from the Cholesterol Lowering via Bempedoic acid, an ACL-Inhibiting Regimen (CLEAR) Outcomes trial were presented and showed that bempedoic acid was associated with a lower risk of major adverse CV events in patients who are statin intolerant. The CLEAR Outcomes trial was a double-blind, randomized, placebo-controlled trial in patients who had or were a high risk for a CV event, defined as death from CV causes, nonfatal myocardial infarction, nonfatal stroke, or coronary revascularization. Esperion has submitted 4 supplemental New Drug Applications (sNDAs) to the FDA for Nexletol® (bempedoic acid) and Nexlizet® (bempedoic acid/ezetimibe), seeking the addition of CV risk reduction and the removal of the statin limitation in the indication, and a Prescription Drug User Fee Act (PDUFA) date of March 31, 2024 has been set.

Pipeline:

- **Lerodalcibep (LIB003):** Lerodalcibep is a novel, third-generation, PCSK9 inhibitor in development to overcome the limitations of current

LDL-C lowering treatments. Although not a monoclonal antibody, lerodalcibep works similarly to the current PCSK9 monoclonal antibodies by binding specifically to PCSK9 and blocking it from attaching to the LDL receptors. Lerodalcibep is currently being studied in the Phase 3 LIBerate Program for patients with CVD, very high risk for CVD, HeFH, or HoFH. Lib Therapeutics is planning to submit a Biologics License Application (BLA) to the FDA in 2024.

- **MK-0616:** MK-0616 is an investigational PCSK9 inhibitor that is being studied for the treatment of adults with hypercholesterolemia. MK-0616 has the same mechanism as the currently approved injectable PCSK9 inhibitors but is an oral formulation. Phase 3 trials have been initiated, and this will be the first Phase 3 program for an oral PCSK9 inhibitor.

Recommendations

The College of Pharmacy recommends the prior authorization of Atorvaliq® (atorvastatin oral suspension) and placement into the Special Prior Authorization (PA) Tier of the Statin Medications and Ezetimibe Product Based Prior Authorization (PBPA) category with the following additional criteria (changes shown in red):

Statin Medications and Ezetimibe	
Tier-1	**Special PA**
atorvastatin (Lipitor®)	**atorvastatin suspension (Atorvaliq®)**
ezetimibe (Zetia®)	fluvastatin (Lescol® & Lescol® XL)
lovastatin (Mevacor®)	lovastatin ER (Altoprev®)
pravastatin (Pravachol®)	pitavastatin (Livalo®)
rosuvastatin (Crestor®)	pitavastatin magnesium (Zypitamag®)
simvastatin (Zocor®)	rosuvastatin capsule (Ezallor Sprinkle™)
	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 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 LDL reduction cannot be used; and
2. Use of Atorvaliq® (atorvastatin oral suspension) will require:
   a. An FDA approved indication; and
   b. Member must be 10 years of age or older; and
   c. A patient specific, clinically significant reason why the member cannot use atorvastatin oral tablets, even when the tablets are crushed; and

3. 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
4. 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.

The College of Pharmacy also recommends the following changes to the Evkeeza® (evinacumab-dgnb), Leqvio® (inclisiran), Nexletol® (bempedoic acid), and Nexlizet® (bempedoic acid/ezetimibe) approval criteria based on the new FDA approved label expansions and updates (changes shown in red):

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 5 ~~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.

Leqvio® (Inclisiran) Approval Criteria:

1. An FDA approved indication as an adjunct to diet and 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; or
    c. 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. 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; or
   c. 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. 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.

Finally, the College of Pharmacy recommends the removal of Welchol® (colesevelam) chewable bar due to product discontinuation (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 formulation of colesevelam, which is available without prior authorization must be provided; and
3. 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 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
STATIN MEDICATIONS AND EZETIMIBE						
TIER-1 UTILIZATION						
ATORVASTATIN TAB 40MG	36,284	12,953	$442,848.66	$12.21	2.8	18.67%
ATORVASTATIN TAB 20MG	27,974	10,481	$337,260.93	$12.06	2.67	14.22%
ATORVASTATIN TAB 10MG	15,386	5,629	$175,406.44	$11.40	2.73	7.40%
ATORVASTATIN TAB 80MG	11,673	4,156	$181,124.88	$15.52	2.81	7.64%
ROSUVASTATIN TAB 20MG	6,907	2,691	$96,372.48	$13.95	2.57	4.06%
ROSUVASTATIN TAB 10MG	6,710	2,573	$79,970.41	$11.92	2.61	3.37%
SIMVASTATIN TAB 20MG	4,570	1,517	$48,333.45	$10.58	3.01	2.04%
EZETIMIBE TAB 10MG	4,467	1,643	$66,745.03	$14.94	2.72	2.81%
ROSUVASTATIN TAB 40MG	4,443	1,679	$74,736.67	$16.82	2.65	3.15%
PRAVASTATIN TAB 40MG	3,628	1,195	$54,142.65	$14.92	3.04	2.28%
SIMVASTATIN TAB 40MG	3,258	1,010	$38,387.29	$11.78	3.23	1.62%
ROSUVASTATIN TAB 5MG	2,703	1,116	$33,154.09	$12.27	2.42	1.40%
PRAVASTATIN TAB 20MG	2,634	941	$32,978.74	$12.52	2.8	1.39%
SIMVASTATIN TAB 10MG	2,042	649	$21,343.40	$10.45	3.15	0.90%
LOVASTATIN TAB 20MG	1,521	531	$18,398.73	$12.10	2.86	0.78%
PRAVASTATIN TAB 10MG	1,149	415	$15,421.64	$13.42	2.77	0.65%
LOVASTATIN TAB 40MG	947	303	$11,714.86	$12.37	3.13	0.49%
PRAVASTATIN TAB 80MG	716	222	$13,175.73	$18.40	3.23	0.56%
LOVASTATIN TAB 10MG	378	141	$4,473.87	$11.84	2.68	0.19%
SIMVASTATIN TAB 80MG	319	114	$4,691.91	$14.71	2.8	0.20%
SIMVASTATIN TAB 5MG	147	54	$1,620.81	$11.03	2.72	0.07%
SUBTOTAL	**137,856**	**50,013**	**$1,752,302.67**	**$12.71**	**2.76**	**73.89%**
SPECIAL PA UTILIZATION						
LIVALO TAB 4MG	14	6	$13,015.38	$929.67	2.33	0.55%
EZETIM/SIMVA TAB 10/40MG	8	2	$437.49	$54.69	4	0.02%
LIVALO TAB 2MG	3	2	$2,172.21	$724.07	1.5	0.09%
VYTORIN TAB 10/80MG	3	1	$3,324.96	$1,108.32	3	0.14%
EZETIM/SIMVA TAB 10/80MG	1	1	$36.27	$36.27	1	0.00%
LIVALO TAB 1MG	1	1	$925.61	$925.61	1	0.04%
SUBTOTAL	**30**	**13**	**$19,911.92**	**$663.73**	**2.31**	**0.84%**
STATINS AND EZETIMIBE TOTAL	**137,886**	**50,026**	**$1,772,214.59**	**$12.85**	**2.76**	**74.73%**
FIBRIC ACID DERIVATIVE MEDICATIONS						
TIER-1 UTILIZATION						
FENOFIBRATE TAB 145MG	3,385	1,059	$56,838.67	$16.79	3.2	2.40%
GEMFIBROZIL TAB 600MG	1,970	595	$34,038.26	$17.28	3.31	1.44%
FENOFIBRATE TAB 160MG	1,831	618	$33,257.74	$18.16	2.96	1.40%
FENOFIBRATE TAB 48MG	943	322	$15,049.94	$15.96	2.93	0.63%
FENOFIBRATE TAB 54MG	819	291	$13,235.57	$16.16	2.81	0.56%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FENOFIBRATE CAP 134MG	498	202	$9,151.05	$18.38	2.47	0.39%
FENOFIBRIC CAP 45MG DR	220	34	$3,692.66	$16.78	6.47	0.16%
FENOFIBRATE CAP 67MG	93	36	$1,372.40	$14.76	2.58	0.06%
SUBTOTAL	**9,759**	**3,157**	**$166,636.29**	**$17.08**	**3.09**	**7.03%**
TIER-2 UTILIZATION						
FENOFIBRIC CAP 135MG DR	110	29	$4,490.00	$40.82	3.79	0.19%
FENOFIBRATE CAP 200MG	73	21	$1,428.26	$19.57	3.48	0.06%
FENOFIBRATE TAB 40MG	16	7	$4,323.54	$270.22	2.29	0.18%
FENOFIBRATE TAB 120MG	14	9	$9,576.12	$684.01	1.56	0.40%
FENOFIBRATE CAP 130MG	13	6	$793.77	$61.06	2.17	0.03%
FENOFIBRATE CAP 150MG	6	3	$3,011.32	$501.89	2	0.13%
FENOFIBRATE CAP 50MG	3	2	$275.28	$91.76	1.5	0.01%
SUBTOTAL	**235**	**77**	**$23,898.29**	**$101.69**	**3.05**	**1.01%**
FIBRIC ACID DERIVATIVE TOTAL	**9,994**	**3,234**	**$190,534.58**	**$19.06**	**3.09**	**8.03%**
OMEGA-3 FATTY ACID MEDICATIONS						
OMEGA-3-ACID CAP 1GM	1,885	680	$67,988.86	$36.07	2.77	2.87%
ICOSAPENT CAP 1GM	221	53	$43,422.04	$196.48	4.17	1.83%
VASCEPA CAP 1GM	68	22	$19,888.61	$292.48	3.09	0.84%
LOVAZA CAP 1GM	8	5	$116.23	$14.53	1.6	0.00%
VASCEPA CAP 0.5GM	1	1	$211.12	$211.12	1	0.01%
OMEGA-3 FATTY ACIDS TOTAL	**2,183**	**761**	**$131,626.86**	**$60.30**	**2.87**	**5.55%**
COLESEVELAM PRODUCTS						
COLESEVELAM TAB 625MG	477	160	$23,331.69	$48.91	2.98	0.98%
COLESEVELAM PAK 3.75GM	30	16	$30,764.95	$1,025.50	1.88	1.30%
COLESEVELAM MEDICATIONS TOTAL	**507**	**176**	**$54,096.64**	**$106.70**	**2.88**	**2.28%**
PCSK9 INHIBITORS						
REPATHA SURE INJ 140MG/ML	275	52	$145,373.23	$528.63	5.29	6.13%
PRALUENT INJ 150MG/ML	51	8	$24,363.68	$477.72	6.38	1.03%
REPATHA INJ 140MG/ML	47	13	$22,079.30	$469.77	3.62	0.93%
REPATHA PUSH INJ 420MG/3.5ML	22	5	$12,632.51	$574.21	4.4	0.53%
PRALUENT INJ 75MG/ML	20	5	$8,328.07	$416.40	4	0.35%
PCSK9 INHIBITORS TOTAL	**415**	**83**	**$212,776.79**	**$512.72**	**5**	**8.97%**
BEMPEDOIC ACID/EZETIMIBE PRODUCTS						
NEXLIZET TAB 180/10MG	16	3	$6,207.10	$387.94	5.33	0.26%
BEMPEDOIC ACID/EZETIMIBE TOTAL	**16**	**3**	**$6,207.10**	**$387.94**	**5.33**	**0.26%**
BEMPEDOIC ACID PRODUCTS						
NEXLETOL TAB 180MG	11	4	$4,176.61	$379.69	2.75	0.18%
BEMPEDOIC ACID TOTAL	**11**	**4**	**$4,176.61**	**$379.69**	**2.75**	**0.18%**
TOTAL	**151,012**	**46,759***	**$2,371,633.17**	**$15.70**	**3.23**	**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 2023 = 07/01/2022 to 06/30/2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
INCLISIRAN INJ (J1306)	3	3	$10,201.28	$3,400.43	1
TOTAL	**3⁺**	**3***	**$10,201.28**	**$3,400.43**	**1**

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

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Appendix D

Fiscal Year 2023 Annual Review of Bladder Control Medications and 30-Day Notice to Prior Authorize Oxybutynin 2.5mg Tablet

Oklahoma Health Care Authority
January 2024

Current Prior Authorization Criteria

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
fesoterodine (Toviaz®)	tolterodine (Detrol®)	darifenacin (Enablex®)	desmopressin acetate SL tablets (Nocdurna®)+
oxybutynin (Ditropan®)	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®)Δ tablets and granulesβ	oxybutynin patch (Oxytrol®)+
oxybutynin ER (Ditropan XL®)		oxybutynin gel (Gelnique®)	vibegron (Gemtesa®)+
solifenacin (VESIcare®)Δ		trospium ER (Sanctura XR®)	
solifenacin oral susp (VESIcare LS™)α			
trospium (Sanctura®)			

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 specific to Gemtesa® (vibegron), Nocdurna® (desmopressin acetate SL tablets), and Oxytrol® (oxybutynin patch) applies.
ΔUnique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.
αAn age restriction of 2 to 10 years of age will apply for VESIcare LS™. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.
βThe Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.
ER = extended-release; PA = prior authorization; SL = sublingual; susp = suspension

Bladder Control Medications Tier-2 Approval Criteria:

1. A trial of all Tier-1 medications that yielded an inadequate clinical response or adverse effects; or
2. A unique indication which the Tier-1 medications lack.

