OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday, August 9, 2023

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

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

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

MEMORANDUM

TO: Drug Utilization Review (DUR) Board Members

FROM: Michyla Adams, Pharm.D.

SUBJECT: Packet Contents for DUR Board Meeting – August 9, 2023

DATE: August 2, 2023

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

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

DUR Board Meeting Minutes – Appendix A

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

Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Xacduro® (Sulbactam/Durlobactam) – Appendix C

Annual Review of Intravenous (IV) Iron Products – Appendix D

Annual Review of Topical Corticosteroids – Appendix E

Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Brixadi™ (Buprenorphine Extended-Release Injection), Nalocet® (Oxycodone/ Acetaminophen Tablet), and Prolate™ (Oxycodone/Acetaminophen Tablet) – Appendix F

30-Day Notice to Prior Authorize Cuvrior™ (Trientine Tetrahydrochloride) – Appendix G

Annual Review of Camzyos® (Mavacamten) – Appendix H

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Packet Meeting – August 9, 2023

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

AGENDA

Discussion and action on the following items:

Items to be presented by Dr. Muchmore, Chairman:

1. **DUR Board Meeting Minutes – See Appendix A**
   A. July 12, 2023 DUR Board Meeting Minutes
   B. July 12, 2023 DUR Board Recommendations Memorandum

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

2. **Update on Medication Coverage Authorization Unit/U.S. Food and Drug Administration (FDA) Safety Alerts – See Appendix B**
   A. Pharmacy Help Desk Activity for July 2023
   B. Medication Coverage Activity for July 2023
   C. FDA Safety Alerts

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

3. **Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Xacduro® (Sulbactam/Durlobactam) – See Appendix C**
   A. Current Prior Authorization Criteria
   B. Utilization of Various Systemic Antibiotics
   C. Prior Authorization of Various Systemic Antibiotics
   D. Market News and Updates
   E. Xacduro® (Sulbactam/Durlobactam) Product Summary
   F. College of Pharmacy Recommendations
   G. Utilization Details of Various Systemic Antibiotics

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

4. **Annual Review of Intravenous (IV) Iron Products – See Appendix D**
   A. Current Prior Authorization Criteria
   B. Utilization of IV Iron Products
   C. Prior Authorization of IV Iron Products
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of IV Iron Products

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

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

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

6. **Annual Review of Opioid Analgesics and Medication-Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Brixadi™ (Buprenorphine Extended-Release Injection), Nalocet® (Oxycodone/ Acetaminophen Tablet), and Prolate™ (Oxycodone/Acetaminophen Tablet) – See Appendix F**
   A. Current Prior Authorization Criteria
   B. Utilization of Opioid Analgesics and MAT Medications
   C. Prior Authorization of Opioid Analgesics and MAT Medications
   D. Market News and Updates
   E. Product Summaries
   F. College of Pharmacy Recommendations
   G. Utilization Details of Opioid Analgesics and MAT Medications

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

7. **30-Day Notice to Prior Authorize Cuvrior™ (Trientine Tetrahydrochloride) – See Appendix G**
   A. Introduction
   B. Cuvrior™ (Trientine Tetrahydrochloride) Product Summary
   C. College of Pharmacy Recommendations

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

8. **Annual Review of Camzyos® (Mavacamten) – See Appendix H**
   A. Current Prior Authorization Criteria
   B. Utilization of Camzyos® (Mavacamten)
   C. Prior Authorization of Camzyos® (Mavacamten)
   D. Market News and Updates
   E. College of Pharmacy Recommendations
   F. Utilization Details of Camzyos® (Mavacamten)

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

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

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

10. **Future Business* (Upcoming Product and Class Reviews)**
    A. Breast Cancer Medications
    B. Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators
    C. Synagis® (Palivizumab)
    D. Zinplava™ (Bezlotoxumab)
    *Future product and class reviews subject to change.

11. **Adjournment**

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

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING JULY 12, 2023

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

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

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mark Brandenburg, M.D., MSC; Medical Director		X
Ellen Buettner; Chief of Staff		X
Kevin Corbett, C.P.A.; Chief Executive Officer		X
Terry Cothran, D.Ph.; Pharmacy Director	X	

Josh Holloway, J.D.; Deputy General Counsel	X	
Brandon Keppner; Chief Operating Officer		X
Traylor Rains; State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Paula Root, M.D.; Senior Medical Director, Interim Chief Medical Officer	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Kara Smith, J.D.; General Counsel		X
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	
Toney Welborn, M.D., MPH, MS; Medical Director		X

OTHERS PRESENT:	
Shellie Keast, Mercer	David Shirkey, ALK
Daniel O'Donnell, Axsome	Maggie Shaffer, Alzheimer's Association
Audrey Rattan, Alkermes	Rusty Hailey, Intra-Cellular Therapies
Todd Dickerson, Jazz Pharmaceuticals	Kenneth Berry, Alkermes
Aaron Austin, Takeda	Robert Greely, Biogen
Chrystal Mayes, Sanofi	Bob Atkins, Biogen
Scott Symes, Pharming	Beth Babler, Recordati
Crystal Henderson, Karuna Therapeutics	JJ Roth, Mirum Pharmaceuticals
Seven Tomek, Caris Life Sciences	Stephanie Undernehr, Caris Life Sciences
Rhonda Clark, Indivior	Karen Ward, Krystal Bio
Andi Stratton, Krystal Bio	Madeline Shurtleff, Otsuka
Richie Crawford, Otsuka	Melissa Abbott, Eisai
Mark Kaiser, Otsuka	Todd Ness, AbbVie
Amanda Nowakowski, ViiV	Jonathan Tran, ALK

PRESENT FOR PUBLIC COMMENT:	
Seven Tomek, Caris Life Sciences	Jonathan Tran, ALK
Karen Ward, Krystal Bio	

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 13 SEVEN TOMEK

2B: AGENDA ITEM NO. 14 JONATHAN TRAN

2C: AGENDA ITEM NO. 16 KAREN WARD

ACTION: NONE REQUIRED

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

3A: JUNE 14, 2023 DUR MINUTES – VOTE

Materials included in agenda packet; presented by Dr. Muchmore

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

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT/CHRONIC MEDICATION ADHERENCE (CMA) PROGRAM UPDATE**

4A: PHARMACY HELPDESK ACTIVITY FOR JUNE 2023
4B: MEDICATION COVERAGE ACTIVITY FOR JUNE 2023
4C: CMA PROGRAM UPDATE

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

AGENDA ITEM NO. 5: **VOTE TO PRIOR AUTHORIZE ALTUVIIIO™ [ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC-VMF-XTEN FUSION PROTEIN-EHTL] AND HEMGENIX® (ETRANACOGENE DEZAPARVOVEC-DRLB)**

5A: MARKET NEWS AND UPDATES
5B: PRODUCT SUMMARIES
5C: OHCA RECOMMENDATIONS

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

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE LUMRYZ™ (SODIUM OXYBATE) AND RELEXXII® (METHYLPHENIDATE EXTENDED-RELEASE TABLET) AND UPDATE THE APPROVAL CRITERIA FOR THE ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) AND NARCOLEPSY MEDICATIONS**

6A: MARKET NEWS AND UPDATES
6B: PRODUCT SUMMARIES
6C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE ABILIFY ASIMTUFII® [ARIPIPRAZOLE EXTENDED-RELEASE (ER) INJECTION], QUETIAPINE 150MG TABLET, AND RYKINDO® (RISPERIDONE ER INJECTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ATYPICAL ANTIPSYCHOTIC MEDICATIONS**

7A: MARKET NEWS AND UPDATES
7B: COST COMPARISONS
7C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE ALLOPURINOL 200MG TABLET, APONVIE™ (APREPITANT INJECTABLE EMULSION), ASPRUZYO SPRINKLE™ [RANOLAZINE EXTENDED-RELEASE (ER) GRANULES], AUSTEDO® XR (DEUTETRABENAZINE ER TABLET), ENTADFI® (FINASTERIDE/TADALAFIL CAPSULE), ERMEZA™ (LEVOTHYROXINE ORAL SOLUTION), FUROSCIX® (FUROSEMIDE ON-BODY INFUSOR), IYUZEH™ (LATANOPROST OPHTHALMIC SOLUTION), JYLAMVO® (METHOTREXATE ORAL SOLUTION), PRIMIDONE 125MG TABLET, VERKAZIA® (CYCLOSPORINE OPHTHALMIC SOLUTION), XACIATO™ (CLINDAMYCIN VAGINAL GEL), AND ZOLPIDEM TARTRATE 7.5MG CAPSULE**

8A: INTRODUCTION
8B: PRODUCT SUMMARIES
8C: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

Dr. Muñoz moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 9:</u> VOTE TO PRIOR AUTHORIZE DAYBUE™ (TROFINETIDE)
9A: MARKET NEWS AND UPDATES
9B: DAYBUE™ (TROFINETIDE) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Wilson
Dr. Patatanian moved to approve; seconded by Mr. Foster
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 10:</u> VOTE TO PRIOR AUTHORIZE JOENJA® (LENIOLISIB)
10A: MARKET NEWS AND UPDATES
10B: JOENJA® (LENIOLISIB) PRODUCT SUMMARY
10C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Adams
Dr. Muñoz moved to approve; seconded by Dr. de los Angeles
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 11:</u> VOTE TO PRIOR AUTHORIZE LYVISPAH™ (BACLOFEN ORAL GRANULES) AND NORGESIC®, NORGESIC® FORTE, AND ORPHENGESIC® FORTE (ORPHENADRINE/ASPIRIN/CAFFEINE)
11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Reynolds
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 12:</u> VOTE TO PRIOR AUTHORIZE ADSTILADRIN® (NADOFARAGENE FIRADENOVAC-VNCG) AND ELAHERE™ (MIRVETUXIMAB SORAVTANSINE-GYNX) AND UPDATE THE APPROVAL CRITERIA FOR THE GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS
12A: MARKET NEWS AND UPDATES
12B: PRODUCT SUMMARIES
12C: COLLEGE OF PHARMACY RECOMMENDATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Muñoz moved to approve; seconded by Dr. Patatanian
ACTION: MOTION CARRIED

<u>AGENDA ITEM NO. 13:</u> ANNUAL REVIEW OF COLORECTAL CANCER MEDICATIONS
13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF COLORECTAL CANCER MEDICATIONS
13C: PRIOR AUTHORIZATION OF COLORECTAL CANCER MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF COLORECTAL CANCER MEDICATIONS
Materials included in agenda packet; presented by Dr. Borders
Dr. Patatanian moved to approve; seconded by Dr. Muñoz
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF ALLERGEN IMMUNOTHERAPIES

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF ALLERGEN IMMUNOTHERAPIES
14C: PRIOR AUTHORIZATION OF ALLERGEN IMMUNOTHERAPIES
14D: MARKET NEWS AND UPDATES
14E: COLLEGE OF PHARMACY RECOMMENDATIONS
14F: UTILIZATION DETAILS OF ALLERGEN IMMUNOTHERAPIES

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

AGENDA ITEM NO. 15: ANNUAL REVIEW OF TESTOSTERONE PRODUCTS AND 30-DAY NOTICE TO PRIOR AUTHORIZE KYZATREX® (TESTOSTERONE UNDECANOATE)

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF TESTOSTERONE PRODUCTS
15C: PRIOR AUTHORIZATION OF TESTOSTERONE PRODUCTS
15D: MARKET NEWS AND UPDATES
15E: KYZATREX® (TESTOSTERONE UNDECANOATE) PRODUCT SUMMARY
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF TESTOSTERONE PRODUCTS

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

AGENDA ITEM NO. 16: 30-DAY NOTICE TO PRIOR AUTHORIZE VYJUVEK™ (BEREMAGENE GEPERPAVEC-SVDT)

16A: INTRODUCTION
16B: VYJUVEK™ (BEREMAGENE GEPERPAVEC-SVDT) PRODUCT SUMMARY
16C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 17: ANNUAL REVIEW OF ALZHEIMER'S DISEASE MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE LEQEMBI® (LECANEMAB-IRMB)

17A: CURRENT PRIOR AUTHORIZATION CRITERIA
17B: UTILIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
17C: PRIOR AUTHORIZATION OF ALZHEIMER'S DISEASE MEDICATIONS
17D: MARKET NEWS AND UPDATES
17E: LEQEMBI® (LECANEMAB-IRMB) PRODUCT SUMMARY
17F: COLLEGE OF PHARMACY RECOMMENDATIONS
17G: UTILIZATION DETAILS OF ALZHEIMER'S DISEASE MEDICATIONS

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

AGENDA ITEM NO. 18: ANNUAL REVIEW OF ISTURISA® (OSILODROSTAT) AND RECORLEV® (LEVOKETOCONAZOLE)

18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF ISTURISA® (OSILODROSTAT) AND RECORLEV® (LEVOKETOCONAZOLE)
18C: PRIOR AUTHORIZATION OF ISTURISA® (OSILODROSTAT) AND RECORLEV® (LEVOKETOCONAZOLE)
18D: MARKET NEWS AND UPDATES

18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF ISTURISA® (OSILODROSTAT) AND RECORLEV® (LEVOKETOCONAZOLE)
Materials included in agenda packet; presented by Dr. Reynolds
ACTION: NONE REQUIRED

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

AGENDA ITEM NO. 20: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
NO LIVE DUR BOARD MEETING SCHEDULED FOR AUGUST 2023. AUGUST 2023 WILL BE A PACKET-ONLY MEETING.
20A: INTRAVENOUS (IV) IRON PRODUCTS
20B: OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
20C: TOPICAL CORTICOSTEROIDS
20D: VARIOUS SYSTEMIC ANTIBIOTICS
*Future product and class reviews subject to change.
Materials included in agenda packet; presented by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: ADJOURNMENT
The meeting was adjourned at 5:26 pm.

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

Memorandum

Date: July 14, 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 July 12, 2023

Recommendation 1: Chronic Medication Adherence (CMA) Program Update

NO ACTION REQUIRED.

Recommendation 2: Vote to Prior Authorize Altuviiio™ [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] and Hemgenix® (Etranacogene Dezaparvovec-drlb)

MOTION CARRIED by unanimous approval.

The Oklahoma Health Care Authority recommends the prior authorization of Altuviiio™ [antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] and Hemgenix® (etranacogene dezaparvovec-drlb) as follows (changes and new criteria shown in red):

Adynovate®, Afstyla®, Alprolix®, Altuviiio™, Eloctate®, Esperoct®, Idelvion®, Jivi®, and Rebinyn® Approval Criteria:

1. An FDA approved indication; and
2. Requested medication must be prescribed by a hematologist specializing in rare bleeding disorders or a mid-level practitioner with a supervising physician that is a hematologist specializing in rare bleeding disorders; and

3. A patient-specific, clinically significant reason why the member cannot use the following must be provided:
    a. Hemophilia A: Advate® or current factor VIII replacement product; or
    b. Hemophilia B: Benefix® or current factor IX replacement product; and
4. A half-life study must be performed to determine the appropriate dose and dosing interval; and
5. Initial approvals will be for the duration of the half-life study. If the half-life study shows significant benefit in prolonged half-life, subsequent approvals will be for the duration of 1 year.

Hemgenix® (Etranacogene Dezaparvovec-drlb) Approval Criteria:

1. Diagnosis of severe or moderately severe congenital, X-linked, hemophilia B; and
2. Member must not have a history of an inhibitor or a recent positive screening, defined as ≥0.6 Bethesda units, prior to administration of etranacogene dezaparvovec-drlb; and
3. Member must not have an AAV5 neutralizing antibody titer >700; and
4. Member must be a male 18 years of age or older; and
5. Member must be on prophylactic therapy with continued frequent breakthrough bleeding episodes or has experienced a life-threatening bleeding episode; and
6. Member must have had >150 previous exposure days of treatment with factor IX; and
7. Member must not have active hepatitis B or C; and
8. Members with human immunodeficiency virus (HIV) must be controlled with antiviral therapy; and
9. Member must not have received prior treatment with any gene therapy for hemophilia B; and
10. Prescriber must perform baseline liver health assessment including:
    a. Enzyme testing (ALT, AST, ALP); and
    b. Hepatic ultrasound; and
11. Member's recent weight must be provided (taken within the last month) to ensure appropriate dosing; and
12. Must be prescribed by a hematologist practicing in a federally recognized Hemophilia Treatment Center (HTC) or mid-level practitioner under the supervision of a physician at an HTC; and
13. Must be administered in a clinical setting and monitoring performed for at least 3 hours post-infusion; and
14. Prescriber must monitor liver enzymes weekly for 3 months following administration of etranacogene dezaparvovec-drlb and continue monitoring until liver enzymes return to baseline; and
    a. Prescriber must agree to begin corticosteroids if indicated; and
15. Approvals will be for 1 dose per member per lifetime.