Bladder Control Medications Tier-3 Approval Criteria:

1. A trial of all Tier-2 medications that yielded inadequate clinical response or adverse effects; or
2. A unique indication which the Tier-2 medications lack; and
3. For use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin), the member must have failed monotherapy with either mirabegron or solifenacin (minimum 4-week trial) defined by continued symptoms of urge urinary incontinence, urgency, and urinary frequency. Current tier structure rules will also apply.

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Nocdurna® (Desmopressin Acetate Sublingual Tablet) Approval Criteria:

1. An FDA approved diagnosis of nocturia due to nocturnal polyuria in adult members who awaken at least 2 times per night to void; and
2. All other causes of nocturia have been ruled out or adequately treated [e.g., benign prostatic hyperplasia (BPH), overactive bladder (OAB), obstructive sleep apnea (OSA)]; and
3. Prescriber must confirm the member has a 6-month history of at least 2 nocturic episodes per night; and
4. Member has failed behavior modifications including reducing caffeine intake, alcohol intake, and nighttime fluid intake; and
5. Member must have failed a trial of DDAVP® (desmopressin acetate tablets) or have a patient-specific, clinically significant reason why the standard tablet formulation of desmopressin cannot be used; and
6. Prescriber must be willing to measure serum sodium levels prior to starting treatment and document levels are acceptable; and
7. Prescriber must agree to monitor serum sodium levels within the first week and approximately 1 month after starting treatment, and periodically during treatment; and
8. Prescriber must confirm the member is not taking loop diuretics; and
9. Prescriber must confirm the member does not have renal impairment with an estimated glomerular filtration rate (eGFR) <50mL/min/1.73m^2; and
10. Initial approvals will be for the duration of 3 months. For continued authorization, the prescriber must provide the following:

a. Documentation that serum sodium levels are acceptable to the prescriber; and
b. Documentation that the member is responding to treatment; and

11. Approvals will be limited to the 27.7mcg dose for female members; and
12. A quantity limit of 30 tablets per 30 days will apply.

Oxytrol® (Oxybutynin 3.9mg/Day Patch) Approval Criteria:

1. An FDA approved diagnosis of overactive bladder; and
2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
3. A quantity limit of 8 patches per 30 days will apply.

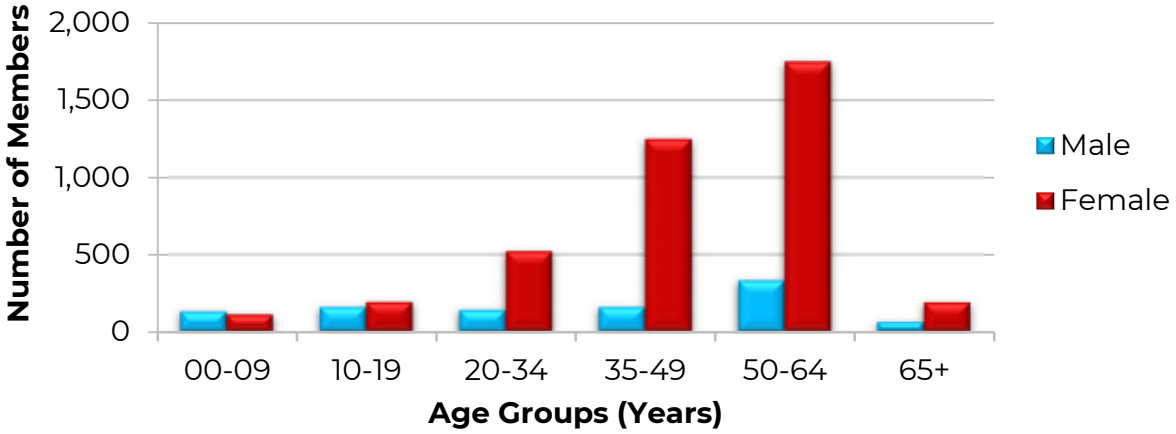
Utilization of Bladder Control Medications: Fiscal Year 2023

Comparison of Fiscal Years

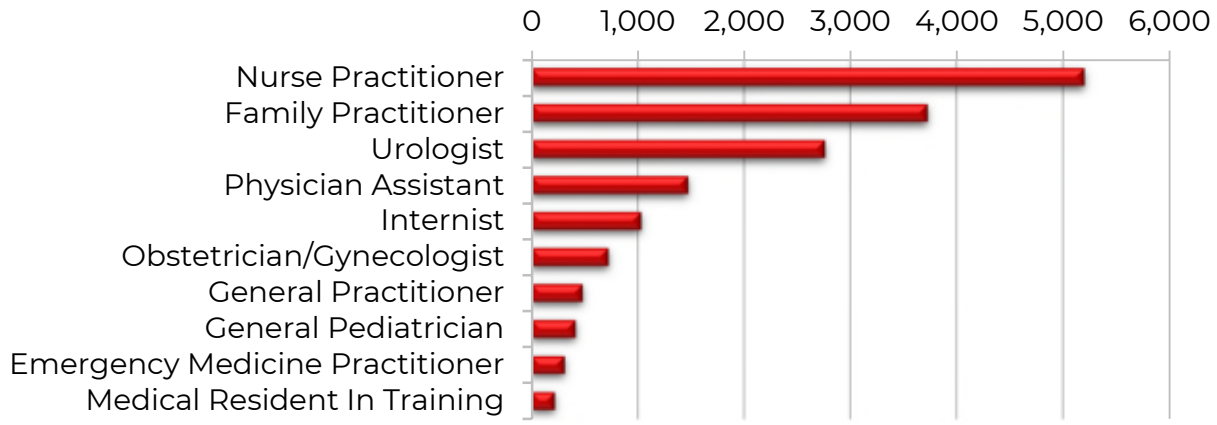
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	4,059	13,889	$767,139.62	$55.23	$1.35	968,672	569,251
2023	4,969	16,957	$784,816.98	$46.28	$1.07	1,147,798	733,098
% Change	**22.40%**	**22.10%**	**2.30%**	**-16.20%**	**-20.70%**	**18.50%**	**28.80%**
Change	**910**	**3,067**	**$17,664.29**	**-$8.95**	**-$0.28**	**179,098**	**163,833**

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

Demographics of Members Utilizing Bladder Control Medications



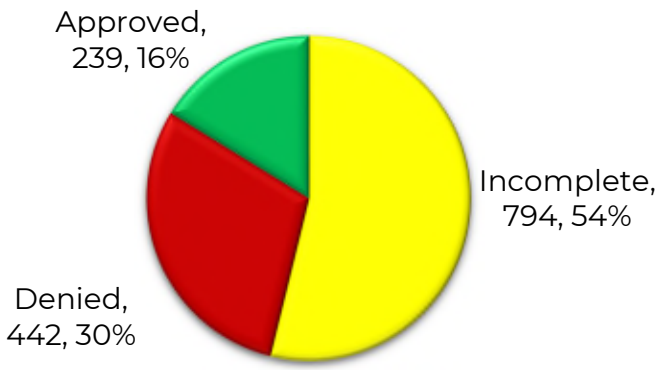
Top Prescriber Specialties of Bladder Control Medications by Number of Claims



Prior Authorization of Bladder Control Medications

There were 1,475 prior authorization requests submitted for bladder control medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Toviaz® (fesoterodine tablet): December 2027
- Myrbetriq® (mirabegron tablet): March 2030
- Nocdurna® (desmopressin acetate sublingual tablet): April 2030
- Gemtesa® (vibegron tablet): December 2030
- Gelnique® (oxybutynin gel): March 2031
- VESIcare LS™ (solifenacin oral suspension): May 2031
- Myrbetriq® (mirabegron granule): October 2036

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

- **February 2023:** The FDA approved an Abbreviated New Drug Application (ANDA) for oxybutynin chloride 2.5mg tablets. Manufactured by Rising Pharmaceuticals, this new strength is indicated for the management of symptoms of bladder instability associated with voiding, similar to other available oxybutynin products.

Cost Comparison

Product	Cost Per Tablet	Cost Per Month	Cost Per Year
oxybutynin IR 2.5mg tablet (generic)	**$2.33**	**$559.20***	**$6,710.40***
oxybutynin IR 5mg tablet (generic)	$0.06	$7.20*	$86.40*
oxybutynin ER 15mg tablet (generic)	$0.15	$9.00[α]	$108.00[α]

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost based on maximum daily dose of 20mg
[α]Cost based on maximum daily dose of 30mg
ER = extended-release; IR = immediate-release

Recommendations

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

1. Adding oxybutynin 2.5mg tablet to the Special Prior Authorization (PA) Tier with the additional criteria listed below; and
2. Making Toviaz® (fesoterodine) brand preferred; and
3. Moving Gelnique® (oxybutynin gel) from Tier-3 to Tier-1.

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
fesoterodine (Toviaz®) – **Brand Preferred**	tolterodine (Detrol®)	darifenacin (Enablex®)	desmopressin acetate SL tablets (Nocdurna®)[+]
oxybutynin (Ditropan®)	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®)[Δ] tablets and granules[β]	**oxybutynin 2.5mg tablet[+]**
oxybutynin ER (Ditropan XL®)		~~**oxybutynin gel (Gelnique®)**~~	oxybutynin patch (Oxytrol®)[+]
oxybutynin gel (Gelnique®)		trospium ER (Sanctura XR®)	vibegron (Gemtesa®)[+]
solifenacin (VESIcare®)[Δ]			

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
solifenacin oral susp (VESIcare LS™)α			
trospium (Sanctura®)			

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 specific to Gemtesa® (vibegron), Nocdurna® (desmopressin acetate SL tablets), **oxybutynin 2.5mg tablet,** and Oxytrol® (oxybutynin patch) applies.
ΔUnique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.
αAn age restriction of 2 to 10 years of age will apply for VESIcare LS™. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.
βThe Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.
ER = extended-release; PA = prior authorization; SL = sublingual; susp = suspension

Oxybutynin 2.5mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use other appropriate Tier-1 products, including splitting an oxybutynin 5mg tablet to achieve a 2.5mg dose, must be provided.

Utilization Details of Bladder Control Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
OXYBUTYNIN PRODUCTS						
OXYBUTYNIN 5MG TAB	4,935	1,723	$71,135.28	$14.41	2.86	9.06%
OXYBUTYNIN ER 10MG TAB	3,039	1,102	$48,183.73	$15.86	2.76	6.14%
OXYBUTYNIN ER 5MG TAB	2,546	987	$37,228.23	$14.62	2.58	4.74%
OXYBUTYNIN ER 15MG TAB	1,242	361	$22,305.11	$17.96	3.44	2.84%
OXYBUTYNIN 5MG/5ML SOL	603	183	$10,930.52	$18.13	3.3	1.39%
SUBTOTAL	**12,365**	**4,356**	**$189,782.87**	**$15.35**	**2.84**	**24.18%**
SOLIFENACIN PRODUCTS						
SOLIFENACIN 5MG TAB	1,141	431	$19,038.50	$16.69	2.65	2.43%
SOLIFENACIN 10MG TAB	984	331	$18,445.92	$18.75	2.97	2.35%
VESICARE LS 5MG/5ML SUS	44	10	$10,891.49	$247.53	4.4	1.39%
VESICARE 10MG TAB	8	4	$5,993.38	$749.17	2	0.76%
VESICARE 5MG TAB	5	3	$1,964.60	$392.92	1.67	0.25%
SUBTOTAL	**2,182**	**779**	**$56,333.89**	**$25.82**	**2.8**	**7.18%**
FESOTERODINE PRODUCTS						
FESOTERODINE ER 8MG TAB	381	122	$26,018.85	$68.29	3.12	3.32%
FESOTERODINE ER 4MG TAB	288	104	$19,027.07	$66.07	2.77	2.42%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TOVIAZ 8MG TAB	124	36	$62,169.66	$501.37	3.44	7.92%
TOVIAZ 4MG TAB	105	39	$49,680.32	$473.15	2.69	6.33%
SUBTOTAL	**898**	**301**	**$156,895.90**	**$174.72**	**2.98**	**19.99%**
TROSPIUM PRODUCTS						
TROSPIUM CL 20MG TAB	328	111	$9,927.69	$30.27	2.95	1.26%
SUBTOTAL	**328**	**111**	**$9,927.69**	**$30.27**	**2.95**	**1.26%**
TIER-1 SUBTOTAL	**15,773**	**5,547**	**$412,940.35**	**$26.18**	**2.84**	**52.62%**
TIER-2 UTILIZATION						
TOLTERODINE PRODUCTS						
TOLTERODINE ER 4MG CAP	122	29	$3,860.61	$31.64	4.21	0.49%
TOLTERODINE 2MG TAB	102	17	$3,212.92	$31.50	6	0.41%
TOLTERODINE ER 2MG CAP	35	8	$1,148.71	$32.82	4.38	0.15%
TOLTERODINE 1MG TAB	11	4	$144.77	$13.16	2.75	0.02%
TIER-2 SUBTOTAL	**270**	**58**	**$8,367.01**	**$30.99**	**4.66**	**1.07%**
TIER-3 UTILIZATION						
MIRABEGRON PRODUCTS						
MYRBETRIQ 50MG TAB	332	52	$139,092.85	$418.95	6.38	17.72%
MYRBETRIQ 25MG TAB	210	44	$87,892.09	$418.53	4.77	11.20%
SUBTOTAL	**542**	**96**	**$226,984.94**	**$418.79**	**5.65**	**28.92%**
TROSPIUM PRODUCTS						
TROSPIUM CL ER 60MG CAP	68	10	$7,464.02	$109.77	6.8	0.95%
SUBTOTAL	**68**	**10**	**$7,464.02**	**$109.77**	**6.8**	**0.95%**
DARIFENACIN PRODUCTS						
DARIFENACIN 15MG TAB	14	2	$663.98	$47.43	7	0.08%
DARIFENACIN 7.5MG TAB	4	1	$161.89	$40.47	4	0.02%
SUBTOTAL	**18**	**3**	**$825.87**	**$45.88**	**6**	**0.11%**
OXYBUTYNIN PRODUCTS						
GELNIQUE 10% GEL	5	1	$4,407.88	$881.58	5	0.56%
SUBTOTAL	**5**	**1**	**$4,407.88**	**$881.58**	**5**	**0.56%**
TIER-3 SUBTOTAL	**633**	**110**	**$239,682.71**	**$378.65**	**5.75**	**30.54%**
SPECIAL PA UTILIZATION						
VIBEGRON PRODUCTS						
GEMTESA 75MG TAB	281	53	$123,826.91	$440.67	5.3	15.78%
SPECIAL PA SUBTOTAL	**281**	**53**	**$123,826.91**	**$440.67**	**5.3**	**15.78%**
TOTAL	**16,957**	**4,969***	**$784,816.98**	**$46.28**	**3.41**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CL = chloride; ER = extended-release; PA = prior authorization; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 12/2023. Last accessed 12/20/2023.
[2] Oxybutynin Chloride Prescribing Information. Rising Pharmaceuticals, Inc. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f8ed80f2-6c3d-4d7f-b761-c2447973c1f9. Last revised 03/2023. Last accessed 12/22/2023.

Appendix E

Fiscal Year 2023 Annual Review of Gastrointestinal (GI) Cancer Medications

Oklahoma Health Care Authority
January 2024

Current Prior Authorization Criteria

Utilization data for Enhertu® (fam-trastuzumab deruxtecan-nxki), Herceptin® (trastuzumab), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ogivri® (trastuzumab-dkst), Ontruzant® (trastuzumab-dttb), and Trazimera® (trastuzumab-qyyp) and approval criteria for indications other than GI cancer can be found in the September 2023 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the breast cancer medications. Utilization data for Keytruda® (pembrolizumab) and Opdivo® (nivolumab) and approval criteria for indications other than GI cancer can be found in the December 2023 DUR Board packet. These medications and criteria are reviewed annually with the skin cancer medications. Utilization data for Lonsurf® (trifluridine/tipiracil) and Stivarga® (regorafenib) and approval criteria for indications other than GI cancer can be found in the July 2023 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the colorectal cancer medications. Utilization data for Sprycel® (dasatinib) and Tasigna® (nilotinib) and approval criteria for indications other than GI cancer can be found in the February 2023 Drug Utilization Review (DUR) Board packet. These medications and criteria are reviewed annually with the leukemia medications.

Ayvakit® (Avapritinib) Approval Criteria [Advanced Systemic Mastocytosis (AdvSM) Diagnosis]:

1. Diagnosis of AdvSM, 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.

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).

Cyramza® (Ramucirumab) Approval Criteria [Colorectal Cancer (CRC) Diagnosis]:

1. Diagnosis of CRC; and

2. Subsequent therapy for metastatic disease after progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine; and
3. In combination with an irinotecan-based regimen.

Cyramza® (Ramucirumab) Approval Criteria [Esophageal Cancer Diagnosis]:

1. Diagnosis of unresectable, locally advanced, recurrent, or metastatic esophageal or esophagogastric junction adenocarcinoma; and
2. Karnofsky performance score ≥60%; and
3. As a single agent or in combination with paclitaxel.

Cyramza® (Ramucirumab) Approval Criteria [Gastric Cancer Diagnosis]:

1. Diagnosis of gastric cancer; and
2. Member is not a surgical candidate or has unresectable, locally advanced, recurrent, or metastatic disease; and
3. Karnofsky performance score ≥60%; and
4. As a single agent or in combination with paclitaxel.

Cyramza® (Ramucirumab) Approval Criteria [Hepatocellular Carcinoma (HCC) Diagnosis]:

1. Diagnosis of HCC; and
2. Second-line or greater therapy; and
3. Previously failed sorafenib; and
4. Alpha-fetoprotein concentration ≥400ng/mL; and
5. As a single agent.

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

1. Diagnosis of metastatic NSCLC; and
2. First-line in combination with erlotinib; and
    a. Epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation; or
3. Subsequent therapy for metastatic disease; and
    a. In combination with docetaxel.

Enhertu® (Fam-Trastuzumab Deruxtecan-nxki) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of locally advanced or metastatic gastric or GEJ adenocarcinoma; and
2. Human epidermal growth factor receptor 2 (HER2)-positive disease; and
3. Member has received at least 1 prior trastuzumab-based regimen.

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

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

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

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

*The Keytruda® criteria listed above for gastric or GEJ adenocarcinoma is pending a vote by the DUR Board. The criteria listed above will be voted on during the February 2024 DUR Board meeting.

Lonsurf® (Trifluridine/Tipiracil) Approval Criteria [Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma Diagnosis]:

1. Diagnosis of metastatic gastric or GEJ adenocarcinoma; and

2. Previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, paclitaxel, docetaxel, or irinotecan; and
3. If human epidermal receptor type 2 (HER2)-positive disease, prior treatment should have included HER2 targeted therapy.

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.

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

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

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.

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.

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.

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

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

Stivarga® (Regorafenib) Approval Criteria [Gastrointestinal Stromal Tumor (GIST) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic GIST; and
2. Previously treated with imatinib and sunitinib.

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

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

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 2023

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

Comparison of Fiscal Years: Medical Claims

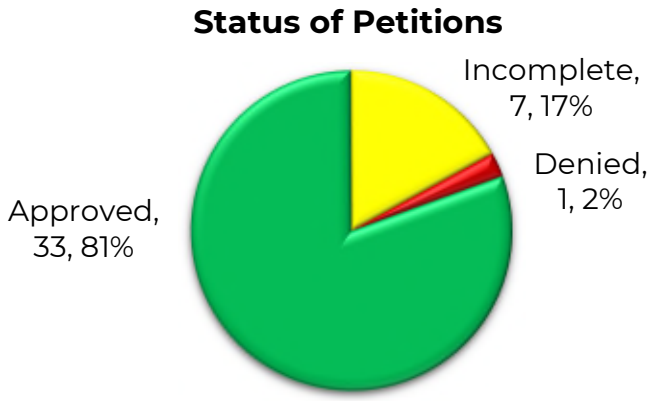
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	11	66	$445,077.39	$6,743.60	6
2023	23	78	$609,810.75	$7,818.09	3.39
% Change	**109.09%**	**18.18%**	**37.01%**	**15.93%**	**-43.50%**
Change	**12**	**12**	**$164,733.36**	**$1,074.49**	**-2.61**

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

- There were no paid pharmacy claims for GI cancer medications during fiscal year 2023.

Prior Authorization of GI Cancer Medications

There were 41 prior authorization requests submitted for GI cancer medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



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

Anticipated Patent or Exclusivity Expiration(s):

- Ayvakit® (avapritinib): October 2034
- Truseltiq® (infigratinib): December 2034
- Lytgobi® (futibatinib): March 2036
- Pemazyre® (pemigatinib): August 2040
- Qinlock® (ripretinib): October 2042

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

- **May 2023:** The FDA approved Ayvakit® (avapritinib) for a new indication for the treatment of adult patients with indolent systemic mastocytosis (ISM). There is a limitation of use stating that Ayvakit® is not recommended for patients with ISM with platelet counts <50 x 10^9/L.

News:

- **November 2022:** Helsinn Therapeutics announced the planned discontinuation of Truseltiq® (infigratinib) due to difficulty enrolling patients into the required confirmatory trial for the medication. The FDA previously granted accelerated approval for Truseltiq® in May 2021 for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement.

Recommendations

The College of Pharmacy recommends updating the approval criteria for Ayvakit® (avapritinib) based on the recent FDA approval for ISM and updating the approval age for the other Ayvakit® indications to be consistent with FDA approved labeling (changes shown in red):

Ayvakit® (Avapritinib) Approval Criteria [Advanced Systemic Mastocytosis (AdvSM) Diagnosis]:

1. Diagnosis of AdvSM, including members with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, or mast cell leukemia; and
2. Member must be 18 years of age or older; and
3. Platelet count ≥50 x 10^9/L.

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

1. Diagnosis of unresectable or metastatic GIST ~~in adult members~~; and
2. Member must be 18 years of age or older; and
3. Member has a PDGFRA exon 18 mutation (including PDGFRA D842V mutations).

Ayvakit® (Avapritinib) Approval Criteria [Indolent Systemic Mastocytosis (ISM) Diagnosis]:

1. Diagnosis of ISM; and
2. Member must be 18 years of age or older; and
3. Platelet count ≥50 x 10^9/L.

The College of Pharmacy also recommends updating the approval criteria for Truseltiq® (infigratinib) based on the manufacturer's planned withdrawal of the medication from the market (changes shown in red):

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; and
5. Members who are new to treatment with Truseltiq® will generally not be approved.

Utilization Details of GI Cancer Medications: Fiscal Year 2023

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J9308 RAMUCIRUMAB INJ	78	23	$609,810.75	$7,818.09	3.39
TOTAL	**78**	**23**	**$609,810.75**	**$7,818.09**	**3.39**

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

[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 12/2023. Last accessed 12/14/2023.
[2] Blueprint Medicines Corporation. FDA Approves Ayvakit® (Avapritinib) as the First and Only Treatment for Indolent Systemic Mastocytosis. Available online at: https://ir.blueprintmedicines.com/news-releases/news-release-details/fda-approves-ayvakitr-avapritinib-first-and-only-treatment. Issued 05/22/2023. Last accessed 12/15/2023.
[3] Ayvakit® (Avapritinib) Prescribing Information. Blueprint Medicines Corporation. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212608s013lbl.pdf. Last revised 05/2023. Last accessed 12/15/2023.
[4] Helsinn Therapeutics – Discontinuation of Truseltiq® (Infigratinib). *OptumRx*®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-withdrawls/drugwithdrawal_truseltiq_2022-1117.pdf. Issued 11/17/2022. Last accessed 12/18/2023.