Recommendation 3: Vote to Prior Authorize Lumryz™ (Sodium Oxybate) and Relexxii® (Methylphenidate Extended-Release Tablet) and Update the Approval Criteria for the Attention-Deficit/Hyperactivity Disorder (ADHD) and Narcolepsy Medications

MOTION CARRIED by unanimous approval.

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

1. The prior authorization of Relexxii® (methylphenidate ER tablet) and placement into the Special PA Tier of the ADHD Medications PBPA Tier chart; and
2. The prior authorization of Lumryz™ (sodium oxybate) with criteria similar to Xywav® (calcium/magnesium/potassium/sodium oxybates); and
3. Moving Dexedrine Spansules® (dextroamphetamine ER capsule) from the Special PA Tier to Tier-2, moving methylphenidate ER 72mg tablet from Tier-3 to the Special PA Tier, moving Vyvanse® (lisdexamfetamine chewable tablet) from the Special PA Tier to Tier-1, and moving Ritalin LA® (methylphenidate ER capsule) from Tier-1 to Tier-2 based on net costs; and
4. Making Aptensio XR® (methylphenidate ER capsule), Daytrana® (methylphenidate ER patch), and Xyrem® (sodium oxybate solution) brand preferred based on net costs; and
5. Updating the approval criteria for Qelbree® (viloxazine) based on the higher FDA approved maximum dosing in adults.

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Amphetamine			amphetamine ER susp (Adzenys ER™) amphetamine ER ODT (Adenyls XR-ODT®) amphetamine (Evekeo®) amphetamine ODT (Evekeo ODT™) amphetamine/ dextroamphetamine ER (Mydayis®) dextroamphetamine (Dexedrine®)
Short-Acting			
amphetamine/ dextroamphetamine (Adderall®)			
Long-Acting			
amphetamine/ dextroamphetamine ER (Adderall XR®) lisdexamfetamine cap **and chew tab** (Vyvanse®)+	amphetamine ER susp and tab (Dyanavel® XR) **dextroamphetamine ER (Dexedrine Spansules®)**		

ADHD Medications			
Tier-1*	**Tier-2***	**Tier-3***	**Special PA**
Methylphenidate			
Short-Acting			
dexmethylphenidate (Focalin®) methylphenidate tab and soln (Methylin®) methylphenidate (Ritalin®)			
Long-Acting			
dexmethylphenidate ER (Focalin XR®) – **Brand Preferred** methylphenidate ER (Concerta®) methylphenidate ER (Daytrana®) **– Brand Preferred** methylphenidate ER (Metadate CD®) methylphenidate ER (Metadate ER®) methylphenidate ER (Methylin ER®) ~~**methylphenidate ER (Ritalin LA®)**~~ methylphenidate ER (Ritalin SR®)	dexmethylphenidate ER (generic Focalin XR®) methylphenidate ER (Aptensio XR®) **– Brand Preferred** methylphenidate ER susp (Quillivant XR®) **methylphenidate ER (Ritalin LA®)**	~~**methylphenidate ER 72mg**~~ methylphenidate ER (Adhansia XR®) methylphenidate ER (Jornay PM®) serdexmethylphen-idate/dexmethylphen-idate (Azstarys®)	~~**dextroamphetamine ER (Dexedrine Spansules®)**~~ dextroamphetamine soln (ProCentra®) dextroamphetamine (Xelstrym™) dextroamphetamine (Zenzedi®) ~~**lisdexamfetamine chew tab (Vyvanse®)**~~[+] methamphetamine (Desoxyn®) **methylphenidate ER 72mg** methylphenidate ER ODT (Cotempla XR-ODT®) **methylphenidate ER (Relexxii®)** methylphenidate chew tab (Methylin®) methylphenidate ER chew tab (QuilliChew ER®) viloxazine (Qelbree®)[Δ]
Non-Stimulants			
atomoxetine (Strattera®) guanfacine ER (Intuniv®)	clonidine ER (Kapvay®)[Δ]		

*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). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.

[+]Unique criteria applies for the diagnosis of binge eating disorder (BED).

[Δ]Unique criteria applies in addition to tier trial requirements.

ADHD = attention-deficit/hyperactivity disorder; cap = capsule; chew tab = chewable tablet; ER = extended-release; ODT = orally disintegrating tablet; PA = prior authorization; soln = solution; susp = suspension; tab = tablet

ADHD Medications Special Prior Authorization (PA) Approval Criteria:

1. Adzenys XR-ODT®, Adzenys ER™, Cotempla XR-ODT®, Evekeo ODT™, QuilliChew ER®, ~~Vyvanse® Chewable Tablets,~~ and Xelstrym™ Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available formulations of stimulant medications that can be used for members who cannot swallow capsules or tablets must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
2. Desoxyn®, Dexedrine®, ~~Dexedrine Spansules®,~~ Evekeo®, Methylphenidate ER 72mg Tablet, ProCentra®, Relexxii®, and Zenzedi® Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
3. Methylin® Chewable Tablets Approval Criteria:
    a. A covered diagnosis; and
    b. A patient-specific, clinically significant reason why the member cannot use methylphenidate immediate-release tablets or oral solution must be provided; and
    c. An age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed.
4. Mydayis® Approval Criteria:
    a. A covered diagnosis; and
    b. Member must be 13 years of age or older; and
    c. A patient-specific, clinically significant reason why the member cannot use all other available stimulant medications must be provided.
5. Qelbree® [Viloxazine Extended-Release (ER) Capsule] Approval Criteria:
    a. An FDA approved diagnosis; and
    b. Member must be 6 years of age or older; and
    c. Previously failed trial(s) (within the last 180 days) with atomoxetine or any 2 Tier-1 or Tier-2 ADHD medications, unless contraindicated, that did not yield adequate results; and
        i. Qelbree® will not require a prior authorization and claims will pay at the point of sale if the member has paid claims for atomoxetine or 2 Tier-1 or Tier-2 ADHD medications within the past 180 days of claims history; and
    d. Member must not be taking a monoamine oxidase inhibitor (MAOI) or have taken an MAOI within the last 14 days; and

e. Member must not be taking sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range (e.g., alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, theophylline) concomitantly with Qelbree®; and
~~f. A quantity limit of 30 capsules per 30 days will apply for the 100mg strengths and 60 capsules per 30 days will apply for the 150mg and 200mg strength.~~
g. Quantity limits will apply based on FDA-approved dosing.

ADHD Medications Additional Criteria:

1. Doses exceeding 1.5 times the FDA maximum dose are not covered.
2. Prior authorization is required for all tiers for members older than 20 years of age and for members younger than 5 years of age. All prior authorization requests for members younger than 5 years of age must be reviewed by an Oklahoma Health Care Authority (OHCA)-contracted psychiatrist.
3. For Daytrana® patches, Methylin® oral solution, and Vyvanse® chewable tablet, an age restriction of 10 years and younger will apply. Members older than 10 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
   a. Daytrana® patches are brand preferred. Approval of generic methylphenidate transdermal patches will require a patient-specific, clinically significant reason why brand name Daytrana® cannot be used.
4. Vyvanse® (Lisdexamfetamine) Approval Criteria [Binge Eating Disorder (BED) Diagnosis]:
   a. An FDA approved diagnosis of moderate-to-severe BED; and
   b. Member must be 18 years of age or older; and
   c. Vyvanse® for the diagnosis of BED must be prescribed by a psychiatrist; and
   d. Authorizations will not be granted for the purpose of weight loss without the diagnosis of BED or for the diagnosis of obesity alone. The safety and effectiveness of Vyvanse® for the treatment of obesity have not been established; and
   e. A quantity limit of 30 capsules or chewable tablets per 30 days will apply; and
   f. Initial approvals will be for the duration of 3 months. Continued authorization will require prescriber documentation of improved response/effectiveness of Vyvanse®.

Idiopathic Hypersomnia (IH) Medications Approval Criteria:

1. Diagnosis of IH meeting the following ICSD-3 (International Classification of Sleep Disorders) criteria:
   a. Daily periods of irresistible need to sleep or daytime lapses into sleep for >3 months; and
   b. Absence of cataplexy; and

c. Multiple sleep latency test (MSLT) results showing 1 of the following:
    i. <2 sleep-onset rapid eye movement (REM) periods (SOREMPs); or
    ii. No SOREMPs if the REM sleep latency on the preceding polysomnogram is ≤15 minutes; and
d. At least 1 of the following:
    i. MSLT showing mean sleep latency ≤8 minutes; or
    ii. Total 24-hour sleep time ≥660 minutes on 24-hour polysomnography monitoring (performed after the correction of chronic sleep deprivation) or by wrist actigraphy in association with a sleep log (averaged over ≥7 days with unrestricted sleep); and
e. Insufficient sleep syndrome has been ruled out; and
f. Hypersomnolence or MSLT findings are not better explained by any other sleep disorder, medical or neurologic disorder, mental disorder, medication use, or substance abuse; and

2. Diagnosis must be confirmed by a sleep specialist; and
3. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; and
4. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
5. Use of Xyrem® (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with at least 4 of the following, unless contraindicated, that did not yield adequate results:
    a. Tier-1 stimulant; or
    b. Tier-2 stimulant; or
    c. Nuvigil®; or
    d. Provigil®; or
    e. Clarithromycin; and
6. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
7. Xywav® (calcium/magnesium/potassium/sodium oxybates) additionally requires a patient-specific, clinically significant reason why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided.

Narcolepsy Medications Approval Criteria:

1. An FDA approved diagnosis; and
2. Use of Nuvigil® (armodafinil) requires a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; and
    a. Nuvigil® is brand name preferred due to net cost after rebates; however, brand name preferred status may be removed if the net cost changes and brand name is more costly than generic; or
3. Use of Provigil® (modafinil) requires a previously failed trial (within the last 180 days) with Nuvigil® and a patient-specific, clinically significant reason why the member cannot use stimulant medications to improve wakefulness during the daytime; or
4. Use of Lumryz™ (sodium oxybate), Sunosi® (solriamfetol), Wakix® (pitolisant), Xyrem® (sodium oxybate), or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires previously failed trials (within the last 180 days) with Tier-1 and Tier-2 stimulants from different chemical categories, Provigil®, and Nuvigil®, unless contraindicated, that did not yield adequate results; and
    a. Xyrem® is brand preferred. Requests for generic sodium oxybate will require a patient-specific, clinically significant reason why brand name Xyrem® cannot be used; and
5. Additionally, use of Lumryz™ (sodium oxybate) or Xywav® (calcium/magnesium/potassium/sodium oxybates) requires a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Xyrem®; and
    a. For members requesting Xywav® due to lower sodium content in comparison to Xyrem®, a patient-specific, clinically significant reason why the member requires a low-sodium product must be provided; and
6. The diagnosis of obstructive sleep apnea requires concurrent treatment for obstructive sleep apnea; and
7. The diagnosis of shift work sleep disorder requires the member's work schedule to be included with the prior authorization request.

Recommendation 4: Vote to Prior Authorize Abilify Asimtufii® [Aripiprazole Extended-Release (ER) Injection], Quetiapine 150mg Tablet, and Rykindo® (Risperidone ER Injection) and Update the Approval Criteria for the Atypical Antipsychotic Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Atypical Antipsychotic Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (changes noted in red in the following PBPA Tier chart and approval criteria):

1. The prior authorization of Abilify Asimtufii® (aripiprazole ER injection), quetiapine 150mg tablet, and Rykindo® (risperidone ER injection) and placement into Tier-3; and
2. The placement of Uzedy™ (risperidone ER injection) into Tier-1 based on supplemental rebate participation; and
3. Moving Fanapt® (iloperidone) and Invega® (paliperidone ER tablet) to Tier-2 based on net costs; and
4. Moving Risperdal Consta® (risperidone ER injection) to Tier-3 based on net costs; and
5. Updating the Tier-3 approval criteria to clarify the number of Tier-2 trials needed; and
6. Adding Vraylar® (cariprazine) to the approval criteria for atypical antipsychotics as adjunctive treatment for MDD; and
7. Updating the Lybalvi® (olanzapine/samidorphan) approval criteria to be more consistent with clinical practice; and
8. Updating the Rexulti® (brexpiprazole) approval criteria based on the new FDA approved indication for the treatment of agitation associated with dementia due to Alzheimer's disease.

Atypical Antipsychotic Medications*		
Tier-1	**Tier-2**	**Tier-3**
aripiprazole (Abilify®)¥	asenapine (Saphris®)	**aripiprazole IM inj (Abilify Asimtufii®)^∞**
aripiprazole IM inj (Abilify Maintena®)^	**iloperidone (Fanapt®)**	aripiprazole tablets with sensor (Abilify MyCite®)~
aripiprazole lauroxil IM inj (Aristada®)^	lurasidone (Latuda®)	asenapine transdermal system (Secuado®)+
aripiprazole lauroxil IM inj (Aristada Initio®)^	**paliperidone (Invega®)**	brexpiprazole (Rexulti®)
clozapine (Clozaril®)◊		cariprazine (Vraylar®)
olanzapine (Zyprexa®)		clozapine (Fazaclo®)+
paliperidone palmitate IM inj (Invega Hafyera)^		clozapine oral susp (Versacloz®)+
paliperidone palmitate IM inj (Invega Sustenna®)^		~~**iloperidone (Fanapt®)**~~
paliperidone palmitate IM inj (Invega Trinza®)^		lumateperone (Caplyta®)
quetiapine (Seroquel®)		olanzapine/fluoxetine (Symbyax®)+
quetiapine ER (Seroquel XR®)		olanzapine/samidorphan (Lybalvi®)β
risperidone (Risperdal®)		~~**paliperidone (Invega®)**~~
~~**risperidone IM inj (Risperdal Consta®)^**~~		**quetiapine 150mg tablets+**

risperidone ER sub-Q inj (Perseris®)^		**risperidone IM inj (Risperdal Consta®)^∞**
risperidone sub-Q inj (Uzedy™)^		**risperidone IM inj (Rykindo®)^∞**
ziprasidone (Geodon®)		

*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). Placement of products shown in blue is based on net cost after federal and/or supplemental rebates, and products may be moved to a higher tier if the net cost changes in comparison to other available products.
ER = extended-release; IM = intramuscular; inj = injection; sub-Q = subcutaneous; susp = suspension
¥Aripiprazole (Abilify®) orally disintegrating tablet (ODT) is considered a special formulation and requires a patient-specific, clinically significant reason why a special formulation product is needed in place of the regular tablet formulation.
◊Clozapine does not count towards a Tier-1 trial.
^Use of a long-acting injectable (LAI) product may require the member to have been adequately treated with another oral or injectable product prior to use and/or during initiation. The package labeling should be referenced for each individual product.
~Unique criteria applies to Abilify MyCite® (aripiprazole tablets with sensor).
+Unique criteria applies in addition to tier trial requirements.
ßUnique criteria applies to Lybalvi® (olanzapine/samidorphan).
∞Unique criteria applies to Tier-3 long-acting injectable (LAI) products.

Atypical Antipsychotic Medications Tier-3 Approval Criteria:

1. A Tier-1 trial at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; and
   a. Clozapine does not count towards a Tier-1 trial; and
2. Trials of 2 ~~all~~ oral Tier-2 medications, at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; or
3. A manual prior authorization may be submitted for consideration of a Tier-3 medication when the member has had at least 4 trials of Tier-1 and Tier-2 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and
4. Use of quetiapine 150mg tablet will require a patient-specific, clinically significant reason why the member cannot use the lower tiered quetiapine products, which are available without a prior authorization; and
5. Use of Fazaclo® (clozapine orally disintegrating tablet) or Versacloz® (clozapine oral suspension) requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
6. Use of Secuado® (asenapine transdermal system) requires a patient-specific, clinically significant reason why the member cannot use the oral sublingual tablet formulation. Tier structure rules continue to apply; and
7. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.

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

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

Long-Acting Injectable (LAI) Products Tier-3 Approval Criteria:

1. Use of LAI products will require a patient-specific, clinically significant reason (beyond convenience) why the member cannot use the lower tiered LAI products available for the medication being requested, which are available without a prior authorization.

Lybalvi® (Olanzapine/Samidorphan) Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must be 18 years of age or older; and
3. Member must have a positive clinical response to ~~be stable on~~ olanzapine ~~for at least 14 days~~ and ~~be experiencing significant weight gain~~ gained ≥10% from baseline body weight after starting olanzapine (baseline and current weight must be provided); or
4. A patient specific, clinically significant reason why the member cannot use a lower-tiered product with a lower weight gain profile must be provided; and
5. Member must not be taking opioids or undergoing acute opioid withdrawal; and
6. Initial approvals will be for 3 months. For continuation consideration, documentation that the member is responding well to treatment and any increase in body weight is <10% of baseline body weight (current weight must be provided) ~~has had no excessive weight gain~~ while on therapy must be provided.

Rexulti® (Brexpiprazole) Approval Criteria [Agitation Associated with Dementia Due to Alzheimer's Disease Diagnosis]:

1. An FDA approved indication of the treatment of agitation associated with dementia due to Alzheimer's disease; and
2. Diagnosis must be confirmed by the following:
    a. Mini-Mental State Exam (MMSE) score between 5 and 22; and
    b. Documentation of the member's dementia due to Alzheimer's disease diagnosis [i.e., chart notes consistent with findings of a diagnosis of dementia due to Alzheimer's disease as per the National Institute on Aging and the Alzheimer's Association (NIA-AA)]; and

c. Other known medical or neurological causes of dementia have been ruled out (i.e., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, Parkinson's disease dementia); and
d. Neuropsychiatric Inventory (NPI)/NPI-Nursing Home (NH) agitation/aggression score ≥4; and
e. Exhibiting sufficient agitation behaviors warranting the use of pharmacotherapy; and

3. Prescriber must document a baseline evaluation using the Cohen-Mansfield Agitation Inventory (CMAI) total score; and
4. Prescriber must verify member will be closely monitored due to the risk of dementia-related psychosis; and
5. Initial approvals will be for 3 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the CMAI total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

Recommendation 5: Vote to Prior Authorize Allopurinol 200mg Tablet, Aponvie™ (Aprepitant Injectable Emulsion), Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules], Austedo® XR (Deutetrabenazine ER Tablet), Entadfi® (Finasteride/Tadalafil Capsule), Ermeza™ (Levothyroxine Oral Solution), Furoscix® (Furosemide On-Body Infusor), Iyuzeh™ (Latanoprost Ophthalmic Solution), Jylamvo® (Methotrexate Oral Solution), Primidone 125mg Tablet, Verkazia® (Cyclosporine Ophthalmic Solution), Xaciato™ (Clindamycin Vaginal Gel), and Zolpidem Tartrate 7.5mg Capsule

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of allopurinol 200mg tablets with the following criteria (shown in red):

Allopurinol 200mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use 2 allopurinol 100mg tablets in place of allopurinol 200mg must be provided.

The College of Pharmacy recommends the prior authorization of Aponvie™ (aprepitant injectable emulsion) with the following criteria (shown in red):

Aponvie™ (Aprepitant 32mg/4.4mL Vial) Approval Criteria:

1. An FDA approved indication for the prevention of postoperative nausea and vomiting (PONV); and
2. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention of PONV (e.g., ondansetron) must be provided.

The College of Pharmacy recommends the prior authorization of Aspruzyo Sprinkle™ (ranolazine ER granules) with the following criteria (shown in red):

Aspruzyo Sprinkle™ [Ranolazine Extended-Release (ER) Granules] Approval Criteria:

1. An FDA approved diagnosis of chronic angina; and
2. A patient-specific, clinically significant reason why the member cannot use ranolazine ER tablets must be provided.

The College of Pharmacy recommends the prior authorization of Austedo® XR (deutetrabenazine ER tablet) with criteria similar to Austedo® (deutetrabenazine). The College of Pharmacy also recommends updating the approval criteria for Huntington's disease diagnosis for safety and consistency with the approval criteria for tardive dyskinesia as follows (changes shown in red):

Austedo® (Deutetrabenazine) and Austedo® XR [Deutetrabenazine Extended-Release (ER) Tablet] Approval Criteria [Huntington's Disease Diagnosis]:

1. An FDA approved diagnosis of chorea associated with Huntington's disease; and
2. Deutetrabenazine ~~Austedo®~~ must be prescribed by a neurologist (or an advanced care practitioner with a supervising physician who is a neurologist); and
3. A previous trial of Xenazine® (tetrabenazine) or a patient-specific, clinically significant reason why the member cannot use Xenazine® (tetrabenazine) must be provided; and
4. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting deutetrabenazine therapy and throughout treatment; and
5. Member must not have hepatic impairment; and
6. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
7. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
8. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with deutetrabenazine; and
9. For members who are using deutetrabenazine ~~Austedo®~~ concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the

member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
10. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and
11. The daily dose of deutetrabenazine ~~Austedo®~~ must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
12. Female members must not be pregnant or breastfeeding; and
13. Approvals will be for the duration of 6 months at which time the prescriber must document that the signs and symptoms of chorea have decreased, and the member is not showing worsening signs of depression.

Austedo® (Deutetrabenazine) and Austedo® XR [Deutetrabenazine Extended-Release (ER) Tablet] Approval Criteria [Tardive Dyskinesia Diagnosis]:

1. An FDA approved diagnosis of tardive dyskinesia meeting the following DSM-5 criteria:
   a. Involuntary athetoid or choreiform movements; and
   b. History of treatment with dopamine receptor blocking agent (DRBA); and
   c. Symptom duration lasting longer than 4 to 8 weeks; and
2. Member must be 18 years of age or older; and
3. Deutetrabenazine ~~Austedo®~~ must be prescribed by a neurologist or psychiatrist (or an advanced care practitioner with a supervising physician who is a neurologist or psychiatrist); and
4. Member must not have hepatic impairment; and
5. Member must not be taking monoamine oxidase inhibitors (MAOIs) or have taken an MAOI within the last 14 days; and
6. Member must not be taking reserpine or have taken reserpine within the last 20 days; and
7. Member must not use another vesicular monoamine transporter 2 (VMAT2) inhibitor (e.g., tetrabenazine, valbenazine) concurrently with deutetrabenazine; and
8. For members who are using deutetrabenazine ~~Austedo®~~ concomitantly with other medications that are known to prolong the QTc interval [antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (e.g., moxifloxacin), Class 1A (e.g., quinidine, procainamide) and Class III (e.g., amiodarone, sotalol) antiarrhythmic medications, or any other medications known to prolong the QTc interval] the prescriber must agree to monitor the member for symptoms of prolonged QTc interval (e.g., syncope, palpitations, seizures); and
9. Member must not have congenital long QT syndrome or a history of cardiac arrhythmias; and

10. The daily dose of deutetrabenazine ~~Austedo®~~ must not exceed 36mg per day if the member is taking strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) or if they are a known poor CYP2D6 metabolizer; and
11. Female members must not be pregnant or breastfeeding; and
12. Prescriber must document a baseline evaluation using the Abnormal Involuntary Movement Scale (AIMS); and
13. Approvals will be for the duration of 6 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by an improvement from baseline in the AIMS total score (a negative change in score indicates improvement) or documentation of a positive clinical response to therapy.

The College of Pharmacy recommends the prior authorization of Entadfi™ (finasteride/tadalafil capsule) with placement into Tier 3 of the Benign Prostatic Hypertrophy (BPH) Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (shown in red):

Entadfi™ (Finasteride 5mg/Tadalafil 5mg) Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH); 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 patient-specific, clinically significant reason why the member cannot use the individual components (finasteride and tadalafil) must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply; and
5. Maximum treatment duration of 26 weeks will apply.

The College of Pharmacy also recommends making Tirosint® (levothyroxine capsule) brand preferred based on net costs and recommends the prior authorization of Ermeza™ (levothyroxine oral solution) with criteria similar to Thyquidity™, Tirosint®, and Tirosint®-SOL as follows (changes shown in red):

Ermeza™ (Levothyroxine Oral Solution), Thyquidity™ (Levothyroxine Oral Solution), Tirosint® (Levothyroxine Capsule), and Tirosint®-SOL (Levothyroxine Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
   a. Hypothyroidism: As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism; or
   b. Pituitary Thyrotropin (thyroid-stimulating hormone, TSH) Suppression: As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer; and
2. A patient-specific, clinically significant reason why the member cannot use all other formulations of levothyroxine must be provided. For the

oral solutions, a reason why the member cannot use the levothyroxine tablet formulation, even when the tablets are crushed, must be provided; and
3. Tirosint® (levothyroxine capsule) is brand preferred. Use of generic levothyroxine capsules will require a patient specific, clinically significant reason why the member cannot use the brand formulation; and
4. Prescriber must verify member has been compliant with levothyroxine tablets at a greatly increased dose for at least 8 weeks; and
5. Prescriber must verify that member has not been able to achieve normal thyroid lab levels despite a greatly increased dose and compliance with levothyroxine tablets.

The College of Pharmacy also recommends the prior authorization of Furoscix® (furosemide on-body infusor) with the following criteria (shown in red):

Furoscix® (Furosemide On-Body Infusor) Approval Criteria:

1. An FDA approved indication for the treatment of congestion due to fluid overload in members with NYHA Class II-III heart failure; and
2. Member must be 18 years of age or older; and
3. Furoscix® must be prescribed by, or in consultation with, a cardiologist or a provider trained in managing acute decompensated heart failure (ADHF); and
4. Member is currently showing signs of fluid overload; and
5. Member has been stable and refractory to at least 1 of the following loop diuretics, at maximally indicated doses:
   a. Bumetanide oral tablets; or
   b. Furosemide oral tablets; or
   c. Torsemide oral tablets; and
6. Prescriber must verify the member will discontinue oral diuretics during the treatment with Furoscix® and will transition back to oral diuretic maintenance therapy when practical; and
7. Prescriber must verify the member is stable and suitable for at-home treatment with Furoscix®, as determined by:
   a. Oxygen saturation ≥90% on exertion; and
   b. Respiratory rate <24 breaths per minute; and
   c. Resting heart rate <100 beats per minute; and
   d. Systolic blood pressure >100mmHg; and
8. Member must have an adequate environment for at-home administration and have been trained on the proper use of Furoscix®; and
9. Member must have a creatinine clearance (CrCl) >30mL/min or an estimated glomerular filtration rate (eGFR) >20mL/min/1.73m^2 and no evidence of acute renal failure; and

10. Member must not have any contraindications for use of Furoscix® including anuria, hepatic cirrhosis, or ascites; and
11. Member must not have acute pulmonary edema or other conditions that require immediate hospitalization; and
12. Approvals will be issued per incident of fluid overload; and
13. Reauthorization is not permitted. A new prior authorization request must be submitted and the member must meet all initial approval criteria for each incident of fluid overload.

The College of Pharmacy also recommends the placement of Iyuzeh™ into the Special PA Tier of the Glaucoma Medications PBPA category with the following criteria:

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; 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. The 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.

The College of Pharmacy recommends the prior authorization of Jylamvo® (methotrexate oral solution) with the following criteria (shown in red):

Jylamvo® (Methotrexate Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen; or
    b. Mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or
    c. Relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or
    d. Rheumatoid arthritis; or
    e. Severe psoriasis; and
2. Member must be 18 years of age or older; and
3. A patient-specific clinically significant reason why the oral tablets and the generic injectable formulation cannot be used must be provided.

The College of Pharmacy recommends the prior authorization of primidone 125mg tablet with the following criteria (shown in red):

Primidone 125mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific clinically significant reason why the member cannot split the 250mg tablet to achieve the 125mg dose must be provided.

The College of Pharmacy recommends the prior authorization of Verkazia® (cyclosporine 0.1% ophthalmic emulsion) with the following criteria (shown in red):

Verkazia® (Cyclosporine 0.1% Ophthalmic Emulsion) Approval Criteria:

1. An FDA approved indication of vernal keratoconjunctivitis (VKC); and
2. Member has had 1 recurrence of VKC in the last year; and
3. Verkazia® must be prescribed by, or in consultation with, an allergist, optometrist, or ophthalmologist (or an advanced care practitioner with a supervising physician who is an allergist, optometrist, or ophthalmologist); and
4. Prescriber must verify that environmental factors (e.g., sun, wind, salt water) have been addressed; and
5. Member must have a trial of a topical mast cell stabilizer, antihistamine, or combination product or a patient-specific, clinically significant reason why those products are not appropriate must be provided; and
6. A patient-specific, clinically significant reason why the member cannot use cyclosporine 0.05% ophthalmic emulsion single-use vials, which are available without a prior authorization, must be provided; and
7. A quantity limit of 120 single-use vials per 30 days will apply.

Additionally, the College of Pharmacy recommends the prior authorization of Xaciato™ (clindamycin vaginal gel) with the following criteria (shown in red):

Xaciato™ (Clindamycin Vaginal Gel) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and
2. A patient specific, clinically significant reason why the member cannot use clindamycin 2% vaginal cream, Clindesse® (clindamycin phosphate 2% vaginal cream), and Cleocin® vaginal ovules (clindamycin phosphate 2.5g vaginal suppositories), which are available without a prior authorization, must be provided.

Lastly, the College of Pharmacy recommends the prior authorization of zolpidem 7.5mg capsules with placement into the Special PA Tier of the Insomnia Medications PBPA category based on net cost (changes noted in red in the following PBPA Tier chart):

Insomnia Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA***
estazolam (ProSom®)	zolpidem CR (Ambien® CR)	lemborexant (Dayvigo®)	daridorexant (Quviviq™)
eszopiclone (Lunesta®)		suvorexant (Belsomra®)	doxepin (Silenor®)

flurazepam (Dalmane®)			quazepam (Doral®)
ramelteon (Rozerem®) – **Brand Preferred**			tasimelteon (Hetlioz®, Hetlioz LQ™)+
temazepam (Restoril®) 15mg and 30mg			temazepam (Restoril®) 7.5mg and 22.5mg
triazolam (Halcion®)			**zolpidem 7.5mg capsule**
zaleplon (Sonata®)			zolpidem SL tablet (Edluar®)
zolpidem (Ambien®)			zolpidem SL tablet (Intermezzo®)
			zolpidem oral spray (Zolpimist®)

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).
*Medications in the Special PA Tier, including unique dosage formulations, require a special reason for use in place of lower-tiered medications.
+Individual criteria specific to tasimelteon applies.
CR = controlled release; PA = prior authorization; SL = sublingual

Recommendation 6: Vote to Prior Authorize Daybue™ (Trofinetide)

MOTION CARRIED by unanimous approval.

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

Daybue™ (Trofinetide) Approval Criteria:

1. Diagnosis of typical Rett syndrome confirmed by all of the following:
    a. Prescriber must verify all clinical diagnostic criteria are met supporting a diagnosis of typical Rett syndrome including:
        i. A period of regression followed by recovery or stabilization; and
        ii. Partial or complete loss of acquired purposeful hand skills; and
        iii. Partial or complete loss of acquired spoken language; and
        iv. Gait abnormalities (impaired/dyspraxic or absence of ability); and
        v. Stereotypic hand movements (e.g., hand wringing/squeezing, clapping/tapping, mouthing, washing/rubbing automatisms); and
        vi. Lack of brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection causing neurological problems; and
        vii. Lack of grossly abnormal psychomotor development in the first 6 months of life; and
    b. Genetic testing documenting a disease-causing mutation in the *MECP2* gene (results of genetic testing must be submitted); and

2. Member must be 2 years of age or older; and
3. Daybue™ must be prescribed by a geneticist, neurologist, or other specialist with expertise in the treatment of Rett syndrome; and
4. Prescriber must agree to counsel members and caregivers on the risks of diarrhea and weight loss associated with Daybue™ and agree to monitor appropriately for these adverse effects; and
5. Prescriber must agree to counsel members and caregivers on proper storage and administration of Daybue™, including the use of a calibrated device for measuring each dose; and
6. Prescriber must verify the member does not have moderate or severe renal impairment; and
7. Member's current weight (kg) taken within the past 3 weeks must be provided on initial and subsequent prior authorization requests to ensure accurate weight-based dosing according to package labeling; and
8. Initial approvals will be for a duration of 3 months. After 3 months of treatment, further approval may be granted if the prescriber documents the member is responding well to treatment. Subsequent approvals will be for a duration of 1 year; and
9. A quantity limit of 3,600mL per 30 days will apply.

Recommendation 7: Vote to Prior Authorize Joenja® (Leniolisib)

MOTION CARRIED by unanimous approval.