Appendix F

Fiscal Year 2023 Annual Review of Glaucoma Medications and 30-Day Notice to Prior Authorize iDose® TR (Travoprost Intracameral Implant)

Oklahoma Health Care Authority
January 2024

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%) – **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%)		
Prostaglandin Analogs		
bimatoprost (Lumigan® 0.01%)	bimatoprost (Lumigan® 0.03%)	latanoprost (Iyuzeh™ 0.005%)
latanoprost (Xalatan® 0.005%)		latanoprost (Xelpros™ 0.005%)
netarsudil/latanoprost (Rocklatan®)		latanoprostene bunod (Vyzulta® 0.024%)
tafluprost (Zioptan® 0.0015%)		omidenepag isopropyl (Omlonti® 0.002%)
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 Intracameral 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 2023

Comparison of Fiscal Years: Pharmacy Claims

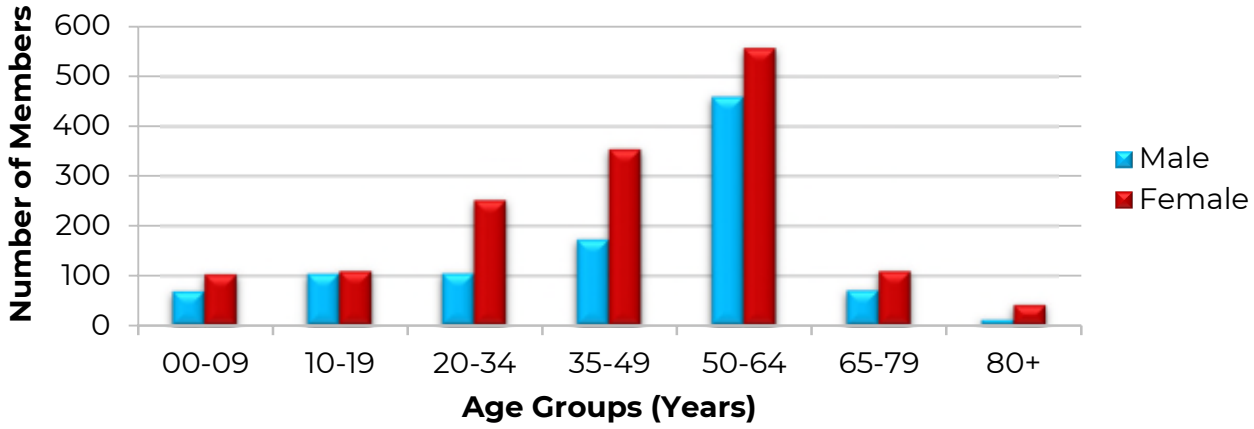
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	2,062	8,681	$659,397.22	$75.96	$1.85	141,702	355,771
2023	2,504	10,699	$771,627.66	$72.12	$1.67	171,629	460,676
% Change	**21.40%**	**23.20%**	**17.00%**	**-5.10%**	**-9.70%**	**21.10%**	**29.50%**
Change	**442**	**2,018**	**$112,230.44**	**-$3.84**	**-$0.18**	**29,927**	**104,905**

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

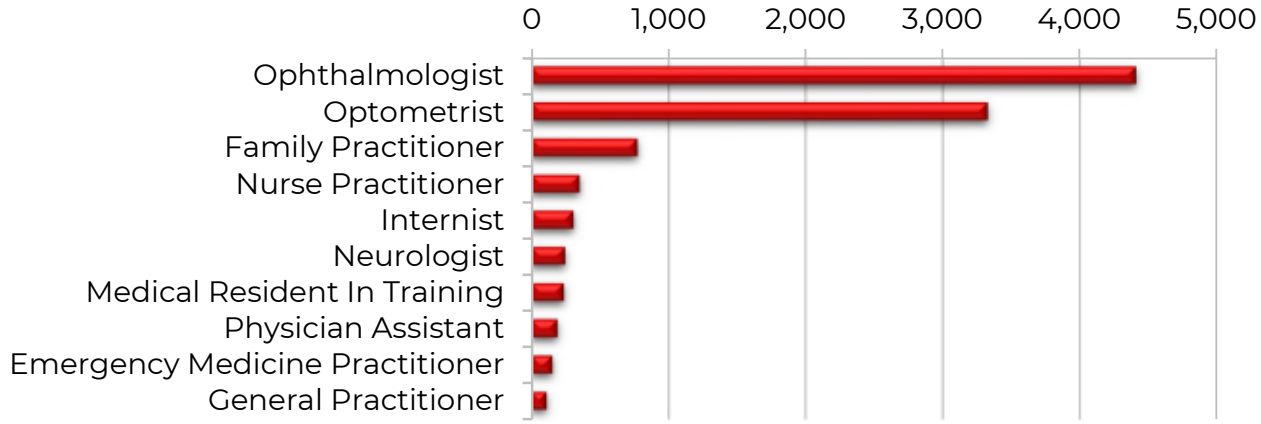
- There were no medical claims for Durysta® (bimatoprost implant) during fiscal year 2023.

- Aggregate drug rebates collected during fiscal year 2023 for the glaucoma medications totaled $554,449.64.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Glaucoma Medications



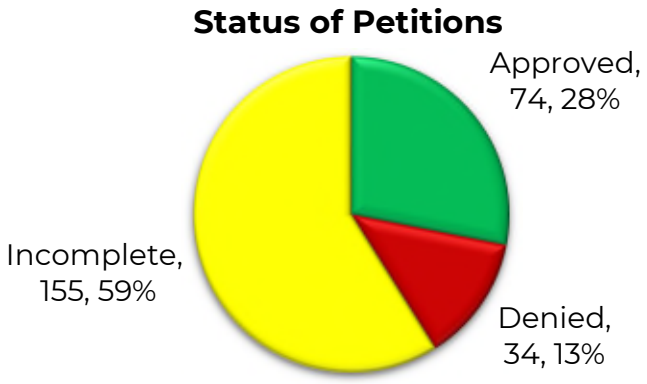
Top Prescriber Specialties of Glaucoma Medications by Number of Claims



Prior Authorization of Glaucoma Medications

There were 263 prior authorization requests submitted for glaucoma medications during fiscal year 2023. Computer edits are in place to detect 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 2023.

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



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- 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):

- **December 2023:** The FDA approved iDose® TR (travoprost intracameral implant) 75mcg, a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with ocular hypertension (OHT) or open-angle glaucoma (OAG).

Pipeline:

- **PDP-716 (Brimonidine Tartrate 0.35%):** PDP-716 is a novel, once daily, ophthalmic suspension of brimonidine tartrate 0.35% used for the treatment of patients with glaucoma. PDP-716 is developed using Sun Pharma Advanced Research Company's (SPARC's) proprietary TearAct™ technology. In July 2023, the FDA issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for PDP-716 due to inspection findings at the third-party active pharmaceutical ingredient (API) manufacturing facility. The FDA did not raise any issues with the clinical efficacy or safety of PDP-176.

iDose® TR (Travoprost Intracameral Implant) Product Summary[4]

Therapeutic class: Prostaglandin analog

Indication(s): The reduction of IOP in patients with OAG or OHT

How Supplied: Intracameral implant containing 75mcg travoprost, pre-loaded in a single-dose inserter

Dosing and Administration:

- For ophthalmic intracameral administration under aseptic conditions only
- iDose® TR should not be readministered to an eye that received a prior iDose® TR implant

Cost Comparison:

Product	Cost Per Implant
iDose® TR (travoprost intracameral implant) 75mcg	**$13,950.00**
Durysta® (bimatoprost intracameral implant) 10mcg	$1,950.00

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).

Recommendations

The College of Pharmacy recommends the prior authorization of iDose® TR (travoprost intracameral implant) with the following criteria (shown in red):

iDose® TR (Travoprost Intracameral 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. iDose® TR must be prescribed by, or in consultation with, an ophthalmologist; and
4. A patient-specific, clinically significant reason why the member requires iDose® TR and cannot utilize ophthalmic preparations, such as solution or suspension, to treat OAG or OHT must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Durysta® (bimatoprost intracameral implant) must be provided; and
6. The affected eye has not received prior treatment with iDose® TR; and
7. Member has no contraindications to iDose® TR; and
8. A quantity limit of (1) iDose® TR 75mcg implant per eye per lifetime will apply.

Additionally, the College of Pharmacy recommends the following changes to the current Glaucoma Medications Product Based Prior Authorization (PBPA) category based on net costs (changes shown in red):

1. Making Alphagan® P 0.1% (brimonidine) brand preferred; and
2. Moving Betoptic-S® 0.25% from Tier-2 to Tier-1; and
3. Making Zioptan® 0.0015% (tafluprost) brand preferred; and
4. Moving Xelpros™ 0.005% from the Special PA Tier to Tier-2.

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%) – **Brand Preferred**		
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**		
brinzolamide/brimonidine (Simbrinza® 0.2%/1%)		
Beta-Blockers		
betaxolol (Betoptic-S® 0.25%)	betaxolol (Betoptic® 0.5%, ~~**Betoptic-S® 0.25%**~~)	timolol maleate (Istalol® 0.5%)
brimonidine/timolol (Combigan® 0.2%/0.5%) – **Brand Preferred**	dorzolamide/timolol (Cosopt® PF 2%/0.5%)	timolol maleate (Timoptic® in Ocudose® 0.25%, 0.5%)
carteolol (Ocupress® 1%)	timolol (Betimol® 0.25%, 0.5%)	
dorzolamide/timolol (Cosopt® 22.3/6.8mg/mL)	timolol maleate (Timoptic-XE® 0.25%, 0.5%)	
levobunolol (Betagan® 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 (Iyuzeh™ 0.005%)
latanoprost (Xalatan® 0.005%)	**latanoprost (Xelpros™ 0.005%)**	~~**latanoprost (Xelpros™ 0.005%)**~~
netarsudil/latanoprost (Rocklatan®)		latanoprostene bunod (Vyzulta® 0.024%)
tafluprost (Zioptan® 0.0015%) – **Brand Preferred**		omidenepag isopropyl (Omlonti® 0.002%)
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