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

Joenja® (Leniolisib) Approval Criteria:

1. An FDA approved diagnosis of activated phosphoinositide 3-kinase (PI3K) delta syndrome (APDS). Diagnosis must be confirmed by the following:
   a. Genetic testing identifying a documented pathogenic variant in either the *PIK3CD* or *PIK3R1* gene (results of genetic testing must be submitted); and
2. Member must be 12 years of age or older and weigh ≥45kg; and
3. Joenja® must be prescribed by, or in consultation with, an immunologist, geneticist, or a specialist with expertise in treatment of APDS; and
4. Female members of reproductive potential must not be breastfeeding, must have a negative pregnancy test prior to initiation, and must agree to use effective contraception during treatment and for 1 week after the final dose of Joenja®; and
5. Member must not have moderate to severe hepatic impairment (Child-Pugh class B or C); and
6. Member must not be taking any of the following medications concomitantly with Joenja®:

a. Strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin); and
b. Strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort, phenobarbital, primidone); and
c. CYP1A2 metabolized drugs with a narrow therapeutic range (e.g., tizanidine, theophylline); and
d. OATP1B1/3 substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and
e. BCRP transporter substrates (e.g., sulfasalazine, ubrogepant, tenofovir); and

7. Initial approvals will be for the duration of 3 months. 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.

Recommendation 8: Vote to Prior Authorize Lyvispah™ (Baclofen Oral Granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Lyvispah™ (baclofen oral granules) and Norgesic®, Norgesic® Forte, and Orphengesic® Forte (orphenadrine/aspirin/caffeine) and placement into the Special PA Tier of the Muscle Relaxant Medications Product Based Prior Authorization (PBPA) category with the following additional criteria (changes and new criteria shown in red):

Fleqsuvy® 25mg/5mL (Baclofen Oral Suspension), Lyvispah™ (Baclofen Oral Granules), and Ozobax® 5mg/5mL (Baclofen Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. Requests for Fleqsuvy® and Ozobax® will require a patient-specific, clinically significant reason why member cannot use Lyvispah™; and
3. Members older than 10 years of age require a patient-specific, clinically significant reason why the member cannot use baclofen oral tablets, even when tablets are crushed.

Norgesic®, Norgesic® Forte, and Orphengesic® Forte (Orphenadrine/Aspirin/Caffeine) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all lower-tiered products must be provided.

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone (Skelaxin®)	baclofen 5mg (Lioresal®)
chlorzoxazone 500mg (Parafon Forte®)		**baclofen oral granules (Lyvispah™)**
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
orphenadrine (Norflex®)		carisoprodol 250mg (Soma®)
tizanidine tabs (Zanaflex®)		carisoprodol 350mg (Soma®)
		carisoprodol/ASA
		carisoprodol/ASA/codeine
		chlorzoxazone 375mg, 750mg (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)
		tizanidine caps (Zanaflex®)

*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).
ASA = aspirin; caps = capsules; ER = extended-release; PA = prior authorization; soln = solution; susp = suspension; tabs = tablets.

Recommendation 9: Vote to Prior Authorize Adstiladrin® (Nadofaragene Firadenovac-vncg) and Elahere™ (Mirvetuximab Soravtansine-gynx) and Update the Approval Criteria for the Genitourinary and Gynecologic Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Adstiladrin® (nadofaragene firadenovec-vncg) and Elahere™ (mirvetuximab soravtansine-gynx) with the following criteria (listed in red):

Adstiladrin® (Nadofaragene Firadenovec-vncg) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC with carcinoma in situ (CIS) with or without papillary tumors; and
2. High-risk disease that was unresponsive to prior Bacillus Calmette-Guérin (BCG) therapy.

Elahere™ (Mirvetuximab Soravtansine-gynx) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. Tumor is folate receptor alpha (FRα) positive; and
3. Member has received 1 to 3 prior systemic treatment regimens.

Next, the College of Pharmacy recommends updating the approval criteria for Lenvima® (lenvatinib), Lynparza® (olaparib), Nubeqa® (darolutamide), and Padcev® (enfortumab vedotin-ejfv) based on recent FDA approvals and label updates (changes and new criteria noted in red):

Lenvima® (Lenvatinib) Approval Criteria [Endometrial Carcinoma Diagnosis]:

1. Advanced disease with progression on prior systemic therapy; and
2. Member is not a candidate for curative surgery or radiation; and
3. Disease is mismatch repair proficient (pMMR) or is not microsatellite instability-high (MSI-H) ~~or mismatch repair deficient (dMMR)~~; and
4. Used in combination with pembrolizumab.

Lynparza® (Olaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Used in 1 of the following settings:
    a. Member must have failed previous first-line therapy; and
        i. Used as a single agent except for the following:
            1. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
        ii. Disease must be positive for a mutation in a homologous recombination gene; or
    b. Used in combination with abiraterone and prednisone (or prednisolone); and
        i. Disease must be positive for a deleterious or suspected deleterious BRCA mutation.

Nubeqa® (Darolutamide) Approval Criteria [Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) Diagnosis]:

1. Diagnosis of mHSPC in combination with docetaxel; and
2. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy.

Padcev® (Enfortumab Vedotin-ejfv) Approval Criteria [Urothelial Cancer Diagnosis]:

1. Diagnosis of locally advanced or metastatic urothelial cancer; and
2. Used in 1 of the following settings:

a. As a single agent and member has previously received a programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting; or
b. As a single agent and member has received at least 1 prior therapy and is ineligible for cisplatin-containing chemotherapy; or
c. Used in combination with pembrolizumab and member is ineligible for cisplatin-containing chemotherapy.

Additionally, the College of Pharmacy recommends updating the approval criteria for Lynparza® (olaparib), Rubraca® (rucaparib), and Zejula® (niraparib) for ovarian, fallopian tube, or primary peritoneal cancer based on the FDA withdrawals and restrictions for these indications (changes shown in red):

Lynparza® (Olaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

~~**1. Treatment of Advanced Recurrent/Refractory Disease:**~~
~~a. Diagnosis of deleterious or suspected deleterious germline BRCA-mutated (*gBRCAm*), advanced disease; and~~
~~b. Previous treatment with ≥2 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and~~
~~c. A quantity limit based on FDA approved dosing will apply; or~~

2. Maintenance Treatment of Advanced Disease:
a. Disease must be in a complete or partial response to primary chemotherapy; and
   i. Used as a single-agent in members with a diagnosis of deleterious or suspected deleterious germline BRCA-mutated (*gBRCAm)* or somatic BRCA-mutated (*sBRCAm*), advanced ovarian cancer; or
   ii. Used in combination with bevacizumab following a primary therapy regimen that included bevacizumab; or
b. Complete or partial response to second-line or greater platinum-based chemotherapy (no mutation required); and
c. A quantity limit based on FDA approved dosing will apply.

Rubraca® (Rucaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

~~**1. Treatment of Advanced Recurrent/Refractory Disease:**~~
~~a. Diagnosis of recurrent or refractory disease; and~~
~~b. Previous treatment with ≥2 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and~~
~~c. Disease is associated with a deleterious or suspected deleterious BRCA mutation; and~~
~~d. Used as a single agent; or~~

2. Maintenance Treatment of ~~Advanced~~ Recurrent Disease:

a. Diagnosis of ~~advanced or~~ recurrent disease; and
b. Disease must be in a complete or partial response to platinum-based chemotherapy; and
c. Positive for a BRCA mutation; and
d. Used as a single agent.

Zejula® (Niraparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

~~**1. Treatment of Advanced Recurrent/Refractory Disease as a Single Agent:**~~
~~a. Diagnosis of recurrent or refractory disease; and~~
~~b. Previous treatment with ≥3 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and~~
~~c. Diagnosis is associated with homologous recombination deficiency (HRD) positive status defined by either:~~
~~i. Deleterious or suspected deleterious BRCA mutation; or~~
~~ii. Genomic instability and progression >6 months after response to last platinum-based chemotherapy; and~~
~~d. Used as a single agent; or~~

~~**2. Treatment of Advanced Recurrent/Refractory Disease in Combination with Bevacizumab:**~~
~~a. Used in combination with bevacizumab for platinum-sensitive persistent disease or recurrence; and~~
~~b. Meets 1 of the following:~~
~~i. As immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or~~
~~ii. Evidence of radiographic and/or clinical relapse in members with previous complete remission and relapse ≥6 months after completing prior chemotherapy; or~~

3. Maintenance Treatment of Advanced Disease:
a. Diagnosis of advanced or recurrent disease; and
b. Disease must be in a complete or partial response to platinum chemotherapy; and
c. If used for maintenance following recurrence:
i. Must be positive for a BRCA mutation (this does not apply if used after first-line therapy); and
d. Used as a single agent.

Lastly, the College of Pharmacy recommends updating the Zytiga® (abiraterone) approval criteria based on net cost (changes shown in red):

Zytiga® (Abiraterone) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:
1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with a corticosteroid; and

3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Zytiga® (Abiraterone) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic, high-risk, CSPC; and
2. Abiraterone must be used in combination with a corticosteroid; and
3. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Recommendation 10: Annual Review of Colorectal Cancer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the Alymsys® (bevacizumab-maly) and Mvasi® (bevacizumab-awwb) approval criteria based on the FDA approval of Vegzelma® (bevacizumab-adcd) and net costs, with the following changes (shown in red):

~~Alymsys® (Bevacizumab-maly) and~~ Mvasi® (Bevacizumab-awwb) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Alymsys® (bevacizumab-maly), Avastin® (bevacizumab), Vegzelma® (bevacizumab-adcd), or Zirabev® (bevacizumab-bvzr), which are available without prior authorization, must be provided. Biosimilars and/or reference products are preferred based on the lowest net cost product(s) and may be moved to either preferred or non-preferred if the net cost changes in comparison to the reference product and/or other available biosimilar products.

Additionally, the College of Pharmacy recommends updating the approval criteria for Stivarga® (regorafenib) based on National Comprehensive Cancer Network (NCCN) Guideline changes in osteosarcoma (shown in red):

Stivarga® (Regorafenib) Approval Criteria [Osteosarcoma Diagnosis]:

1. Used for relapsed or refractory disease; and
2. Used in the second line or greater setting; and
3. Used as a single agent.

Recommendation 11: Annual Review of Allergen Immunotherapies

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the approval criteria for Odactra® (house dust mite allergen extract) and Ragwitek® (short ragweed pollen allergen extract) based on the new FDA approved age expansions (changes shown in red):

Odactra® (House Dust Mite Allergen Extract) Approval Criteria:

1. Member must be ~~18~~ 12 to 65 years of age; and
2. Member must have a positive skin test (labs required) to licensed house dust mite allergen extracts or *in vitro* testing for immunoglobulin E (IgE) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each; and
6. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
7. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
8. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
9. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and
10. A quantity limit of 1 tablet daily will apply; and
11. Initial approvals will be for the duration of 6 months of therapy, at which time the prescriber must verify the member is responding well to Odactra® therapy. Additionally, compliance will be evaluated for continued approval.

Ragwitek® (Short Ragweed Pollen Allergen Extract) Approval Criteria:

1. Member must be ~~18~~ 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to short ragweed pollen; and
3. Member must not have severe uncontrolled asthma; and

4. Member must have failed conservative attempts to control allergic rhinitis symptoms; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of ragweed pollen season (May 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

Recommendation 12: Annual Review of Testosterone Products and 30-Day Notice to Prior Authorize Kyzatrex® (Testosterone Undecanoate)

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

Recommendation 13: 30-Day Notice to Prior Authorize Vyjuvek™ (Beremagene Geperpavec-svdt)

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

Recommendation 14: Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® (Lecanemab-irmb)

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

Recommendation 15: Annual Review of Isturisa® (Osilodrostat) and Recorlev® (Levoketoconazole)

NO ACTION REQUIRED.

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

NO ACTION REQUIRED.

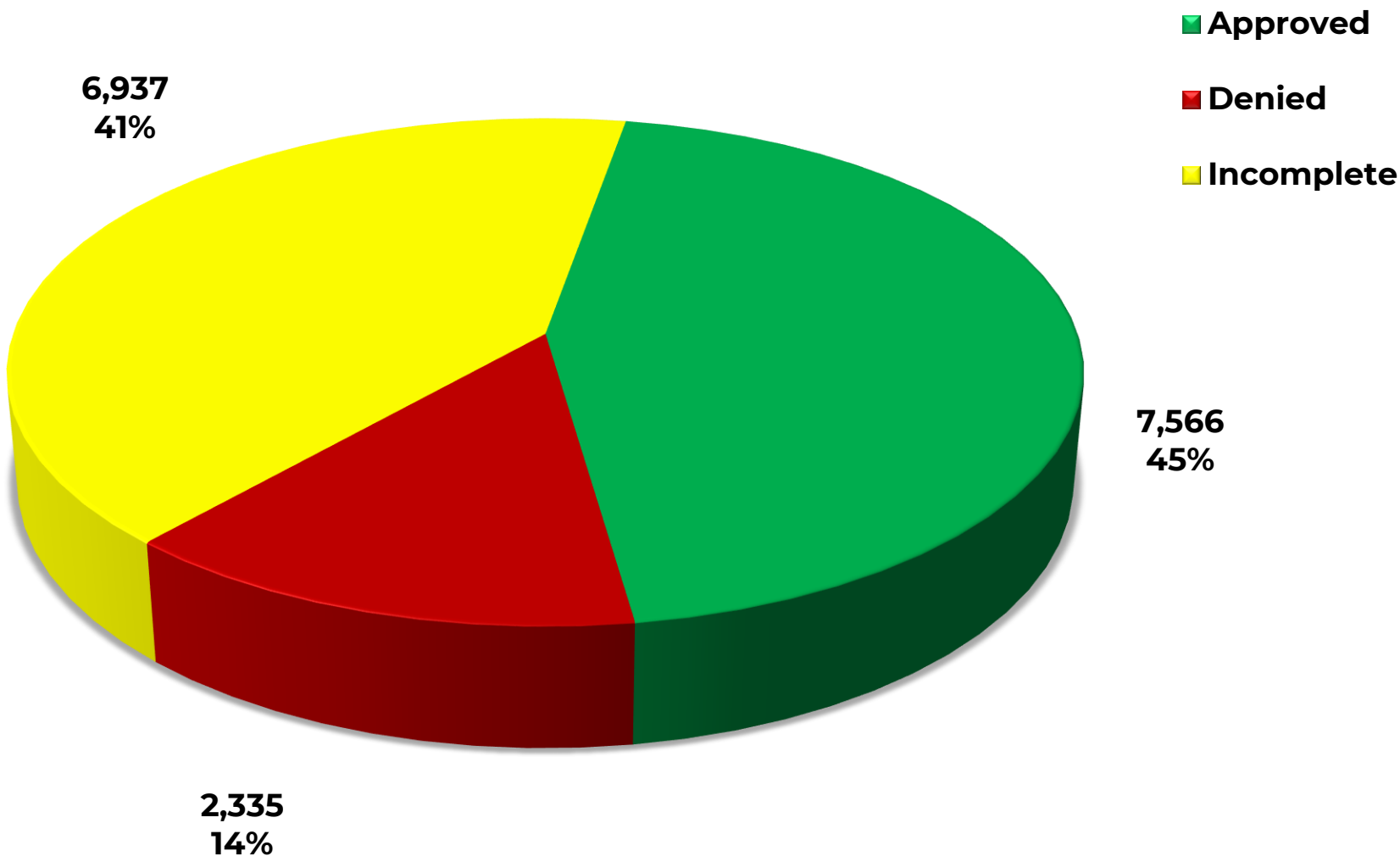
Recommendation 17: Future Business

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

NO ACTION REQUIRED.