Utilization Details of Glaucoma Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
TIER-1 PRODUCTS						
LATANOPROST SOL 0.005%	3,612	1,069	$57,125.48	3.38	$15.82	7.40%
TIMOLOL MAL SOL 0.5% OP	1,108	490	$19,063.59	2.26	$17.21	2.47%
DORZOL/TIMOL SOL 22.3-6.8MG/ML	1,107	387	$24,110.12	2.86	$21.78	3.12%
BRIMONIDINE SOL 0.2% OP	952	414	$14,340.79	2.3	$15.06	1.86%
ACETAZOLAMIDE TAB 250MG	620	205	$16,207.40	3.02	$26.14	2.10%
ACETAZOLAMIDE CAP 500MG ER	560	167	$18,191.74	3.35	$32.49	2.36%
TRAVATAN Z DRO 0.004%	374	94	$108,595.80	3.98	$290.36	14.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM	% COST
DORZOLAMIDE SOL 2% OP	372	133	$8,340.38	2.8	$22.42	1.08%
LUMIGAN SOL 0.01%	336	117	$133,848.16	2.87	$398.36	17.35%
BRIMO/TIMOL SOL 0.2/0.5%	328	119	$68,306.33	2.76	$208.25	8.85%
COMBIGAN SOL 0.2/0.5%	219	59	$67,289.48	3.71	$307.26	8.72%
SIMBRINZA SUS 1-0.2%	216	76	$45,850.44	2.84	$212.27	5.94%
ALPHAGAN-P SOL 0.1%	156	55	$44,308.49	2.84	$284.03	5.74%
RHOPRESSA SOL 0.02%	151	50	$65,153.72	3.02	$431.48	8.44%
ACETAZOLAMIDE TAB 125MG	110	41	$2,068.02	2.68	$18.80	0.27%
TIMOLOL MAL SOL 0.25% OP	108	45	$1,552.01	2.4	$14.37	0.20%
ROCKLATAN DRO 0.02%/0.005%	79	20	$29,322.76	3.95	$371.17	3.80%
AZOPT SUS 1% OP	43	11	$15,444.30	3.91	$359.17	2.00%
PILOCARPINE SOL 1% OP	13	11	$793.58	1.18	$61.04	0.10%
LEVOBUNOLOL SOL 0.5% OP	12	2	$196.52	6	$16.38	0.03%
ZIOPTAN DRO 0.0015%	11	3	$2,986.50	3.67	$271.50	0.39%
TAFLUPROST SOL 0.0015%	8	3	$1,232.93	2.67	$154.12	0.16%
TRAVOPROST DRO 0.004%	8	1	$598.58	8	$74.82	0.08%
PILOCARPINE SOL 2% OP	4	2	$234.88	2	$58.72	0.03%
PILOCARPINE SOL 4% OP	4	1	$247.96	4	$61.99	0.03%
SUBTOTAL	**10,511**	**3,575**	**$745,409.96**	**2.94**	**$70.92**	**96.60%**
TIER-2 PRODUCTS						
TIMOLOL GEL SOL 0.5% OP	44	27	$2,238.16	1.63	$50.87	0.29%
DORZOL/TIMOL SOL 2%-0.5% PF	42	7	$5,595.53	6	$133.23	0.73%
BIMATOPROST SOL 0.03%	29	10	$2,710.43	2.9	$93.46	0.35%
BETIMOL SOL 0.5%	1	1	$449.11	1	$449.11	0.06%
SUBTOTAL	**116**	**45**	**$10,993.23**	**2.58**	**$94.77**	**1.42%**
SPECIAL PA PRODUCTS						
VYZULTA SOL 0.024%	37	7	$9,620.76	5.29	$260.02	1.25%
BRIMONIDINE SOL 0.15%	24	2	$4,135.36	12	$172.31	0.54%
METHAZOLAMIDE TAB 50MG	9	3	$1,259.31	3	$139.92	0.16%
METHAZOLAMIDE TAB 25MG	2	2	$209.04	1	$104.52	0.03%
SUBTOTAL	**72**	**14**	**$15,224.47**	**5.14**	**$211.45**	**1.97%**
TOTAL	**10,699**	**2,504***	**$771,627.66**	**4.27**	**$72.12**	**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 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2023. Last accessed 12/18/2023.
[2] Glaukos Corporation. Glaukos Announces FDA Approval of iDose® TR (Travoprost Intracameral Implant). Available online at: https://investors.glaukos.com/investors/news/news-details/2023/Glaukos-Announces-FDA-Approval-of-iDoseTR-travoprost-intracameral-implant/default.aspx. Issued 12/14/2023. Last accessed 12/19/2023.
[3] Sun Pharma Advanced Research Company Ltd. (SPARC). FDA Issues Complete Response Letter for PDP-176 NDA due to Inspection Findings at Third-Party API Manufacturing Facility. Available online at: https://www.sparc.life/sites/default/files/2023-07/PDP-716%20press%20release_13th%20July_0.pdf. Issued 07/13/2023. Last accessed 12/18/2023.
[4] iDose® TR (Travoprost Intracameral Implant) Prescribing Information. Glaukos Corporation. Available online at: https://www.idosetrhcp.com/wp-content/uploads/2023/12/iDose-TR-Prescribing-Information.pdf. Last revised 12/2023. Last accessed 12/19/2023.

Appendix G

Fiscal Year 2023 Annual Review of Hyperphosphatemia Medications and 30-Day Notice to Prior Authorize Xphozah® (Tenapanor)

Oklahoma Health Care Authority
January 2024

Current Prior Authorization Criteria

Generic calcium acetate containing products, Fosrenol® (lanthanum carbonate 500mg and 750mg chewable tablet), PhosLo® (calcium acetate gel capsule), Phoslyra® (calcium acetate oral solution), Renagel® (sevelamer hydrochloride tablet), and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
    a. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; or
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in members with CKD not on dialysis; and
    a. Documented lab results verifying IDA; and
    b. Documented intolerance or inadequate response to prior treatment with oral iron; and
3. A quantity limit of 12 tablets per day will apply based on the maximum recommended dose.

Fosrenol® (Lanthanum Carbonate) 1,000mg Chewable Tablets, 750mg Oral Powder, and 1,000mg Oral Powder Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with end stage renal disease (ESRD); and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided; and
3. For the approval of Fosrenol® oral powder, a patient-specific, clinically significant reason why a special formulation is needed over a phosphate binder available without prior authorization, such as brand

Fosrenol® 500mg or 750mg chewable tablets which can be crushed, must be provided; and
4. For the approval of Fosrenol® 1,000mg chewable tablets, a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without a prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets, must be provided; and
5. Fosrenol® 500mg or 750mg chewable tablets are brand preferred. Authorization of the generic formulation requires a patient-specific, clinically significant reason why the member cannot use the brand formulation.

Velphoro® (Sucroferric Oxyhydroxide) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without prior authorization must be provided.

Utilization of Hyperphosphatemia Medications: Fiscal Year 2023

Comparison of Fiscal Years

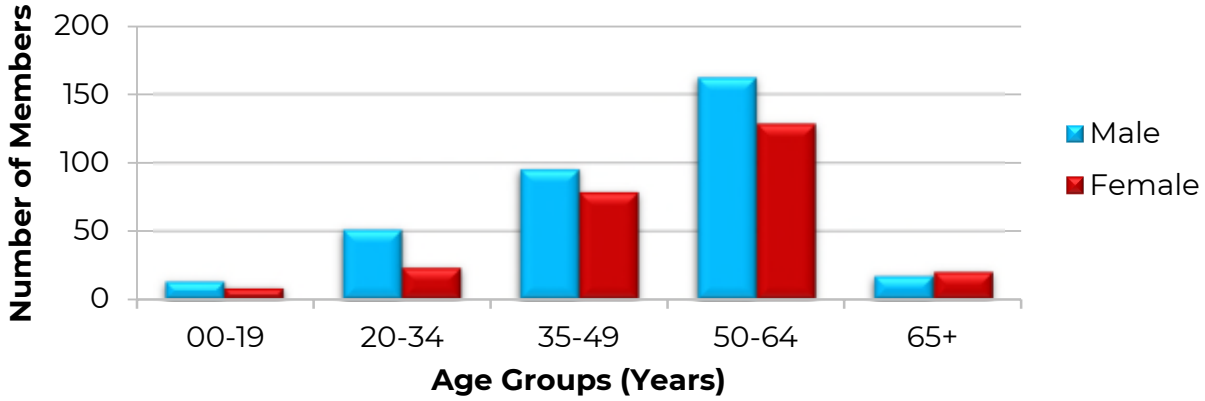
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	486	1,873	$725,620.14	$387.41	$13.34	366,422	54,380
2023	595	2,247	$710,782.22	$316.32	$10.80	439,487	65,801
% Change	**22.40%**	**20.00%**	**-2.00%**	**-18.40%**	**-19.00%**	**19.90%**	**21.00%**
Change	**109**	**374**	**-$14,837.92**	**-$71.09**	**-$2.54**	**73,065**	**11,421**

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

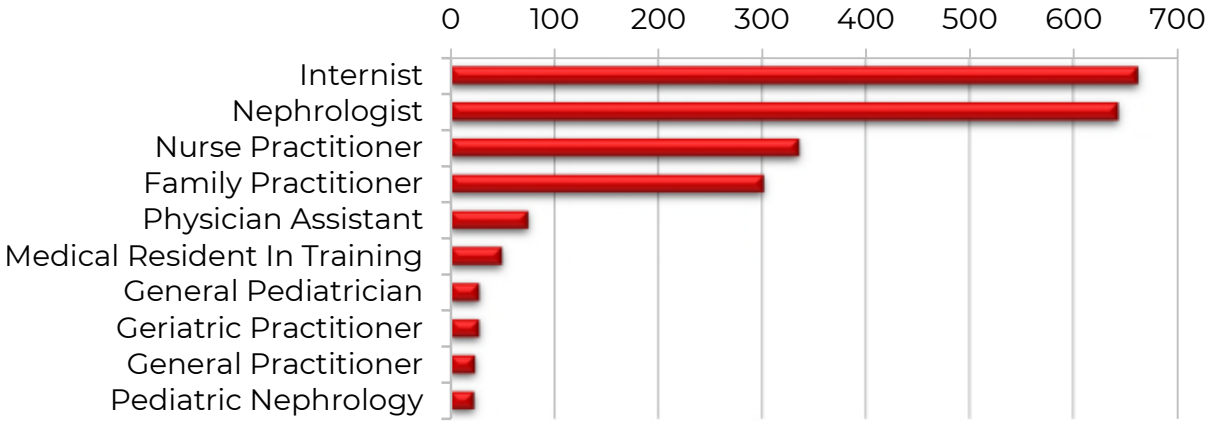
- Aggregate drug rebates collected during fiscal year 2023 for the hyperphosphatemia medications totaled $471,303.56.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Hyperphosphatemia Medications



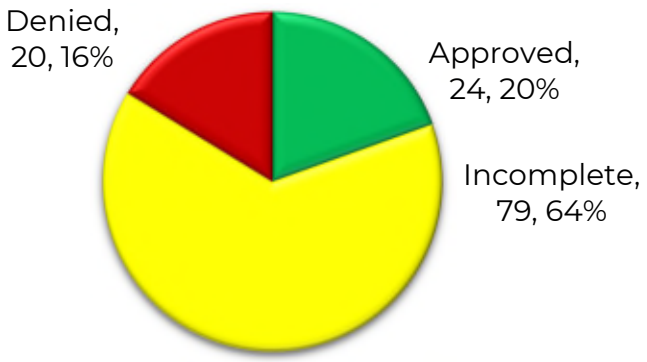
Top Prescriber Specialties of Hyperphosphatemia Medications by Number of Claims



Prior Authorization of Hyperphosphatemia Medications

There were 123 prior authorization requests submitted for hyperphosphatemia medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent Expiration(s):

- Fosrenol® (lanthanum carbonate): August 2024
- Renvela® (sevelamer carbonate tablet): October 2025
- Phoslyra® (calcium acetate): February 2030
- Auryxia® (ferric citrate): July 2030
- Renvela® (sevelamer carbonate packet for suspension): December 2030
- Xphozah® (tenapanor): April 2034
- Velphoro® (sucroferric oxyhydroxide): May 2035

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

- **October 2023:** The FDA approved Xphozah® (tenapanor) to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. The FDA previously issued a Complete Response Letter (CRL) for Xphozah® in 2021, stating that the magnitude of the treatment effect was small and of unclear clinical significance. Ardelyx appealed the decision and, following a positive advisory committee vote in November 2022, the New Drug Application (NDA) for Xphozah® was resubmitted to the FDA in April 2023 and approved in October 2023. Xphozah® was launched to the market in the United States in November 2023.

Xphozah® (Tenapanor) Product Summary[6]

Therapeutic Class: Sodium hydrogen exchanger 3 (NHE3) inhibitor

Indication(s): To reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy

How Supplied: 10mg, 20mg, and 30mg oral tablets

Dosing and Administration:

- Recommended dose is 30mg twice daily before the morning and evening meals
- Serum phosphorus should be monitored, and dosage should be adjusted as needed to manage gastrointestinal tolerability
- Xphozah® should not be taken right before a hemodialysis session; the dose should be taken right before the next meal following dialysis, as patients may experience diarrhea after taking Xphozah®

Cost Comparison: Hyperphosphatemia Medications

Product	Cost Per Unit	Cost Per 30 Days*	Cost Per Year
Xphozah® (tenapanor) 30mg tab	**$49.33**	**$2,959.80**	**$35,517.60**
Velphoro® (sucroferric oxyhydroxide) 500mg tab	$17.05	$1,534.50	$18,414.00
Auryxia® (ferric citrate) 210mg tab	$7.17	$1,290.60	$15,487.20
Fosrenol® (lanthanum carbonate) 500mg tab	$12.01	$1,080.90	$12,970.80
sevelamer hydrochloride 800mg tab (generic)	$2.30	$414.00	$4,968.00
calcium acetate 667mg cap (generic)	$0.27	$48.60	$583.20
sevelamer carbonate 800mg tab (generic)	$0.24	$43.20	$518.40

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
*Cost per 30 days based on the initial FDA recommended dosing for each product
cap = capsule; tab = tablet; unit = each tablet or capsule

Recommendations

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

Xphozah® (Tenapanor) Approval Criteria:

1. An FDA approved indication to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis; and
2. Member must be 18 years of age or older; and
3. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use all phosphate binders available without prior authorization must be provided; and
4. Documented trial of inadequate response to at least 1 iron-based phosphate binder [e.g., Auryxia® (ferric citrate), Velphoro® (sucroferric oxyhydroxide)] or a patient-specific clinically significant reason why the member cannot use an iron-based phosphate binder must be provided.