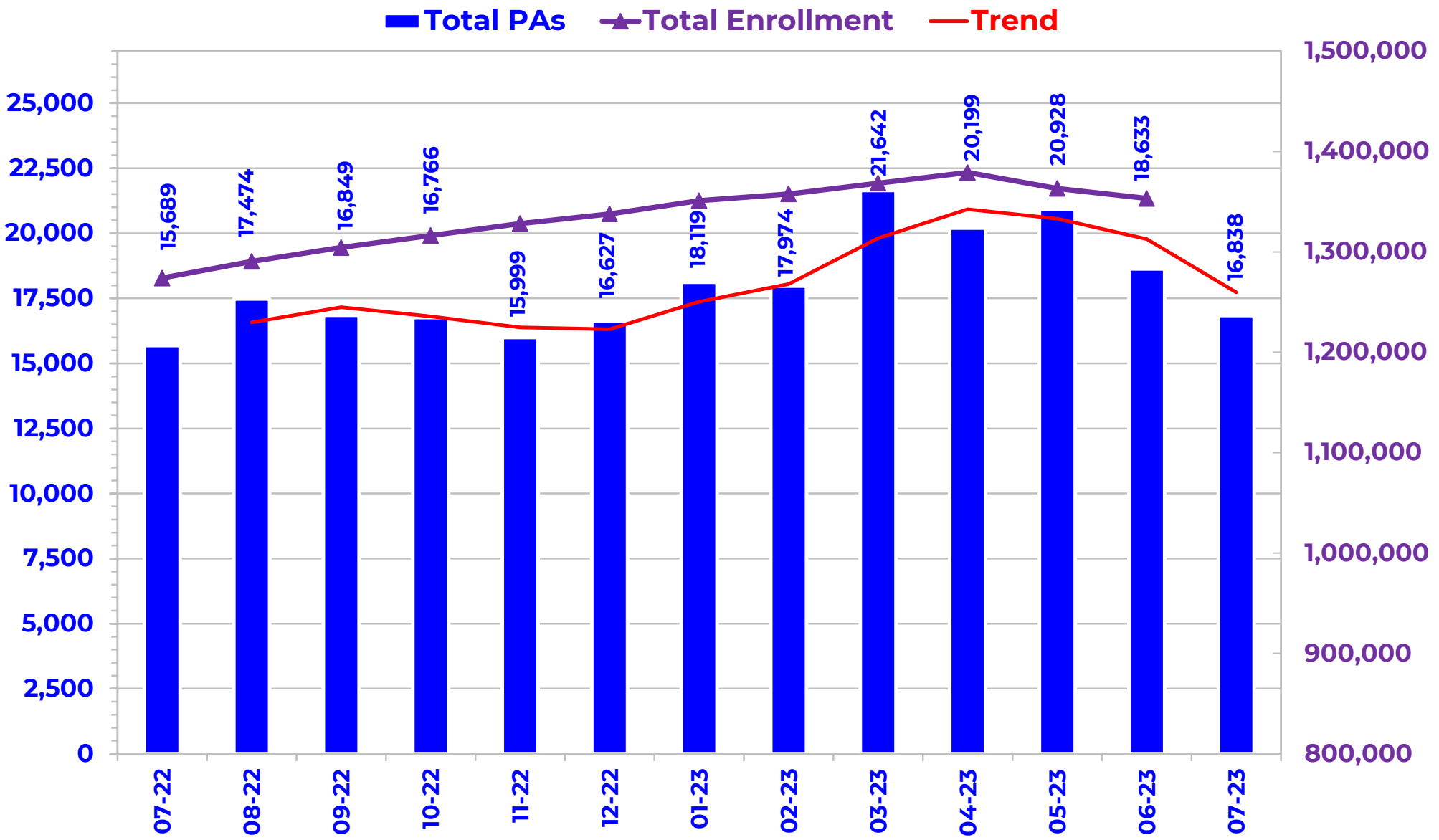
Appendix B

PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JULY 2023



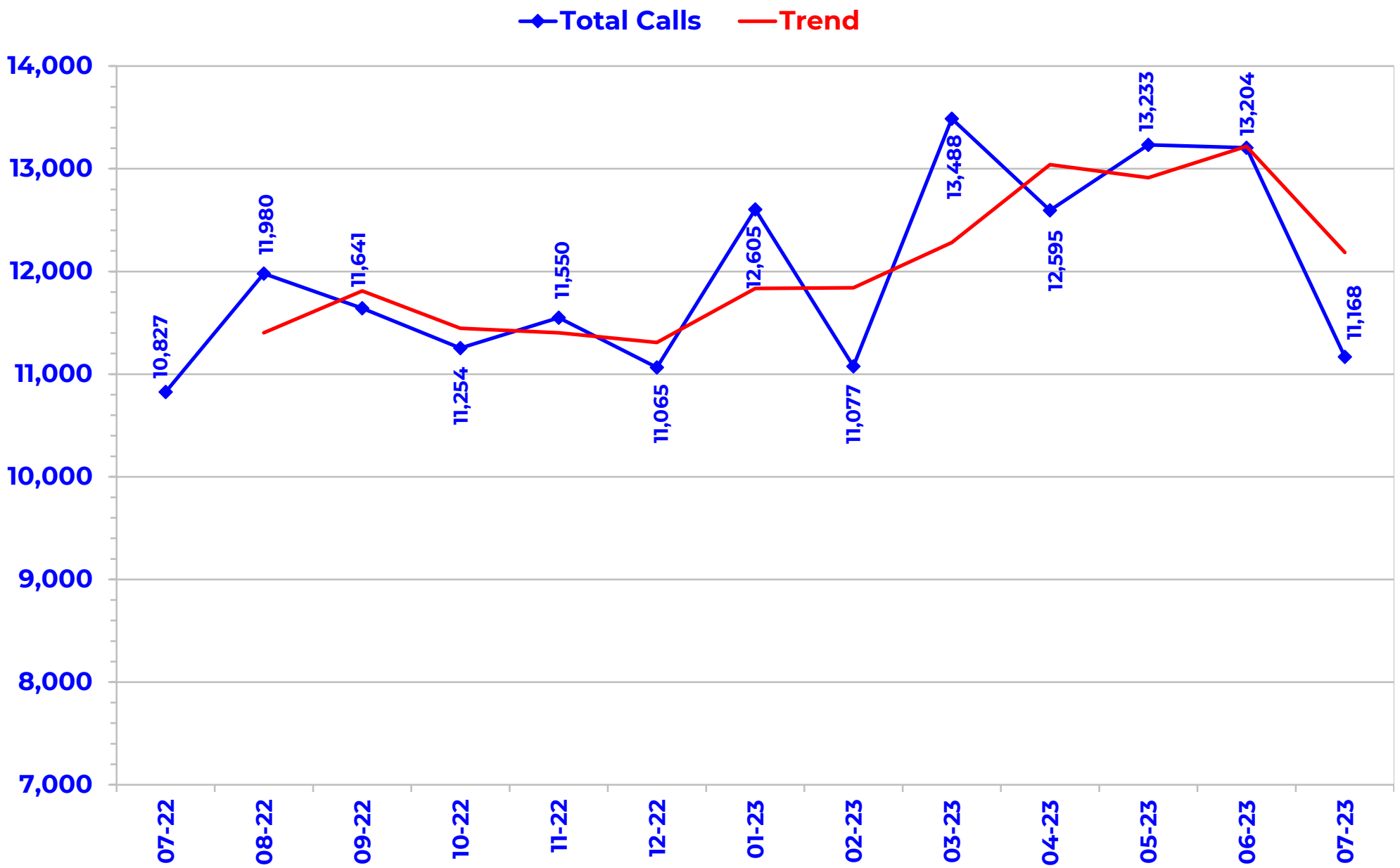
PA totals include approved/denied/incomplete/overrides

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



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT:
JULY 2022 – JULY 2023



Prior Authorization Activity

7/1/2023 Through 7/31/2023

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Advair/Symbicort/Dulera	282	183	5	94	360
Analgesic - NonNarcotic	18	1	1	16	361
Analgesic, Narcotic	405	181	37	187	155
Angiotensin Receptor Antagonist	13	2	5	6	362
Anti-inflammatory	12	5	2	5	85
Antiasthma	132	48	31	53	209
Antibiotic	52	24	4	24	179
Anticonvulsant	229	120	7	102	320
Antidepressant	415	105	54	256	296
Antidiabetic	2,662	771	645	1,246	356
Antigout	15	4	1	10	315
Antihistamine	56	17	12	27	360
Antimigraine	591	111	172	308	270
Antineoplastic	279	188	23	68	176
Antiobesity	45	4	27	14	360
Antiparasitic	43	12	11	20	47
Antiparkinsons	11	0	4	7	0
Antiulcers	37	8	4	25	171
Anxiolytic	38	7	2	29	312
Atypical Antipsychotics	745	267	61	417	356
Benign Prostatic Hypertrophy	16	0	8	8	0
Biologics	393	227	25	141	308
Bladder Control	107	20	33	54	353
Blood Thinners	57	14	2	41	356
Botox	69	42	16	11	352
Buprenorphine Medications	121	46	11	64	126
Calcium Channel Blockers	21	1	1	19	361
Cardiovascular	166	79	12	75	343
Chronic Obstructive Pulmonary Disease	284	60	52	172	355
Constipation/Diarrhea Medications	341	80	75	186	206
Contraceptive	65	27	7	31	340
Corticosteroid	13	4	3	6	150
Dermatological	684	236	154	294	232
Diabetic Supplies	521	200	70	251	183
Endocrine & Metabolic Drugs	59	25	5	29	290
Erythropoietin Stimulating Agents	24	14	3	7	111
Estrogen Derivative	17	3	2	12	259
Fibromyalgia	22	1	5	16	361
Fish Oils	33	6	8	19	361
Gastrointestinal Agents	182	46	27	109	251

* 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	13	1	6	6	361
Glaucoma	21	4	6	11	132
Growth Hormones	117	82	8	27	140
Hematopoietic Agents	43	17	5	21	181
Hepatitis C	43	22	7	14	9
HFA Rescue Inhalers	16	0	1	15	0
Insomnia	167	13	40	114	191
Insulin	298	136	25	137	351
Miscellaneous Antibiotics	17	1	1	15	25
Multiple Sclerosis	85	33	8	44	236
Muscle Relaxant	55	8	9	38	198
Nasal Allergy	51	4	20	27	292
Neurological Agents	213	58	58	97	192
Neuromuscular Agents	17	6	3	8	240
NSAIDs	55	1	13	41	5
Ocular Allergy	13	1	2	10	87
Ophthalmic	25	4	5	16	284
Ophthalmic Anti-infectives	20	5	2	13	14
Ophthalmic Corticosteroid	15	2	0	13	360
Osteoporosis	45	21	7	17	336
Other*	453	156	53	244	279
Otic Antibiotic	45	12	3	30	11
Pediculicide	14	5	1	8	14
Prenatal Vitamins	10	0	3	7	0
Respiratory Agents	51	28	2	21	259
Statins	51	9	18	24	238
Stimulant	2,356	1,607	100	649	350
Testosterone	213	40	60	113	343
Thyroid	38	13	7	18	360
Topical Antifungal	60	10	19	31	178
Topical Corticosteroids	37	0	12	25	0
Vitamin	148	36	81	31	97
Pharmacotherapy	63	58	1	4	302
Emergency PAs	1	1	0	0	
Total	**14,144**	**5,583**	**2,213**	**6,348**	

* 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	87	68	2	17	164
Compound	8	8	0	0	23
Dosage Change	438	408	2	28	17
High Dose	6	5	0	1	253
Ingredient Duplication	6	3	1	2	14
Lost/Broken Rx	132	125	2	5	19
MAT Override	338	275	9	54	78
NDC vs Age	315	220	36	59	267
NDC vs Sex	16	13	0	3	148
Nursing Home Issue	94	87	0	7	16
Opioid MME Limit	128	38	7	83	120
Opioid Quantity	43	25	1	17	150
Other	94	70	11	13	21
Quantity vs Days Supply	852	548	47	257	266
STBS/STBSM	7	4	0	3	50
Step Therapy Exception	31	20	3	8	344
Stolen	21	19	0	2	31
Temporary Unlock	1	1	0	0	11
Third Brand Request	77	46	1	30	46
Overrides Total	**2,694**	**1,983**	**122**	**589**	
Total Regular PAs + Overrides	**16,838**	**7,566**	**2,335**	**6,937**	

Denial Reasons	
Unable to verify required trials.	5,878
Does not meet established criteria.	2,364
Lack required information to process request.	1,024
Other PA Activity	
Duplicate Requests	1,496
Letters	44,238
No Process	3
Changes to existing PAs	1,325
Helpdesk Initiated Prior Authorizations	1,181
PAs Missing Information	1,617

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

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

***Additional information, including the full news release, on the following FDA Safety Communications can be found on the FDA website at: https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications.**

Oklahoma Health Care Authority
August 2023

Introduction[1,2,3]

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

Date	Drug	Issue
04/13/2023	**Opioid Medications**	**Updated guidance for the safe use of opioid pain medicines**

Issue Details: Due to the FDA's ongoing efforts to address the nation's opioid crisis, the FDA issued a Drug Safety Communication regarding several updates to be made to the *Prescribing Information* for opioid pain medications. The communication noted that there has been a decrease in the number of dispensed prescriptions for opioids, however overdose deaths involving prescription opioids have remained steady. The data also suggests the following:

- Many patients do not require more than a few days of opioids for acute pain conditions in the outpatient setting, however this could vary based on individual patient factors.
- Many patients using opioids after surgery have unused tablets, which may pose a risk of accidental use, misuse and abuse, addiction, and overdose, including by children and teenagers.
- Extended-release/long-acting (ER/LA) opioid pain medications have unique risks and should be used only for those with severe persistent pain.

The FDA has also determined that a new warning is needed regarding opioid-induced hyperalgesia (OIH), which is when an opioid that is prescribed and taken for pain relief causes an increase in pain, called hyperalgesia, or an increased sensitivity to pain, called allodynia. OIH can occur at any opioid dose; however, the risk increases with higher doses used long term. This condition is difficult to recognize and may result in opioid dose increases which could result in worsening symptoms of OIH and an increased risk of respiratory depression.

FDA Recommendation(s): The FDA is requiring several updates to the *Prescribing Information* for both the immediate-release (IR) and ER/LA opioid products. The updates include the following:

- Stating for all opioids that the risk of overdose increases as the dose increases.
- IR opioid products will now include a statement that these products should not be used for an extended period unless the pain remains severe enough to require them and alternative treatments continue to be inadequate, and that many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid.
- The approved use for ER/LA products will be updated to recommend they be reserved for severe and persistent pain that requires an extended treatment period with a daily opioid and for which alternative treatment options are inadequate.
- Additionally, the FDA is adding a new warning about OIH for both IR and ER/LA opioid products. This includes information describing the symptoms that differentiate OIH from opioid tolerance and withdrawal.
- Information in the *Boxed Warning* for all opioid products will be updated and reordered to elevate the importance of warnings concerning life-threatening respiratory depression and risks associated with the use of opioids in conjunction with benzodiazepines or other medications that depress the central nervous system (CNS).
- Other changes are also being required to several sections of the *Prescribing Information*, including to the *Indications and Usage, Dosage and Administration, and Warnings and Precautions* sections.
- The Medication Guide is also being updated to help educate patients and caregivers about these risks.

Pharmacy Claims Evaluation: During calendar year (CY) 2022, a total of 104,602 SoonerCare members had paid claims for opioid medications, accounting for 305,697 paid claims and an average of 2.92 claims per member.

SoonerCare Action: Currently, Tier-1 opioid medications, which are available without a prior authorization, include several IR opioid products and lower dose opioid ER products to ensure tolerance is established before the member is started on a higher dose Tier-2 opioid medication. A quantity limit edit for IR opioid products is in place which limits the amount of short acting opioids to 120 units for a 30-day supply for long term use, and for acute use, members are limited to 42 units for a 7-day supply. Additionally, SoonerCare members are limited to an opioid morphine milligram equivalent (MME) of 90 per day, and SoonerCare members with a daily MME greater than 90 require a prior authorization. A targeted prescriber mailing was recently completed (mailings sent September 2022 through June 2023)

for prescribers of members with a cumulative MME >90 per day to encourage decreasing chronic opioid use where appropriate. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
05/11/2023	**Stimulant Medications**	**Misuse, abuse, addiction, and overdose of prescription stimulants**

Issue Details: To address concerns of misuse, abuse, addiction, and overdose of prescription stimulants, the FDA is requiring updates to the *Boxed Warning* and other information to ensure the *Prescribing Information* is made consistent across the entire class of stimulant medications. Currently, the *Prescribing Information* for some stimulants do not provide the most up to date warnings about the harms of misuse and abuse including warnings that most individuals who misuse prescription stimulants get their medications from other family members or peers. Additionally, individuals who are prescribed stimulants often get requests to share their medication which can lead to the development of substance use disorder and addiction in those with whom the medications are shared.

FDA Recommendation(s): The FDA is requiring the *Boxed Warning* to be updated and additional information be added to the *Prescribing Information* for all prescription stimulants to include:

- Patients should never share their prescription stimulants with anyone.
- The *Boxed Warning* will describe the risks of misuse, abuse, addiction, and overdose consistently across all medications in this class, and it will also advise health care professionals to monitor patients closely for signs and symptoms of misuse, abuse, and addiction.
- Updates will also be made to the *Medication Guide* to help educate patients and caregivers about these risks.

Pharmacy Claims Evaluation: During CY 2022, a total of 39,917 SoonerCare members had paid claims for stimulant medications, accounting for 261,595 paid claims and an average of 7.09 claims per member.

SoonerCare Action: Currently, stimulant medications require a prior authorization for members 21 years of age or older to ensure appropriate use. Members 5 years to younger than 21 years of age can fill Tier-1 medications without a prior authorization; however, quantity limit edits are in place to match the FDA approved dosing to ensure members are not taking more than the FDA recommended amount. Additionally, a cumulative early refill edit is in place on all stimulant medications to prevent SoonerCare members from stockpiling large quantities of medication in excess of what is actually needed based on the prescriber's directions. Stimulant medications require a prior authorization and review by an OHCA-contracted SoonerCare psychiatrist for members younger than 5 years of age to ensure appropriate

use in this young population. The College of Pharmacy will continue to monitor the FDA recommendations.

[1] U.S. Food and Drug Administration (FDA). Drug Safety Communications. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications. Last revised 05/11/2023. Last accessed 07/18/2023.
[2] U.S. FDA. FDA Updates Prescribing Information for all Opioid Pain Medicines to Provide Additional Guidance for Safe Use. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use. Issued 04/13/2023. Last accessed 07/18/2023.
[3] U.S. FDA. FDA Updating Warnings to Improve Safe Use of Prescription Stimulants Used to Treat ADHD and other Conditions. Available online at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-updating-warnings-improve-safe-use-prescription-stimulants-used-treat-adhd-and-other-conditions. Issued 05/11/2023. Last accessed 07/18/2023.

Appendix C

Calendar Year 2022 Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Xacduro® (Sulbactam/Durlobactam)

Oklahoma Health Care Authority
August 2023

Current Prior Authorization Criteria

Oral Antibiotic Special Formulation Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.
2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:
   - Amoxicillin 500mg tablets
   - Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)
   - Cephalexin 250mg and 500mg tablets
   - Cephalexin 750mg capsules
   - Doxycycline hyclate 75mg and 150mg tablets (Acticlate®)
   - Doxycycline hyclate 50mg tablet (Targadox®)
   - Doxycycline hyclate delayed-release (DR) tablets (Doryx®)
   - Doxycycline monohydrate 150mg capsules and tablets
   - Doxycycline monohydrate DR 40mg capsules (Oracea®)
   - Minocycline ER capsules (Ximino®)
   - Minocycline ER tablets (Minolira™)
   - Minocycline ER tablets (Solodyn®)

Arikayce® (Amikacin Liposome Inhalation Suspension) Approval Criteria:

1. An FDA approved indication for the treatment of *Mycobacterium avium* complex (MAC) lung disease in adult members who have limited or no alternative treatment options; and
2. Member must have had a minimum of 6 consecutive months of a multidrug background regimen therapy used compliantly and have not achieved negative sputum cultures within the last 12 months. Dates of previous treatments and regimens must be listed on the prior authorization request; and
   a. If claims for a multidrug background regimen are not in the member's claims history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the prescriber; and

3. Member must continue a multidrug background regimen therapy while on Arikayce®, unless contraindicated, or provide reasoning why continuation of a multidrug background regimen is not appropriate for the member; and
4. A patient-specific, clinically significant reason why the member requires an inhaled aminoglycoside in place of an intravenous or intramuscular aminoglycoside (e.g., amikacin, streptomycin) must be provided; and
5. Arikayce® will not be approved for members with non-refractory MAC lung disease; and
6. Arikayce® must be prescribed by, or in consultation with, a pulmonary disease or infectious disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary disease or infectious disease specialist); and
7. Initial approvals will be for the duration of 6 months after which time the prescriber must document the member is responding to treatment for continued approval; and
8. A quantity limit of 28 vials per 28 days will apply.

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
    a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
    b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
    c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 3 months of age or older; and
3. For the diagnosis of cIAI, Avycaz® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:

1. An FDA approved diagnosis of ABSSSI caused by designated susceptible bacteria; and

2. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

Baxdela® (Delafloxacin) Tablet and Vial Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:

1. An FDA approved diagnosis of CABP caused by designated susceptible bacteria; and
2. A patient-specific, clinically significant reason why the member cannot use an appropriate beta lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem, ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, monotherapy with a respiratory fluoroquinolone (e.g., levofloxacin, moxifloxacin, gemifloxacin), or other cost-effective therapeutic equivalent alternative(s) must be provided; and
3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s); and
    a. For Baxdela® vials, an initial quantity limit of 6 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablets for the remainder of therapy.

Ciprofloxacin 100mg Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use alternative strengths of ciprofloxacin tablets, levofloxacin tablets, moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

Ciprofloxacin 500mg and 1,000mg Extended-Release (ER) Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use the immediate-release formulation of ciprofloxacin tablets, levofloxacin tablets, moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

Ciprofloxacin 250mg/mL and 500mg/mL Oral Suspension and Levofloxacin 25mg/mL Oral Solution:

1. Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations cannot be used.

Dalvance® (Dalbavancin) Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent and resistant to the cephalosporin-class of antibiotics and other antibiotics commonly used for diagnosis or infection; and
2. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, or other cost effective therapeutic equivalent medication(s) must be provided; and
3. A quantity limit of 3 vials per 7 days will apply.

Fetroja® (Cefiderocol) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
    a. Complicated urinary tract infection (cUTI), including pyelonephritis; or
    b. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
3. The prescriber must verify that limited or no alternative treatment options are available; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime), or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Kimyrsa™ (Oritavancin) Approval Criteria:

1. An FDA approved indication for the treatment of acute bacterial skin and skin structure infection (ABSSSI) caused or suspected to be caused by susceptible isolates of designated gram-positive microorganisms; and
2. Member must be 18 years of age or older; and
3. The prescriber must verify that limited or no alternative treatment options are available; and
4. A patient-specific, clinically significant reason why the member cannot use Orbactiv® (oritavancin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and

5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Minocycline (50, 75, 100mg) Immediate-Release (IR) Tablet:

1. Approval requires a patient-specific, clinically significant reason why the member requires the IR tablet formulation and cannot use the IR capsule formulation and/or other cost effective therapeutic equivalent medication(s).

Nuzyra® (Omadacycline) Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:

1. An FDA approved diagnosis of ABSSSI caused by designated susceptible microorganisms; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use vancomycin, linezolid, doxycycline, trimethoprim/sulfamethoxazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Use of Nuzyra® vials will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Nuzyra® (Omadacycline) Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:

1. An FDA approved diagnosis of CABP caused by designated susceptible microorganisms; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem, ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).
    a. For Nuzyra® vials, an initial quantity limit of 4 vials for a 3-day supply will apply. Continued authorization will require a patient-specific, clinically significant reason why the member cannot switch to the oral tablet formulation for the remainder of therapy.

Ofloxacin 300mg and 400mg Tablet Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member cannot use ciprofloxacin tablets, levofloxacin tablets,

moxifloxacin tablets, or other cost-effective therapeutic equivalent alternative(s).

Recarbrio™ (Imipenem/Cilastatin/Relebactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   a. Complicated intra-abdominal infection (cIAI); or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; and
2. Member must be 18 years of age or older; and
3. The prescriber must verify that limited or no alternative treatment options are available; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. A quantity limit of 56 vials per 14 days will apply.

Seysara® (Sarecycline) Approval Criteria:

1. An FDA approved diagnosis of inflammatory lesions of non-nodular, moderate-to-severe acne vulgaris; and
2. Member must be 9 years of age or older; and
3. Seysara® is not covered for members older than 20 years of age; and
4. A patient-specific, clinically significant reason why the member cannot use minocycline, doxycycline, tetracycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate strength according to package labeling; and
6. A quantity limit of 30 tablets per 30 days will apply.

Sivextro® (Tedizolid) Tablet and Vial Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent and resistant to the cephalosporin class of antibiotics and other antibiotics commonly used for diagnosis or infection; and
2. A patient-specific, clinically significant reason why the member cannot use linezolid or other cost effective therapeutic equivalent medication(s) must be provided; and
3. A quantity limit of 6 tablets or vials per 6 days will apply.

Solosec® (Secnidazole Oral Granules) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis; and

2. A patient-specific, clinically significant reason why the member cannot use metronidazole, tinidazole, or other cost effective therapeutic equivalent alternative(s) must be provided; and
3. A quantity limit of 1 packet per 30 days will apply.

Suprax® (Cefixime) and Cedax® (Ceftibuten) Approval Criteria:

1. An indicated diagnosis or infection known to be susceptible to requested agent; and
2. A patient-specific, clinically significant reason why the member cannot use cephalexin, cefdinir, or other cost effective therapeutic equivalent medication(s) must be provided.

Tetracycline 250mg and 500mg Capsule Approval Criteria:

1. Approval requires a patient-specific, clinically significant reason why the member requires tetracycline and cannot use doxycycline, minocycline capsules, and/or other cost effective therapeutic equivalent medication(s).

Vabomere® (Meropenem/Vaborbactam Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI) or pyelonephritis; and
2. A patient-specific, clinically significant reason why the member cannot use piperacillin/tazobactam or other cost effective therapeutic equivalent alternative(s) must be provided; and
3. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Xenleta® (Lefamulin) Approval Criteria:

1. An FDA approved diagnosis of community-acquired bacterial pneumonia (CABP) caused by designated susceptible microorganisms; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., ceftriaxone, cefotaxime, ceftaroline, ertapenem, ampicillin/sulbactam) in combination with a macrolide (e.g., azithromycin, clarithromycin) or doxycycline, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Xerava™ (Eravacycline) Approval Criteria:

1. An FDA approved diagnosis of complicated intra-abdominal infection (cIAI) caused by designated susceptible microorganisms; and
2. Member must be 18 years of age or older; and

3. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Zemdri® (Plazomicin) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI), including pyelonephritis, caused by designated susceptible microorganisms; and
2. A patient-specific, clinically significant reason why the member cannot use an appropriate alternative aminoglycoside (e.g., gentamicin, tobramycin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
    a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
    b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
    c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Zerbaxa® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Utilization of Various Systemic Antibiotics: Calendar Year 2022

Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	270	408	$276,635.73	$678.03	$54.75	42,531	5,053
2022	326	496	$1,067,069.50	$2,151.35	$152.85	55,733	6,981
% Change	**20.70%**	**21.60%**	**285.70%**	**217.30%**	**179.20%**	**31.00%**	**38.20%**
Change	**56**	**88**	**$790,433.77**	**$1,473.32**	**$98.10**	**13,202**	**1,928**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

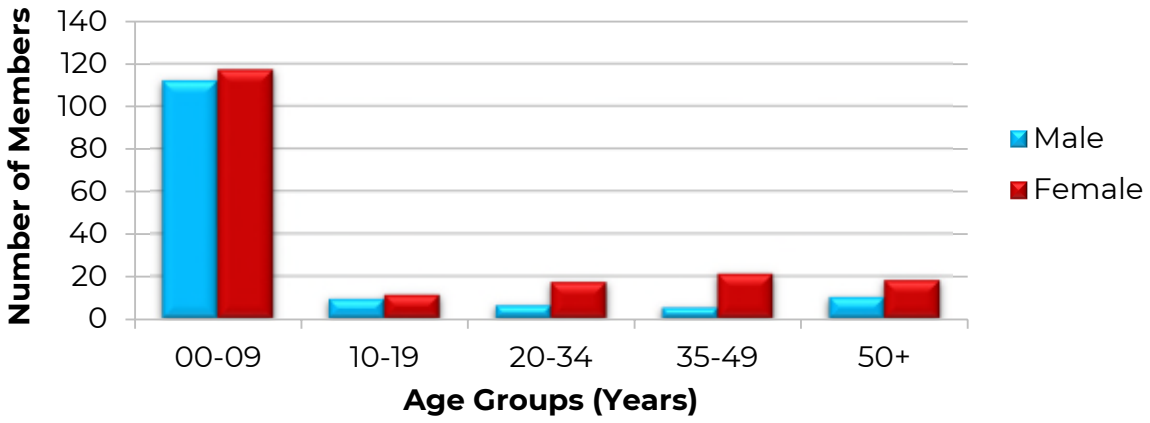
Comparison of Calendar Years: Medical Claims

Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	8	17	$77,498.00	$4,558.71	2.13
2022	19	28	$126,388.80	$4,513.87	1.47
% Change	**137.50%**	**64.71%**	**63.09%**	**-0.98%**	**-30.99%**
Change	**11**	**11**	**$48,890.80**	**-$44.84**	**-0.66**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

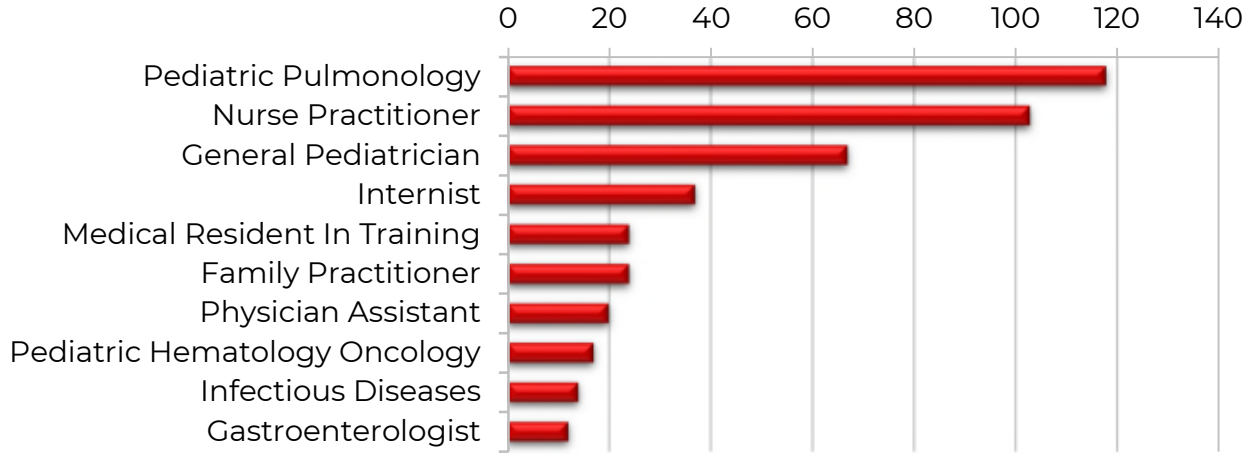
- Aggregate drug rebates collected during calendar year 2022 for the various systemic antibiotics: $173,602.29.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Various Systemic Antibiotics



[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.

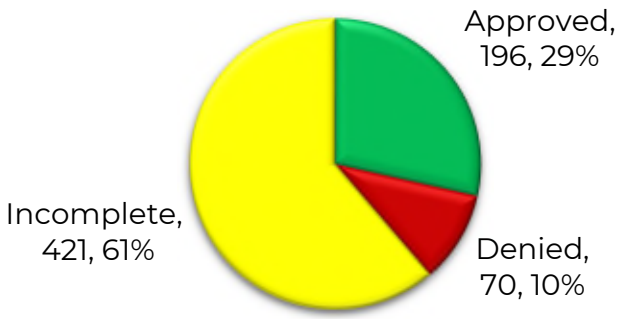
Top Prescriber Specialties of Various Systemic Antibiotics by Number of Claims



Prior Authorization of Various Systemic Antibiotics

There were 687 prior authorization requests submitted for various systemic antibiotics during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2,3,45,6,7]

Anticipated Patent Expiration(s):

- Ximino® [minocycline extended-release (ER) capsule]: April 2027
- Doryx® [doxycycline hyclate delayed-release (DR) tablet]: February 2028
- Dalvance® [dalbavancin vial for intravenous (IV) infusion]: May 2028
- Suprax® (cefixime 500mg/5mL oral suspension): December 2028
- Xenleta® (lefamulin vial for IV infusion): January 2029
- Recarbrio™ (imipenem/cilastatin/relebactam vial for IV infusion): November 2029
- Sivextro® (tedizolid tablet and vial for IV infusion): December 2030
- Xenleta® (lefamulin tablet): May 2031

- Baxdela® (delafloxacin tablet): June 2031
- Zemdri® (plazomicin vial for IV infusion): June 2031
- Solodyn® (minocycline ER tablet): November 2031
- Avycaz® (ceftazidime/avibactam vial for IV infusion): June 2032
- Baxdela® (delafloxacin vial for IV infusion): February 2033
- Seysara® (sarecycline tablet): February 2033
- Orbactiv® (oritavancin vial for IV infusion): July 2035
- Kimyrsa™ (oritavancin vial for IV infusion): July 2035
- Zerbaxa® (ceftolozane/tazobactam vial for IV infusion): August 2035
- Fetroja® (cefiderocol vial for IV infusion): September 2035
- Solosec® (secnidazole 2g oral granules): September 2035
- Xacduro® (sulbactam/durlobactam vial for IV infusion): November 2035
- Nuzyra® (omadacycline tablet and vial for IV infusion): October 2037
- Xerava™ (eravacycline vial for IV infusion): October 2037
- Vabomere® (meropenem/vaborbactam vial for IV infusion): April 2039

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

- **June 2020:** The FDA approved an expanded indication for Recarbrio™ (imipenem/cilastatin/relebactam) to treat hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) in adult patients 18 years of age and older. Previously, Recarbrio™ was only FDA approved to treat patients with complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI) who had limited or no treatment options.
- **July 2021:** The FDA approved an expanded indication for Solosec® (secnidazole oral granules) to include treatment of trichomoniasis in adults. Previously, Solosec® was only FDA approved to treat bacterial vaginosis (BV) in adult women.
- **April 2022:** The FDA approved Zerbaxa® (ceftolozane/tazobactam) for the treatment of cIAI and cUTI in pediatric patients (birth to younger than 18 years of age). Previously, Zerbaxa® was only approved in adults and is still only approved in adults for the treatment of HABP/VABP.
- **May 2023:** The FDA approved Xacduro® (sulbactam/durlobactam) for the treatment of HABP/VABP caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex in patients 18 years of age and older. It is the first pathogen-targeted therapy addressing *Acinetobacter,* including resistant strains.