The College of Pharmacy also recommends the prior authorization of Renagel® (sevelamer hydrochloride) based on net cost with the following criteria (shown in red):

Renagel® (Sevelamer Hydrochloride) Approval Criteria:

1. An FDA approved indication for the control of serum phosphorus in members with chronic kidney disease (CKD) on dialysis; and
2. A patient-specific, clinically significant reason why the member cannot use Renvela® (sevelamer carbonate) 800mg tablets or other phosphate binders available without prior authorization must be provided.

Additionally, the College of Pharmacy recommends updating the Auryxia® (ferric citrate), Fosrenol® (lanthanum carbonate), and Velphoro® (sucroferric oxyhydroxide) approval criteria based on net cost (changes shown in red):

Auryxia® (Ferric Citrate) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
   a. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use ~~a~~ all phosphate binders available without prior authorization must be provided; ~~or~~ and
   b. A patient-specific, clinically significant reason why the member cannot use Velphoro® (sucroferric oxyhydroxide) must be provided; or
2. An FDA approved diagnosis of iron deficiency anemia (IDA) in members with CKD not on dialysis; and
   a. Documented lab results verifying IDA; and
   b. Documented intolerance or inadequate response to prior treatment with oral iron; and
3. A quantity limit of 12 tablets per day will apply based on the maximum recommended dose.

Lanthanum Carbonate (Generic Fosrenol®) ~~(Lanthanum Carbonate) 1,000mg Chewable Tablets, 750mg Oral Powder, and 1,000mg Oral Powder~~ Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with end stage renal disease (ESRD); and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use ~~a~~ all phosphate binders available without prior authorization must be provided; and
~~3. For the approval of Fosrenol® oral powder, a patient-specific, clinically significant reason why a special formulation is needed over a phosphate binder available without prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets which can be crushed, must be provided; and~~
~~4. For the approval of Fosrenol® 1,000mg chewable tablets, a patient-specific, clinically significant reason why the member cannot use a phosphate binder available without a prior authorization, such as brand Fosrenol® 500mg or 750mg chewable tablets, must be provided; and~~
5. Fosrenol® ~~500mg or 750mg chewable tablets are~~ is brand preferred. Authorization of the generic formulation requires a patient-specific,

clinically significant reason why the member cannot use the brand formulation.

Velphoro® (Sucroferric Oxyhydroxide) Approval Criteria:

1. An FDA approved diagnosis of hyperphosphatemia in members with chronic kidney disease (CKD) on dialysis; and
2. Documented trials of inadequate response to at least 2 of the phosphate binders available without prior authorization or a patient-specific, clinically significant reason why the member cannot use ~~a~~ all phosphate binders available without prior authorization must be provided.

Generic calcium acetate containing products, brand name Fosrenol® (lanthanum carbonate ~~500mg and 750mg~~ chewable tablet and oral powder packet), PhosLo® (calcium acetate gel capsule), Phoslyra® (calcium acetate oral solution), ~~Renagel® (sevelamer hydrochloride tablet),~~ and Renvela® (sevelamer carbonate tablet and packet for suspension) are currently available without prior authorization.

Utilization Details of Hyperphosphatemia Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
NO PRIOR AUTHORIZATION (PA) REQUIRED						
SEVELAMER CARBONATE PRODUCTS						
SEVELAMER CARB TAB 800MG	1,289	386	$66,504.41	$51.59	3.34	9.36%
SEVELAMER CARB POW 2.4GM	88	26	$25,954.91	$294.94	3.38	3.65%
SEVELAMER CARB POW 0.8GM	15	9	$4,342.72	$289.51	1.67	0.61%
SUBTOTAL	**1,392**	**421**	**$96,802.04**	**$69.54**	**3.31**	**13.62%**
CALCIUM ACETATE PRODUCTS						
CALC ACETATE CAP 667MG	528	174	$31,192.59	$59.08	3.03	4.39%
CALC ACETATE TAB 667MG	16	12	$2,026.73	$126.67	1.33	0.29%
PHOSLYRA SOL 667MG/5ML	11	3	$3,576.72	$325.16	3.67	0.50%
SUBTOTAL	**555**	**189**	**$36,796.04**	**$66.30**	**2.94**	**5.18%**
LANTHANUM CARBONATE PRODUCTS						
FOSRENOL CHW 750MG	49	12	$75,754.70	$1,546.01	4.08	10.66%
FOSRENOL CHW 500MG	28	7	$65,424.82	$2,336.60	4	9.20%
SUBTOTAL	**77**	**19**	**$141,179.52**	**$1,833.50**	**4.05**	**19.86%**
SEVELAMER HYDROCHLORIDE PRODUCTS						
SEVELAMER HCL TAB 800MG	74	27	$53,263.70	$719.78	2.74	7.49%
SEVELAMER HCL TAB 400MG	2	2	$807.01	$403.51	1	0.11%
SUBTOTAL	**76**	**29**	**$54,070.71**	**$711.46**	**2.62**	**7.61%**
NO PA SUBTOTAL	**2,100**	**658**	**$328,848.31**	**$156.59**	**3.19**	**46.27%**
PA REQUIRED						
SUCROFERRIC OXYHYDROXIDE PRODUCTS						
VELPHORO CHW 500MG	112	26	$318,381.21	$2,842.69	4.31	44.79%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**112**	**26**	**$318,381.21**	**$2,842.69**	**4.31**	**44.79%**
LANTHANUM CARBONATE PRODUCTS						
LANTHANUM CHW 500MG	12	1	$29,262.04	$2,438.50	12	4.12%
FOSRENOL POW 1,000MG	7	2	$7,632.21	$1,090.32	3.5	1.07%
LANTHANUM CHW 1,000MG	6	1	$10,610.01	$1,768.34	6	1.49%
SUBTOTAL	**25**	**4**	**$47,504.26**	**$1,900.17**	**6.25**	**6.68%**
FERRIC CITRATE PRODUCTS						
AURYXIA TAB 210MG	10	6	$16,048.44	$1,604.84	1.67	2.26%
SUBTOTAL	**10**	**6**	**$16,048.44**	**$1,604.84**	**1.67**	**2.26%**
PA REQUIRED SUBTOTAL	**147**	**36**	**$381,933.91**	**$2,598.19**	**4.08**	**53.73%**
TOTAL	**2,247**	**595***	**$710,782.22**	**$316.32**	**3.78**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CALC = calcium; CAP = capsule; CARB = carbonate; CHW = chewable; HCL = hydrochloride; POW = powder; SOL = solution; TAB = tablet
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 12/2023. Last accessed 12/18/2023.
[2] Ardelyx, Inc. FDA Approves Xphozah® (Tenapanor), a First-In-Class Phosphate Absorption Inhibitor. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/fda-approves-xphozahr-tenapanor-first-class-phosphate-absorption. Issued 10/17/2023. Last accessed 12/18/2023.
[3] Ardelyx, Inc. Ardelyx Receives Complete Response Letter from U.S. FDA for New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-receives-complete-response-letter-us-fda-new-drug. Issued 07/29/2021. Last accessed 12/19/2023.
[4] Ardelyx, Inc. Ardelyx Announces FDA Advisory Committee Votes that the Benefits of Xphozah® (Tenapanor) Outweigh its Risks for the Control of Serum Phosphorus in Adult Patients with Chronic Kidney Disease on Dialysis. Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-announces-fda-advisory-committee-votes-benefits-xphozahr. Issued 11/16/2022. Last accessed 12/19/2023.
[5] Ardelyx, Inc. Ardelyx Resubmits New Drug Application to U.S. Food and Drug Administration for Xphozah® (Tenapanor). Available online at: https://ir.ardelyx.com/news-releases/news-release-details/ardelyx-resubmits-new-drug-application-us-food-and-drug. Issued 04/18/2023. Last accessed 12/19/2023.
[6] Xphozah® (Tenapanor) Prescribing Information. Ardelyx, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213931s000lbl.pdf. Last revised 10/2023. Last accessed 12/18/2023.

Appendix H

Fiscal Year 2023 Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Iwilfin™ (Eflornithine), Kepivance® (Palifermin), Loqtorzi™ (Toripalimab-tpzi), and Omisirge® (Omidubicel-onlv)

Oklahoma Health Care Authority
January 2024

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 Tumor (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.

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.

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

1. Pediatric members 1 month to 18 years of age with a diagnosis of localized, non-metastatic solid tumor; and
2. An FDA approved indication to reduce the risk of ototoxicity associated with cisplatin; and
    a. Member's cisplatin regimen must be provided (i.e., frequency of chemotherapy cycles, number of treatment days per cycle, number of chemotherapy cycles remaining); and
3. Pedmark® will be administered as follows:
    a. Starting 6 hours after completion of cisplatin infusion; or
    b. For multi-day cisplatin regimens, Pedmark® will be administered 6 hours after each cisplatin infusion but at least 10 hours before the next cisplatin infusion; and
4. Member has a baseline serum sodium <145mmol/L.

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.

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.

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 2023

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1	4	$6,929.44	$1,732.36	$57.75	120	120
2023	7	52	$1,457,811.69	$28,034.84	$971.87	3,030	1,500
% Change	**600.0%**	**1,200.0%**	**20,937.9%**	**1,518.3%**	**1,582.9%**	**2,425.0%**	**1,150.0%**
Change	**6**	**48**	**$1,450,882.25**	**$26,302.48**	**$914.12**	**2,910**	**1,380**

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

Comparison of Fiscal Years: Medical Claims

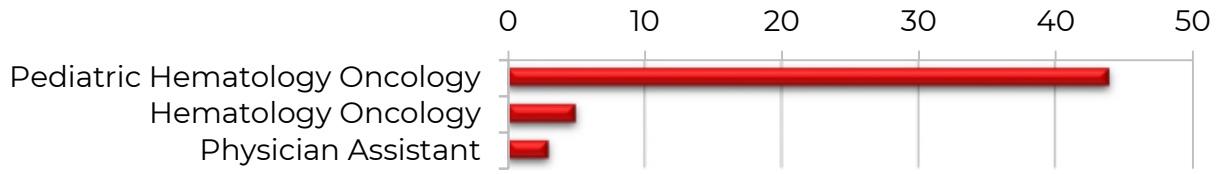
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	4	8	$351,788.00	$43,973.50	2
2023	0	0	$0.00	$0.00	0
% Change	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**	**-100.0%**
Change	**-4**	**-8**	**-$351,788.00**	**-$43,973.50**	**-2**

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; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Demographics of Members Utilizing Miscellaneous Cancer Medications: Pharmacy Claims

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

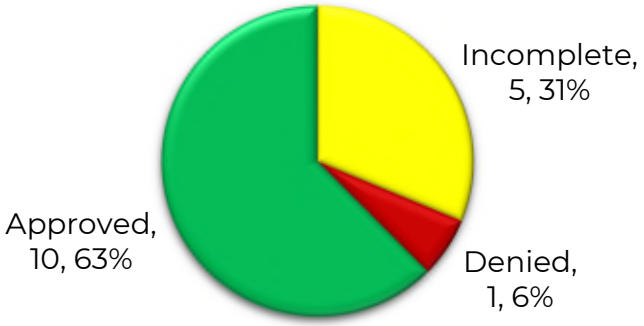
Top Prescriber Specialties of Miscellaneous Cancer Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Miscellaneous Cancer Medications

There were 16 prior authorization requests submitted for miscellaneous cancer medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions



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

Anticipated Patent or Exclusivity Expiration(s):

- Azedra® (iobenguane I-131): July 2025
- Koselugo® (selumetinib): March 2029
- Vijoice® (alpelisib): April 2033
- Rezurock® (belumosudil): April 2035
- Vitrakvi® (larotrectinib): April 2037
- 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):

- **December 2004:** The FDA initially approved Kepivance® (palifermin) in December 2004. Kepivance® is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of autologous hematopoietic stem cell support. Kepivance® is indicated as supportive care for preparative regimens predicted to result in ≥WHO Grade 3 mucositis in the majority of patients. Following an announcement in

February 2023 that Kepivance® was currently unavailable due to FDA regulatory delay, Kepivance® was re-launched in October 2023 with a new 5.16mg vial size.

- **April 2023:** The FDA approved Omisirge® (omidubicel-onlv) for use in adult and pediatric patients 12 years of age and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.
- **October 2023:** The FDA approved Loqtorzi™ (toripalimab-tpzi) for use in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent, locally advanced nasopharyngeal carcinoma (NPC). Additionally, the FDA approved Loqtorzi™ as a single agent for adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.
- **December 2023:** The FDA approved Iwilfin™ (eflornithine) to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.

Iwilfin™ (Eflornithine) Product Summary[8]

Therapeutic Class: Ornithine decarboxylase inhibitor

Indication(s): To reduce the risk of relapse in adult and pediatric patients with HRNB who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy

How Supplied: 192mg oral tablets

Dosing and Administration: Dosed based on body surface area (BSA) twice daily, with or without food, for 2 years or until recurrence of disease or unacceptable toxicity

- Tablets may be swallowed whole, chewed, or crushed

BSA	Dosage
>1.5m^2	768mg (4 tablets) twice daily
0.75 to 1.5m^2	576mg (3 tablets) twice daily
0.5 to <0.75m^2	384mg (2 tablets) twice daily
0.25 to <0.5m^2	192mg (1 tablet) twice daily

BSA = body surface area

Cost: The Wholesale Acquisition Cost (WAC) of Iwilfin™ is $90 per tablet, resulting in a cost of $21,600 per month or $259,200 per year based on the maximum recommended dose of 768mg twice daily.

Kepivance® (Palifermin) Product Summary[9]

Therapeutic Class: Mucocutaneous epithelial human growth factor

Indication(s): To decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of autologous hematopoietic stem cell support; Kepivance® is indicated as supportive care for preparative regimens predicted to result in ≥WHO Grade 3 mucositis in the majority of patients

Limitation(s) of Use:

- The safety and efficacy of Kepivance® have not been established in patients with non-hematologic malignancies.
- Kepivance® was not effective in decreasing the incidence of severe mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of allogeneic hematopoietic stem cell support.
- Kepivance® is not recommended for use with melphalan 200mg/m^2 as a conditioning regimen.

How Supplied: 5.16mg lyophilized powder in a single-dose vial (SDV)

Dosing and Administration: 60mcg/kg as an intravenous (IV) bolus injection given for 3 consecutive days before and 3 consecutive days after myelotoxic therapy, for a total of 6 doses

Cost: The WAC of Kepivance® is $3,313.61 per SDV. For a member weighing 80kg, it would require the use of 1 SDV per dose, resulting in a cost of $19,881.66 for the recommended 6 doses.

Loqtorzi™ (Toripalimab-tpzi) Product Summary[10]

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

Indication(s):

- In combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or recurrent locally advanced NPC
- As a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy

How Supplied: 240mg/6mL solution in a SDV

Dosing and Administration:

- In combination with cisplatin and gemcitabine: 240mg every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months
- As a single agent: 3mg/kg every 2 weeks until disease progression or unacceptable toxicity

- Administered as an IV infusion over 60 minutes for the first infusion or over 30 minutes for subsequent infusions if no infusion-related reactions occurred during the first infusion

Cost: The WAC of Loqtorzi™ is $1,482.01 per milliliter, resulting in a cost of $8,892.06 per SDV. For a member weighing 80kg and using Loqtorzi™ every 2 weeks as a single agent, it would result in an estimated cost of $17,784.12 per 28 days or $231,193.56 per year.

Omisirge® (Omidubicel-onlv) Product Summary[11]

Therapeutic Class: Nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood

Indication(s): For use in adults and pediatric patients 12 years of age and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection

How Supplied: Omisirge® is a cell suspension for IV infusion that consists of a cultured fraction (CF) and a non-cultured fraction (NF) supplied cryopreserved in 2 separate bags containing the following:

- CF: Contains a minimum of 8.0×10^8 total viable cells of which a minimum of 8.7% is CD34+ and a minimum of 9.2×10^7 CD34+ cells
- NF: Contains a minimum of 4.0×10^8 total viable cells with a minimum of 2.4×10^7 CD3+ cells

Dosing and Administration:

- Should be administered by gravity infusion, preferably through central venous access
- The CF bag should be thawed, diluted, and infused first; infusion time should not exceed 2 hours from the end of dilution to the end of the CF infusion
- The NF bag should be thawed, diluted, and infused within 1 hour of safely administering the CF infusion; infusion time should not exceed 1 hour from the end of dilution to the end of infusion

Cost: The WAC of Omisirge® is $338,000 per dose.

Recommendations

The College of Pharmacy recommends the prior authorization of Iwilfin™ (eflornithine), Kepivance® (palifermin), Loqtorzi™ (toripalimab-tpzi), and Omisirge® (omidubicel-onlv) with the following criteria (shown in red):

Iwilfin™ (Eflornithine) Approval Criteria [Neuroblastoma Diagnosis]:

1. Diagnosis of high-risk neuroblastoma (HRNB); and

2. Member has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy; and
3. Used as a single agent to reduce the risk of relapse for a maximum of 2 years; and
4. Member's recent body surface area (BSA) must be provided.

Kepivance® (Palifermin) Approval Criteria [Oral Mucositis Associated with Autologous Stem Cell Transplant Conditioning Diagnosis]:

1. Diagnosis of hematologic malignancy; and
2. Undergoing autologous stem cell transplantation; and
3. Using a preparative regimen predicted to result in ≥Grade 3 mucositis in >50% of patients; and
4. The preparative regimen and a reference for the preparative regimen must be provided; and
    a. Single dose melphalan 200mg/m^2 is not included as an appropriate preparative regimen due to lack of efficacy of palifermin with this regimen.

Loqtorzi™ (Toripalimab-tpzi) Approval Criteria [Nasopharyngeal Carcinoma (NPC) Diagnosis]:

1. Diagnosis of metastatic or recurrent, locally advanced NPC; and
    a. Used in the first-line setting; and
    b. Used in combination with cisplatin and gemcitabine; and
    c. Dose as follows:
        i. 240mg every 3 weeks; and
        ii. Maximum duration of 2 years; or
2. Diagnosis of previously treated recurrent unresectable or metastatic NPC; and
    a. Disease has progressed on or following a platinum-containing chemotherapy; and
    b. Used as a single agent; and
    c. Dose as follows:
        i. 3mg/kg every 2 weeks.

Omisirge® (Omidubicel-onlv) Approval Criteria:

1. Member is 12 years of age or older; and
2. Diagnosis of hematological malignancy; and
3. Allogeneic stem cell transplant using umbilical cord blood donor source is planned; and
    a. Documentation of the donor source must be provided; and
4. Myeloablative conditioning regimen will be used; and
    a. Documentation of the member's conditioning regimen must be provided; and
5. Will be used to reduce time to neutrophil recovery and incidence of infection.

Utilization Details of Miscellaneous Cancer Medications: Fiscal Year 2023

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALPELISIB PRODUCTS						
VIJOICE TAB 50MG	35	4	$1,137,899.35	$32,511.41	8.75	78.06%
SUBTOTAL	**35**	**4**	**$1,137,899.35**	**$32,511.41**	**8.75**	**78.06%**
LAROTRECTINIB PRODUCTS						
VITRAKVI SOL 20MG/ML	12	2	$310,683.92	$25,890.33	6	21.31%
SUBTOTAL	**12**	**2**	**$310,683.92**	**$25,890.33**	**6**	**21.31%**
BELUMOSUDIL PRODUCTS						
REZUROCK TAB 200MG	5	1	$9,228.42	$1,845.68	5	0.63%
SUBTOTAL	**5**	**1**	**$9,228.42**	**$1,845.68**	**5**	**0.63%**
TOTAL	**52**	**7***	**$1,457,811.69**	**$28,034.84**	**7.43**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 12/2023. Last accessed 12/18/2023.
[2] Amgen Inc. FDA Approves Kepivance® for Severe Oral Mucositis in Cancer Patients Undergoing Bone Marrow Transplant; Pivotal Phase 3 Study Published in This Week's New England Journal of Medicine. Available online at: https://investors.amgen.com/news-releases/news-release-details/fda-approves-kepivance-severe-oral-mucositis-cancer-patients. Issued 12/15/2004. Last accessed 12/18/2023.
[3] Ernst D. Oral Mucositis Therapy Kepivance® Currently Unavailable. *Medical Professionals Reference*. Available online at: https://www.empr.com/home/news/oral-mucositis-therapy-kepivance-currently-unavailable/. Issued 02/13/2023. Last accessed 12/18/2023.
[4] Sobi. Kepivance® (Palifermin) for Injection, for Intravenous Use Clarification Regarding the Labeled Quantity and Change in Vial Size. Available online at: https://www.sobi.com/sites/default/files/2023-10/Kepivance%20DHCP_October%202023.pdf. Issued 10/2023. Last accessed 12/18/2023.
[5] U.S. FDA. FDA Approves Omidubicel to Reduce Time to Neutrophil Recovery and Infection in Patients with Hematologic Malignancies. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-omidubicel-reduce-time-neutrophil-recovery-and-infection-patients-hematologic. Issued 04/17/2023. Last accessed 12/18/2023.
[6] U.S. FDA. FDA Approves Toripalimab-Tpzi for Nasopharyngeal Carcinoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-toripalimab-tpzi-nasopharyngeal-carcinoma. Issued 10/27/2023. Last accessed 12/18/2023.
[7] U.S. FDA. FDA Approves Eflornithine for Adult and Pediatric Patients with High-Risk Neuroblastoma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-eflornithine-adult-and-pediatric-patients-high-risk-neuroblastoma. Issued 12/13/2023. Last accessed 12/26/2023.
[8] Iwilfin™ (Eflornithine) Prescribing Information. US WorldMeds, LLC. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215500s000lbl.pdf. Last revised 12/2023. Last accessed 12/26/2023.
[9] Kepivance® (Palifermin) Prescribing Information. Swedish Orphan Biovitrum. Available online at: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=426f6e64-2c20-4a61-6d65-7320426f6e64&type=pdf. Last revised 07/2023. Last accessed 12/18/2023.
[10] Loqtorzi™ (Toripalimab-tpzi) Prescribing Information. Coherus BioSciences, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761240s000lbl.pdf. Last revised 10/2023. Last accessed 12/18/2023.
[11] Omisirge® (Omidubicel-onlv) Prescribing Information. Gamida Cell, Inc. Available online at: https://www.fda.gov/media/167202/download?attachment. Last revised 04/2023. Last accessed 12/18/2023.

Appendix I

Fiscal Year 2023 Annual Review of Non-Malignant Solid Tumor Medications and 30-Day Notice to Prior Authorize Ogsiveo™ (Nirogacestat)

Oklahoma Health Care Authority
January 2024

Current Prior Authorization Criteria

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

1. Documented diagnosis of TSC; and
2. Member has facial angiofibromas that are at least 2mm in diameter with redness in each; and
3. Member must be 6 to 20 years of age; or
    a. For members older than 20 years of age, a clinical exception may apply for medical issues caused by facial angiofibromas (specific documentation of clinically significant medical issues must be provided; Hyftor® is not covered for cosmetic use); and
4. Initial approvals will be for a duration of 12 weeks, as the need for continuing Hyftor® should be reevaluated if symptoms do not improve within 12 weeks of treatment. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and documents the anticipated duration of treatment.

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.

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.