Guideline Update(s):

- **Infectious Diseases Society of America (IDSA) 2023 Guideline Update:** In June 2023, the IDSA released updated guidance on the treatment of antimicrobial resistant gram-negative infections including guidance on the treatment of infections caused by extended-spectrum beta-lactamase-producing Enterobacterales (ESBL-E), AmpC beta-

lactamase-producing Enterobacterales (AmpC-E), carbapenem-resistant Enterobacterales (CRE), *Pseudomonas aeruginosa* with difficult-to-treat resistance (DTR-*P. aeruginosa*), carbapenem-resistant *Acinetobacter baumannii* species (CRAB), and *Stenotrophomonas maltophilia*.

Pipeline:

- **Aztreonam-avibactam (ATM-AVI):** In June 2023, Pfizer announced positive results from the Phase 3 trials, REVISIT and ASSEMBLE, which evaluated the efficacy, safety, and tolerability of ATM-AVI in the treatment of bacterial infections due to gram-negative bacteria, including metallo-beta-lactamase (MBL)-producing multidrug-resistant pathogens for which there are limited or no treatment options. The trials showed that ATM-AVI is effective and well tolerated.

Xacduro® (Sulbactam/Durlobactam) Product Summary[8]

Therapeutic Class: Dual beta-lactamase inhibitor and beta-lactam antibacterial

Indication(s): Treatment of HABP/VABP caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex in patients 18 years of age and older

- Limitation(s) of Use: Xacduro® is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.

How Supplied: Xacduro® is a 1g/1g sulbactam/durlobactam co-packaged kit containing the following 2 components as sterile powders for reconstitution:

- 1 clear single-dose vial (SDV) of 1g of sulbactam for injection
- 2 amber SDVs of 0.5g of durlobactam for injection

Dosing and Administration: The recommended dose of Xacduro® is 1g of sulbactam and 1g of durlobactam every 6 hours administered by IV infusion over 3 hours in adults with creatinine clearance (CrCl) of 45 to 120mL/min. Refer to the package labeling for dose adjustments for patients with CrCl <45mL/min or ≥130mL/min.

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

Recommendations

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

Xacduro® (Sulbactam/Durlobactam) Approval Criteria:

1. An FDA approved diagnosis of hospital-acquired bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use a carbapenem, ampicillin/sulbactam, polymyxin B, or other cost effective therapeutic equivalent alternative(s); or
4. For members with carbapenem-resistant *Acinetobacter baumannii* (CRAB), a patient-specific, clinically significant reason why the member cannot use high dose ampicillin/sulbactam in combination with polymyxin B, minocycline, or tigecycline must be provided; and
5. The prescriber must confirm that the member will be treated for other pathogens present, if applicable; and
6. Approval quantity will be based on Xacduro® package labeling and FDA approved dosing regimen(s).

Additionally, the College of Pharmacy recommends updating the current approval criteria for Fetroja® (cefiderocol), Kimyrsa™ (oritavancin), Recarbrio™ (imipenem/cilastatin/relebactam), Solosec® (secnidazole oral granules), and Zerbaxa® (ceftolozane/tazobactam) to be consistent with the FDA approved indications (changes shown in red):

Fetroja® (Cefiderocol) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   a. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   b. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
3. ~~The prescriber must verify that limited or no alternative treatment options are available; and~~
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime), or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Kimyrsa™ (Oritavancin) Approval Criteria:

1. An FDA approved indication for the treatment of acute bacterial skin and skin structure infection (ABSSSI) caused or suspected to be caused by susceptible isolates of designated gram-positive microorganisms; and
2. Member must be 18 years of age or older; and
3. ~~The prescriber must verify that limited or no alternative treatment options are available; and~~
4. A patient-specific, clinically significant reason why the member cannot use Orbactiv® (oritavancin) or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Recarbrio™ (Imipenem/Cilastatin/Relebactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:
   a. Complicated intra-abdominal infection (cIAI); or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. Member must be 18 years of age or older; and
3. ~~The prescriber must verify that limited or no alternative treatment options are available; and~~
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. A quantity limit of 56 vials per 14 days will apply.

Solosec® (Secnidazole Oral Granules) Approval Criteria:

1. An FDA approved diagnosis of bacterial vaginosis or trichomoniasis; and
2. A patient-specific, clinically significant reason why the member cannot use metronidazole, tinidazole, or other cost effective therapeutic equivalent alternative(s) must be provided; and
3. A quantity limit of 1 packet per 30 days will apply.

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms:

   a. Complicated intra-abdominal infection (cIAI), used in combination with metronidazole; or
   b. Complicated urinary tract infection (cUTI), including pyelonephritis; or
   c. Hospital-acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP); and
2. For the diagnosis of HABP/VABP, member must be 18 years of age or older; and
3. For the diagnosis of cIAI, Zerbaxa® must be used in combination with metronidazole; and
4. A patient-specific, clinically significant reason why the member cannot use an appropriate penicillin/beta lactamase inhibitor combination (e.g., piperacillin/tazobactam), a carbapenem (e.g., ertapenem, meropenem, imipenem/cilastatin), a cephalosporin (e.g., ceftriaxone, ceftazidime) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Finally, the College of Pharmacy recommends removing the prior authorization of amoxicillin 500mg tablets based on net costs (changes shown in red):

Oral Antibiotic Special Formulation Approval Criteria:

1. Member must have a patient-specific, clinically significant reason why the immediate-release formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.
2. The following oral antibiotics currently require prior authorization and the special formulation approval criteria will apply:
   - ~~Amoxicillin 500mg tablets~~
   - Amoxicillin/clavulanate potassium extended-release (ER) tablets (Augmentin XR®)
   - Cephalexin 250mg and 500mg tablets
   - Cephalexin 750mg capsules
   - Doxycycline hyclate 75mg and 150mg tablets (Acticlate®)
   - Doxycycline hyclate 50mg tablet (Targadox®)
   - Doxycycline hyclate delayed-release (DR) tablets (Doryx®)
   - Doxycycline monohydrate 150mg capsules and tablets
   - Doxycycline monohydrate DR 40mg capsules (Oracea®)
   - Minocycline ER capsules (Ximino®)
   - Minocycline ER tablets (Minolira™)
   - Minocycline ER tablets (Solodyn®)

Utilization Details of Various Systemic Antibiotics: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LEVOFLOXACIN PRODUCTS					
LEVOFLOXACIN SOL 25MG/ML	186	124	$23,880.15	$128.39	1.5
SUBTOTAL	**186**	**124**	**$23,880.15**	**$128.39**	**1.5**
CIPROFLOXACIN PRODUCTS					
CIPRO 10% SUS 500MG/5ML	83	56	$14,248.47	$171.67	1.48
CIPRO 5% SUS 250MG/5ML	77	69	$11,904.91	$154.61	1.15
SUBTOTAL	**160**	**125**	**$26,153.38**	**$163.46**	**1.28**
TETRACYCLINE PRODUCTS					
TETRACYCLINE CAP 500MG	43	42	$3,010.27	$70.01	1.02
TETRACYCLINE CAP 250MG	4	4	$218.31	$54.58	1
SUBTOTAL	**47**	**46**	**$3,228.58**	**$68.69**	**1.02**
AMIKACIN PRODUCTS					
ARIKAYCE SUS 590MG/8.4ML	24	4	$321,203.38	$13,383.47	6
SUBTOTAL	**24**	**4**	**$321,203.38**	**$13,383.47**	**6**
OMADACYCLINE PRODUCTS					
NUZYRA TAB 150MG	21	8	$261,008.06	$12,428.96	2.63
SUBTOTAL	**21**	**8**	**$261,008.06**	**$12,428.96**	**2.63**
TEDIZOLID PRODUCTS					
SIVEXTRO TAB 200MG	19	5	$311,611.40	$16,400.60	3.8
SUBTOTAL	**19**	**5**	**$311,611.40**	**$16,400.60**	**3.8**
CEFIXIME PRODUCTS					
CEFIXIME SUS 200MG/5ML	7	4	$1,825.90	$260.84	1.75
CEFIXIME CAP 400MG	6	5	$668.46	$111.41	1.2
CEFIXIME SUS 100MG/5ML	2	2	$508.57	$254.29	1
SUBTOTAL	**15**	**11**	**$3,002.93**	**$200.16**	**1.36**
CEFTAZIDIME/AVIBACTAM PRODUCTS					
AVYCAZ INJ 2-0.5GM	8	4	$41,826.33	$5,228.29	2
SUBTOTAL	**8**	**4**	**$41,826.33**	**$5,228.29**	**2**
CEFTOLOZANE/TAZOBACTAM PRODUCTS					
ZERBAXA INJ 1.5GM	4	3	$37,831.34	$9,457.84	1.33
SUBTOTAL	**4**	**3**	**$37,831.34**	**$9,457.84**	**1.33**
DALBAVANCIN PRODUCTS					
DALVANCE SOL 500MG	4	2	$16,949.39	$4,237.35	2
SUBTOTAL	**4**	**2**	**$16,949.39**	**$4,237.35**	**2**
MINOCYCLINE PRODUCTS					
MINOCYCLINE TAB 50MG	3	1	$103.50	$34.50	3
SUBTOTAL	**3**	**1**	**$103.50**	**$34.50**	**3**
AMOXICILLIN PRODUCTS					
AMOX-POT CLA TAB ER 1000-62.5MG	2	2	$1,094.88	$547.44	1
SUBTOTAL	**2**	**2**	**$1,094.88**	**$547.44**	**1**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DELAFLOXACIN PRODUCTS					
BAXDELA TAB 450MG	1	1	$1,605.41	$1,605.41	1
SUBTOTAL	**1**	**1**	**$1,605.41**	**$1,605.41**	**1**
SECNIDAZOLE PRODUCTS					
SOLOSEC GRA 2GM	1	1	$283.36	$283.36	1
SUBTOTAL	**1**	**1**	**$283.36**	**$283.36**	**1**
MEROPENEM/VABORBACTAM PRODUCTS					
VABOMERE INJ 2GM	1	1	$17,287.41	$17,287.41	1
SUBTOTAL	**1**	**1**	**$17,287.41**	**$17,287.41**	**1**
TOTAL	**496**	**326***	**$1,067,069.50**	**$2,151.35**	**1.52**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMOX-POT CLA = amoxicillin/clavulanate potassium; CAP = capsule; ER = extended-release; GRA = granules; INJ = injection; SOL = solution; SUS = suspension; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DALBAVANCIN INJ 5MG (J0875)	21	13	$91,503.60	$4,357.31	1.62
ORITAVANCIN INJ 10MG (J2406)	7	6	$34,885.20	$4,983.60	1.17
TOTAL	**28†**	**19***	**$126,388.80**	**$4,513.87**	**1.47**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
INJ = injection

[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 07/2023. Last accessed 07/10/2023.
[2] FDA. FDA Approves Antibiotic to Treat Hospital-Acquired Bacterial Pneumonia and Ventilator Associated Bacterial Pneumonia. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-antibiotic-treat-hospital-acquired-bacterial-pneumonia-and-ventilator-associated. Issued 06/04/2020. Last accessed 08/02/2023.
[3] Lupin Pharmaceuticals, Inc. Lupin Announces FDA Approval of Supplemental New Drug Application for Solosec® (Secnidazole) for the Treatment of Trichomoniasis. Available online at: https://www.lupin.com/lupin-announces-fda-approval-of-supplemental-new-drug-application-for-solosec-secnidazole-for-the-treatment-of-trichomoniasis/. Issued on 07/01/2021. Last accessed 08/02/2023.
[4] Park, B. Zerbaxa® Approved for Complicated Pediatric Intra-abdominal, Urinary Tract Infections. *Medical Professionals Reference*. Available online at: https://www.empr.com/home/news/zerbaxa-approved-for-complicated-pediatric-intra-abdominal-urinary-tract-infections/. Issued 04/26/2022. Last accessed 08/02/2023.
[5] Innoviva, Inc. Innoviva Specialty Therapeutics Announces FDA Approval for Xacduro® (Sulbactam for Injection; Durlobactam for Injection), Co-packaged for Intravenous Use. Available online at: https://investor.inva.com/news-releases/news-release-details/innoviva-specialty-therapeutics-announces-fda-approval-xacduror. Issued 05/23/2023. Last accessed 07/19/2023.
[6] Tamma PD, Aitken SL, Bonomo RA, et al. Infectious Disease Society of American Antimicrobial-Resistant Treatment Guidance: Gram-Negative Bacterial Infections. *IDSA* 2023. Available online at: https://www.idsociety.org/practice-guideline/amr-guidance/#Carbapenem-ResistantAcinetobacterbaumannii%C2%A0. Issued 06/07/2023. Last accessed 07/25/2023.
[7] Pfizer Inc. Phase 3 Studies of Pfizer's Novel Antibiotic Combination Offer New Treatment Hope for Patients with Multidrug-Resistant Infections and Limited Treatment Options. Available online at: https://www.pfizer.com/news/press-release/press-release-detail/phase-3-studies-pfizers-novel-antibiotic-combination-offer. Issued 06/01/2023. Last accessed 07/19/2023.
[8] Xacduro® (Sulbactam/Durlobactam) Prescribing Information. Entasis Therapeutics Inc. Available online at: https://xacduro-assets.s3.amazonaws.com/prescribing-information.pdf. Last revised 05/2023. Last accessed 07/19/2023.

Appendix D

Annual Review of Intravenous (IV) Iron Products

Oklahoma Health Care Authority
August 2023

Current Prior Authorization Criteria

Feraheme® (Ferumoxytol) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Iron deficiency anemia (IDA); or
   b. IDA with chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. Prescriber must verify the member does not have a previous history of allergic reaction to any intravenous iron medications; and
5. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided.

Injectafer® (Ferric Carboxymaltose) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Iron deficiency anemia (IDA); or
   b. IDA in members with non-dialysis dependent chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided.

Monoferric® (Ferric Derisomaltose) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Iron deficiency anemia (IDA); or
   b. IDA in members with non-dialysis dependent chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided.

Utilization of IV Iron Products: Medical Claims

Comparison of Calendar Years

Calendar Year	Total Members*	Total Claims†	Total Cost	Cost/ Claim	Claims/ Member
2021	667	927	$265,724.45	$286.65	1.39
2022	1,349	3,916	$482,251.84	$123.15	2.9
% Change	**102.25%**	**322.44%**	**81.49%**	**-57.04%**	**108.84%**
Change	**682**	**2,989**	**$216,527.39**	**-$163.50**	**1.51**

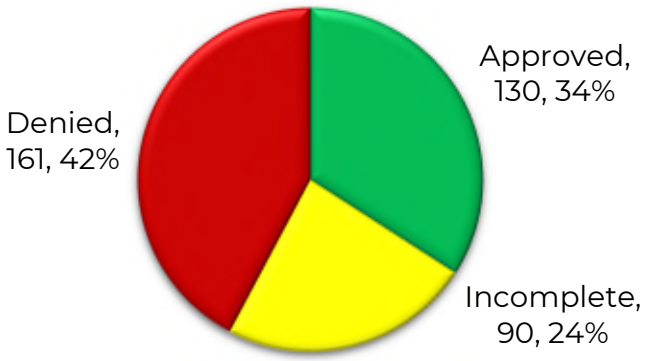
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

- Aggregate drug rebates collected during calendar year 2022 for IV iron products: $134,111.52.[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.