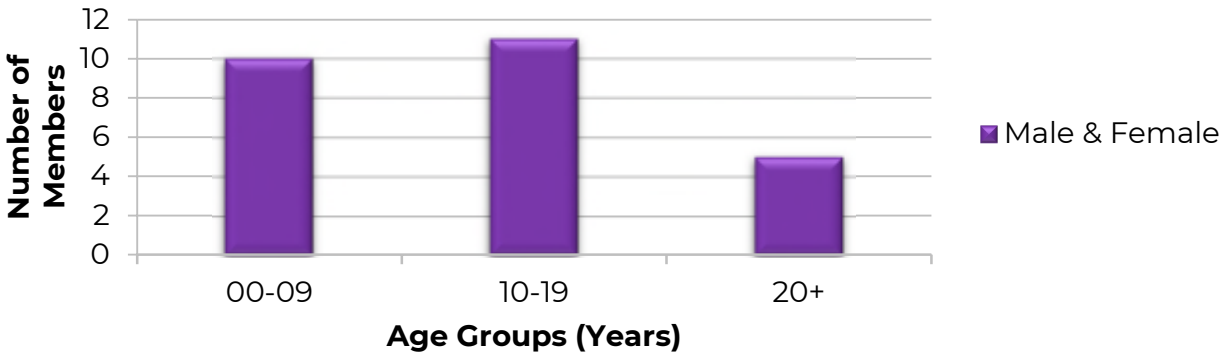
Utilization of Non-Malignant Solid Tumor Medications: Fiscal Year 2023

Comparison of Fiscal Years: Pharmacy Claims

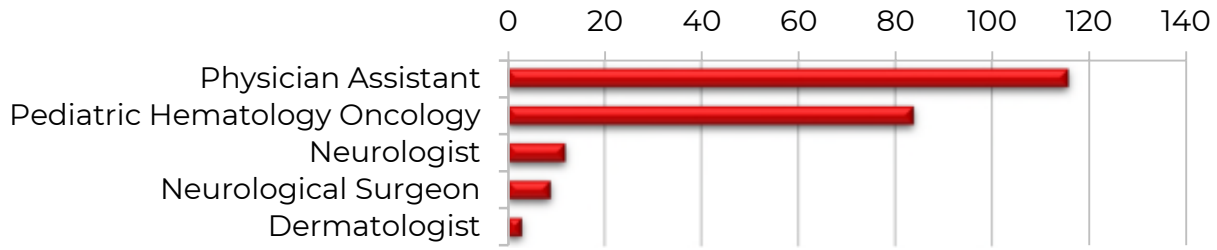
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	14	124	$1,554,226.25	$12,534.08	$421.43	13,824	3,688
2023	26	224	$2,540,617.43	$11,342.04	$379.54	24,058	6,694
% Change	**85.70%**	**80.60%**	**63.50%**	**-9.50%**	**-9.90%**	**74.00%**	**81.50%**
Change	**12**	**100**	**$986,391.18**	**-$1,192.04**	**-$41.89**	**10,234**	**3,006**

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

Demographics of Members Utilizing Non-Malignant Solid Tumor Medications: Pharmacy Claims



Top Prescriber Specialties of Non-Malignant Solid Tumor Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Non-Malignant Solid Tumor Medications

There were 69 prior authorization requests submitted for 27 unique members for non-malignant solid tumor medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

Status of Petitions

Market News and Updates[1,2]

Anticipated Patent or Exclusivity Expiration(s):

- Hyftor® (sirolimus gel): March 2029
- Koselugo® (selumetinib): March 2029
- Turalio® (pexidartinib): July 2038
- Ogsiveo™ (nirogacestat): September 2042

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

- **November 2023:** The FDA approved Ogsiveo™ (nirogacestat) for adult patients with progressing desmoid tumors who require systemic treatment. This is the first FDA approved treatment for desmoid tumors.

Ogsiveo™ (Nirogacestat) Product Summary[3]

Therapeutic Class: Gamma secretase inhibitor

Indication(s): Treatment of adult patients with progressing desmoid tumors who require systemic treatment

How Supplied: 50mg oral tablets

Dose: 150mg [(3) 50mg tablets] twice daily until disease progression or unacceptable toxicity

Cost: The Wholesale Acquisition Cost (WAC) of Ogsiveo™ is $161.11 per tablet, resulting in a cost of $28,999.80 per 30 days or $347,997.60 per year based on the recommended dosing.

Recommendations

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

Ogsiveo™ (Nirogacestat) Approval Criteria [Desmoid Tumor Diagnosis]:

1. Tumor is progressing, requiring systemic treatment.

Utilization Details of Non-Malignant Solid Tumor Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SELUMETINIB PRODUCTS						
KOSELUGO CAP 10MG	127	17	$1,351,641.23	$10,642.84	7.47	53.20%
KOSELUGO CAP 25MG	92	15	$1,176,677.15	$12,789.97	6.13	46.31%
SUBTOTAL	**219**	**23***	**$2,528,318.38**	**$11,544.83**	**9.52**	**99.52%**
SIROLIMUS PRODUCTS						
HYFTOR GEL 0.2%	5	3	$12,299.05	$2,459.81	1.67	0.48%
SUBTOTAL	**5**	**3***	**$12,299.05**	**$2,459.81**	**1.67**	**0.48%**
TOTAL	**224**	**26***	**$2,540,617.43**	**$11,342.04**	**8.62**	**100%**

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

[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 12/2023. Last accessed 12/18/2023.
[2] U.S. FDA. FDA Approves Nirogacestat for Desmoid Tumors. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-nirogacestat-desmoid-tumors. Issued 11/27/2023. Last accessed 12/18/2023.
[3] Ogsiveo™ (Nirogacestat) Prescribing Information. SpringWorks Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217677Orig1s000_Corrected_lbl.pdf. Last revised 11/2023. Last accessed 12/18/2023.

Appendix J

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

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

FDA NEWS RELEASE

For Immediate Release: December 12, 2023

FDA Creates New Advisory Committee for Evaluation of Genetic Metabolic Disease Treatments

The FDA announced it is creating a new advisory committee related to potential treatments for genetic metabolic diseases.

Genetic metabolic diseases are conditions that disrupt an individual's metabolism. These diseases develop when a genetic flaw causes a protein or enzyme to be absent or faulty, interfering with certain vital metabolic functions. There are hundreds of different genetic metabolic diseases, most of which are rare and carry significant morbidity and can be life-limiting.

When called upon, the Genetic Metabolic Diseases Advisory Committee will provide the FDA independent, knowledgeable advice, and recommendations on technical, scientific, and policy issues around medical products for genetic metabolic diseases. Committee members will evaluate evidence on key issues about the applications brought before the advisory committee and offer their recommendations for FDA consideration. The group will be comprised of experts in the areas of metabolic genetics, management of inborn errors of metabolism, small population trial design, translational science, pediatrics, epidemiology, or statistics and related specialties.

The committee will consist of 9 voting members, including the committee chairperson. Individuals nominated as scientific members must be technically qualified experts in their relevant fields and have experience interpreting complex data. The committee will include a consumer representative and an industry representative. Non-Federal members of this committee will serve either as special government employees or non-voting representatives. Members will be invited to serve for overlapping terms of up to 4 years.

The FDA aims to cultivate a diverse committee membership with respect to gender, race, ethnicity, and disability. The FDA is encouraging qualified individuals interested in serving or nominating a representative to serve on the committee to submit nominations. Nominations can either be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal or by mail.

FDA NEWS RELEASE

For Immediate Release: December 08, 2023

FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease

The FDA approved 2 milestone treatments, Casgevy™ and Lyfgenia™, representing the first cell-based gene therapies for the treatment of sickle cell disease (SCD) in patients 12 years of age and older. Additionally, Casgevy™ is the first FDA-approved treatment to utilize a type of novel genome editing technology, signaling an innovative advancement in the field of gene therapy.

SCD is a group of inherited blood disorders affecting approximately 100,000 people in the United States. It is most common in African Americans and, while less prevalent, also affects Hispanic Americans. The primary problem in SCD is a mutation in

hemoglobin (Hb). This mutation causes red blood cells (RBC) to develop a crescent or "sickle" shape. These sickled RBCs restrict the flow in blood vessels and limit oxygen delivery to the body's tissues, leading to severe pain and organ damage called vaso-occlusive events (VOEs) or vaso-occlusive crises (VOCs). The recurrence of these events or crises can lead to life-threatening disabilities and/or early death.

Casgevy™, a cell-based gene therapy, is approved for the treatment of SCD in patients 12 years of age and older with recurrent VOCs. Casgevy™ is the first FDA-approved therapy utilizing CRISPR/Cas9, a type of genome editing technology. Patients' hematopoietic stem cells are modified by genome editing using CRISPR/Cas9 technology. CRISPR/Cas9 can be directed to cut DNA in targeted areas, enabling the ability to accurately edit DNA where it was cut. The modified blood stem cells are transplanted back into the patient where they engraft within the bone marrow and increase the production of fetal hemoglobin (HbF), a type of Hb that facilitates oxygen delivery. In patients with SCD, increased levels of HbF prevent the sickling of RBCs.

The safety and effectiveness of Casgevy™ were evaluated in an ongoing single-arm, multi-center trial in adult and adolescent patients with SCD. Patients had a history of at least 2 protocol-defined severe VOCs during each of the 2 years prior to screening. The primary efficacy outcome was freedom from severe VOC episodes for at least 12 consecutive months during the 24-month follow-up period. A total of 44 patients were treated with Casgevy™. Of the 31 patients with sufficient follow-up time to be evaluable, 29 (93.5%) achieved this outcome. All treated patients achieved successful engraftment with no patients experiencing graft failure or graft rejection. The most common side effects were low levels of platelets and white blood cells, mouth sores, nausea, musculoskeletal pain, abdominal pain, vomiting, febrile neutropenia, headache, and itching.

Lyfgenia™ is a cell-based gene therapy that uses a lentiviral vector for genetic modification and is approved for the treatment of patients 12 years of age and older with SCD and a history of VOEs. With Lyfgenia™, the patient's blood stem cells are genetically modified to produce HbA^{T87Q}, a gene-therapy derived Hb that functions similarly to HbA, which is the normal adult Hb produced in persons not affected by SCD. RBCs containing HbA^{T87Q} have a lower risk of sickling and occluding blood flow. These modified stem cells are then delivered to the patient.

The safety and effectiveness of Lyfgenia™ is based on the analysis of data from a single-arm, 24-month multicenter study in patients with SCD and history of VOEs between 12 and 50 years of age. Effectiveness was evaluated based on complete resolution of VOEs (VOE-CR) between 6 and 18 months after infusion with Lyfgenia™. Twenty-eight (88%) of 32 patients achieved VOE-CR during this time period. The most common side effects included stomatitis, low levels of platelets, white blood cells, and red blood cells, and febrile neutropenia, consistent with chemotherapy and underlying disease. Hematologic malignancy has occurred in patients treated with Lyfgenia™. A black box warning is included in the label for Lyfgenia™ with information regarding this risk. Patients receiving this product should have lifelong monitoring for these malignancies.

Both products are made from the patients' own blood stem cells, which are modified, and are given back as a one-time, single-dose infusion as part of a hematopoietic stem cell transplant. Prior to treatment, a patients' own stem cells are collected, and then the patient must undergo myeloablative conditioning, a process that removes cells from the bone marrow so they can be replaced with the modified cells in

Casgevy™ and Lyfgenia™. Patients who received Casgevy™ or Lyfgenia™ will be followed in a long-term study to evaluate each product's safety and effectiveness.

Both the Casgevy™ and Lyfgenia™ applications received Priority Review, Orphan Drug, Fast Track, and Regenerative Medicine Advanced Therapy designations.

The FDA granted approval of Casgevy™ to Vertex Pharmaceuticals Inc. and approval of Lyfgenia™ to Bluebird Bio Inc.

Current Drug Shortages Index (as of December 28, 2023):

The information provided in this section is provided voluntarily to the FDA by manufacturers and is not specific to Oklahoma. Additional information regarding drug shortages can be found on the FDA website at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

Albuterol Sulfate Solution	***Currently in Shortage***
Alprostadil Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amoxapine Tablet	***Currently in Shortage***
Amoxicillin Powder, For Suspension	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropa Belladonna, Opium Suppository	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***
Bazedoxifene Acetate, Estrogens, Conjugated Tablet	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Capecitabine Tablet	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefixime Capsule	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Collagenase Clostridium Histolyticum Ointment	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Cyclopentolate Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cyclopentolate Hydrochloride, Phenylephrine Hydrochloride Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***

Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate Injection	***Currently in Shortage***
Dextrose Monohydrate, Lidocaine Hydrochloride Anhydrous Injection	***Currently in Shortage***
Diazepam Gel	***Currently in Shortage***
Difluprednate Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Disopyramide Phosphate Capsule	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Epinephrine Injection	***Currently in Shortage***
Erythromycin Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Fluconazole Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl Cellulose (1600000 Wamw) Insert	***Currently in Shortage***
I.V. Fat Emulsion	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Isoniazid Tablet	***Currently in Shortage***
Ketamine Hydrochloride Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Tablet, Film Coated	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Lidocaine Hydrochloride Solution	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***

Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablet	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***
Methotrexate Sodium Tablet	***Currently in Shortage***
Methyldopa Tablet, Film Coated	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric) Injection	***Currently in Shortage***
Neomycin Sulfate Tablet	***Currently in Shortage***
Nitroglycerin Injection	***Currently in Shortage***
Nizatidine Capsule	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection	***Currently in Shortage***
Sodium Chloride 0.9% Irrigation	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sucralfate Tablet	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***

Sulfasalazine Tablet	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsule	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide Injection	***Currently in Shortage***
Vinblastine Sulfate Injection	***Currently in Shortage***