Prior Authorization of IV Iron Products

There were 381 prior authorization requests submitted for IV iron products during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Injectafer® (ferric carboxymaltose injection): February 2028
- Monoferric® (ferric derisomaltose injection): June 2036

[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.

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

- **May 2023:** The FDA approved Injectafer® (ferric carboxymaltose injection) for a new indication for the treatment of iron deficiency in adult patients with New York Heart Association class II-III heart failure (HF) to improve exercise capacity. The FDA approved dosing for this indication is an initial dose of 500mg or 1,000mg given on day 1 with a potential second dose given at week 6 (the recommended dose and number of doses is based on the patient's weight and hemoglobin level). Subsequent maintenance doses of 500mg may be given at 12, 24, and 36 weeks if serum ferritin is <100ng/mL (or 100-300ng/mL if transferrin saturation is <20%).

Cost Comparison: IV Iron Products

Product	Cost Per mg	Cost Per Treatment Course*
Monoferric® (ferric derisomaltose inj) 1,000mg/10mL	$2.06	$2,060
Injectafer® (ferric carboxymaltose inj) 1,000mg/20mL	$1.13	$1,130
Feraheme® (ferumoxytol inj) 510mg/17mL	$0.50	$510
Infed® (iron dextran inj) 100mg/2mL	$0.34	$340
Venofer® (iron sucrose inj) 200mg/2mL	$0.21	$210

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 treatment course based on 1,000mg for Monoferric®, Injectafer®, and Infed®, (2) 510mg doses for Feraheme®, and (5) 200mg doses for Venofer®.
inj = injection

Recommendations

The College of Pharmacy recommends updating the Injectafer® (ferric carboxymaltose) approval criteria based on recent FDA approved indication for iron deficiency in patients with HF (new criteria and changes shown in red):

Injectafer® (Ferric Carboxymaltose) Approval Criteria [Iron Deficiency Diagnosis]:

1. An FDA approved indication of iron deficiency in adult members with New York Heart Association (NYHA) class II-III heart failure (HF) to improve exercise capacity; and
2. Member must be 18 years of age or older; and
3. Documented lab results verifying iron deficiency; and
4. Prescriber must verify member is already receiving optimal background therapy for HF; and
5. Member must have left ventricular ejection fraction (LVEF) <45%; and

6. Member's current weight (kg) and hemoglobin (Hb) (g/dL) must be provided to ensure appropriate dosing according to package labeling; and
7. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided; and
8. Initial approvals will be for 1 or 2 doses only (depending on member's weight and Hb) according to package labeling; and
9. Subsequent requests for maintenance doses at weeks 12, 24, and 36 will require submission of updated lab results verifying continued iron deficiency for each dose and will be approved for (1) 500mg dose at a time.

Injectafer® (Ferric Carboxymaltose) Approval Criteria [Iron Deficiency Anemia (IDA) Diagnosis]:

1. An FDA approved indication of 1 of the following:
   a. IDA; or
   b. IDA in members with non-dialysis dependent chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided.

Additionally, the College of Pharmacy recommends updating the Monoferric® (ferric derisomaltose) approval criteria based on net cost (changes shown in red):

Monoferric® (Ferric Derisomaltose) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Iron deficiency anemia (IDA); or
   b. IDA in members with non-dialysis dependent chronic kidney disease (CKD); and
2. Documented lab results verifying IDA; and
3. Documentation of intolerance or inadequate response to oral iron therapy after at least 3 months at recommended dosing; and
4. A recent trial of Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Infed® and Venofer® must be provided; and
5. A patient-specific, clinically significant reason why the member cannot utilize Feraheme® (ferumoxytol) and Injectafer® (ferric carboxymaltose) must be provided.

Utilization Details of IV Iron Products: Calendar Year 2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS[+]	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
J1756 IRON SUCROSE INJ 1MG (VENOFER)	2,919	714	$92,719.05	$31.76
J1750 IRON DEXTRAN INJ 50MG (INFED)	880	595	$188,298.99	$213.98
J1437 FERRIC DERISOMALTOSE INJ 10MG (MONOFERRIC)	74	69	$171,247.00	$2,314.15
J1439 FERRIC CARBOXYMALTOSE INJ 1MG (INJECTAFER)	24	13	$20,332.50	$847.19
Q0138 FERUMOXYTOL INJ 1MG (NON-ESRD) (FERAHEME)	19	13	$9,654.30	$508.12
TOTAL	**3,916**	**1,349**	**$482,251.84**	**$123.15**

Costs do not reflect rebated prices or net costs.
[+]Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
ESRD = end-stage renal disease; INJ = injection
Please note: Reimbursement of IV iron products for members with ESRD receiving dialysis is included in the bundled dialysis payment and cannot be reimbursed separately. Utilization data for IV iron products reimbursed in the bundled dialysis payment is not included in the above table or in this report.

[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 07/2023. Last accessed 07/06/2023.
[2] Daiichi Sankyo, Inc. Injectafer® Approved in the U.S. for the Treatment of Iron Deficiency in Adult Patients with Heart Failure. Available online at: https://www.businesswire.com/news/home/20230605005213/en/INJECTAFER%C2%AE-Approved-in-the-U.S.-for-the-Treatment-of-Iron-Deficiency-in-Adult-Patients-with-Heart-Failure. Issued 06/05/2023. Last accessed 07/07/2023.
[3] Injectafer® (Ferric Carboxymaltose) Prescribing Information. American Regent, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/203565s020lbl.pdf. Last revised 05/2023. Last accessed 07/19/2023.

Appendix E

Calendar Year 2022 Annual Review of Topical Corticosteroids

Oklahoma Health Care Authority
August 2023

Current Prior Authorization Criteria

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®, Diprolene AF®)	C,O	amcinonide 0.1%	C,L	clobetasol propionate 0.05% (Clobex®)	Sh,Spr
betamethasone dipropionate 0.05% (Diprosone®)	C,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G,L	clobetasol propionate 0.05% (Olux®, Olux-E®, Tovet®)	F
Clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Clobex®)	L	Clobetasol propionate 0.05% (Impeklo™)	L
desoximetasone 0.25% (Topicort®)	C,O	clobetasol propionate 0.05% (Temovate®)	G	desoximetasone 0.25% (Topicort®)	Spr
fluocinonide 0.05%	C,O,So	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
fluocinonide 0.1% (Vanos®)	C	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon E®)	C
halobetasol propionate 0.05% (Ultravate®)	C,O	flurandrenolide tape 0.05% (Cordran®)	Tape	halobetasol propionate 0.01% (Bryhali®)	L
		halcinonide 0.1% (Halog®)	C,O,So	halobetasol propionate 0.05% (Lexette®)	F
		halobetasol propionate 0.05% (Ultravate®)	L		
		halobetasol propionate/lactic acid 0.05%/10% (Ultravate X®)	C		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone dipropionate/calcipotriene 0.064%/0.005% (Taclonex®)	O,Spr, Sus	desoximetasone 0.05% (Topicort LP®)	C,O
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.12% (Luxiq®)	F		
fluticasone propionate 0.005% (Cutivate®)	O	betamethasone valerate 0.1% (Beta-Val®)	L	hydrocortisone valerate 0.2% (Westcort®)	C,O
fluticasone propionate 0.05% (Cutivate®)	C	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F		
mometasone furoate 0.1% (Elocon®)	C,L,O, So	clocortolone pivalate 0.1% (Cloderm®)	C		
triamcinolone acetonide 0.025%	O	fluocinolone acetonide 0.025% (Synalar®)	C,O		
triamcinolone acetonide 0.1%	C,L,O	fluocinonide emollient 0.05% (Lidex E®)	C		
triamcinolone acetonide 0.5%	C,O	flurandrenolide 0.05%			
		fluticasone propionate 0.05% (Cutivate®)	C,L,O		
		hydrocortisone butyrate 0.1%	L		
		hydrocortisone probutate 0.1% (Pandel®)	C,L,O, So		
		prednicarbate 0.1% (Dermatop®)	C,O		
		triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr		
		triamcinolone acetonide 0.05% (Trianex®)	O		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C	alclometasone dipropionate 0.05% (Aclovate®)	O
fluocinolone acetonide 0.01% (Capex®)	Sh	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Synalar®)	C	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	hydrocortisone 2.5% (Texacort®)	So		
hydrocortisone acetate 2.5%	C,L,O	hydrocortisone/pramoxine 1%/1% (Pramosone®)	C,L		
hydrocortisone/urea 1%/10% (U-Cort®)	C				
triamcinolone acetonide 0.025%	C,L				

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).
C = cream; F = foam; G = gel; L= lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

Topical Corticosteroids Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 topical corticosteroids of similar potency in the past 30 days that did not yield adequate relief; and
2. If Tier-1 trials are completed and do not yield adequate relief, the member must also provide a patient-specific, clinically significant reason for requesting a Tier-2 medication in the same potency instead of trying a higher potency; and
3. When the same medication is available in Tier-1, a patient-specific, clinically significant reason must be provided for using a special dosage formulation of that medication in Tier-2 (e.g., foams, shampoos, sprays, kits); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over standard formulations.

Topical Corticosteroids Tier-3 Approval Criteria:

1. Documented trials of all Tier-1 and Tier-2 topical corticosteroids of similar potency in the past 90 days that did not yield adequate relief; and
2. If Tier-1 and Tier-2 trials are completed and do not yield adequate relief, the member must also provide a patient-specific, clinically significant reason for requesting a Tier-3 medication in the same potency instead of trying a higher potency; and
3. When the same medication is available in Tier-1 or Tier-2, a patient-specific, clinically significant reason must be provided for using a special dosage form of that medication in Tier-3 (e.g., foams, shampoos, sprays, kits); and
4. Topical corticosteroid kits require tier trials and a patient-specific, clinically significant reason for use of the kit over other standard formulations.

Utilization of Topical Corticosteroids: Calendar Year 2022

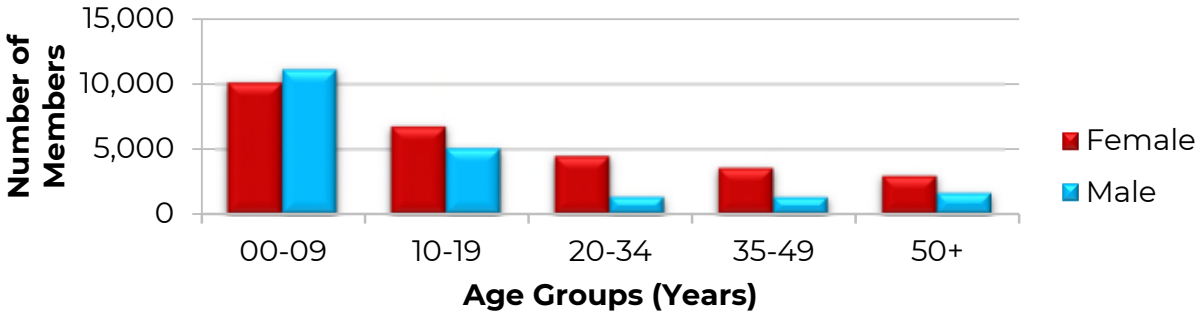
Comparison of Calendar Years: Pharmacy Claims

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	40,644	62,222	$1,098,892.84	$17.66	$0.98	4,565,887	1,125,234
2022	48,090	73,517	$1,217,084.53	$16.56	$0.88	5,597,195	1,384,151
% Change	**18.3%**	**18.2%**	**10.8%**	**-6.2%**	**-10.2%**	**22.6%**	**23.0%**
Change	**7,446**	**11,295**	**$118,191.69**	**-$1.10**	**-$0.10**	**1,031,308**	**258,917**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.

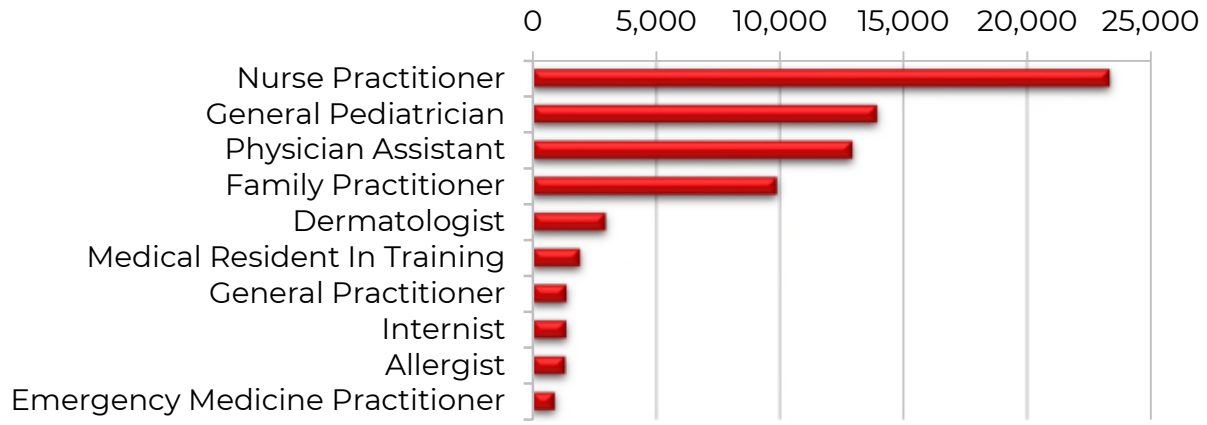
- Aggregate drug rebates collected during calendar year 2022 for topical corticosteroids: $40,326.18.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Demographics of Members Utilizing Topical Corticosteroids



[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.

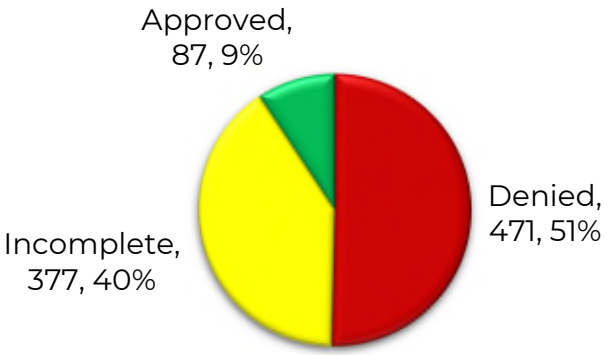
Top Prescriber Specialties of Topical Corticosteroids by Number of Claims



Prior Authorization of Topical Corticosteroids

There were 935 prior authorization requests submitted for topical corticosteroids during calendar year 2022. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Verdeso® (desonide 0.05% foam): August 2027
- Topicort® (desoximetasone 0.25% spray): September 2028
- Sernivo® (betamethasone dipropionate 0.05% topical spray): August 2030
- Bryhali® (halobetasol propionate 0.01% lotion): November 2031
- Enstilar® (calcipotriene/betamethasone dipropionate 0.64%/0.005% foam): December 2031
- Ultravate® (halobetasol 0.05% lotion): June 2033
- Impoyz® (clobetasol propionate 0.025% cream): March 2035

Recommendations

The College of Pharmacy recommends the following changes to the topical corticosteroids Product Based Prior Authorization (PBPA) Tier chart based on net costs (changes are shown in red in the following Tier chart):

1. Ultra-High to High Potency:
   a. Move clobetasol propionate 0.05% foam (Olux®) from Tier-3 to Tier-1
   b. Move clobetasol propionate 0.05% shampoo (Clobex®) from Tier-3 to Tier-2
2. Medium-High to Medium Potency:
   a. Move triamcinolone acetonide 0.147mg/g spray (Kenalog®) from Tier-2 to Tier-3
3. Low Potency:
   a. Move hydrocortisone 2.5% solution (Texacort®) from Tier-2 to Tier-3

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Ultra-High to High Potency					
augmented betamethasone dipropionate 0.05% (Diprolene®) Diprolene AF®)	C,O	amcinonide 0.1%	C,L	clobetasol propionate 0.05% (Clobex®)	~~**Sh,**~~Spr
betamethasone dipropionate 0.05% (Diprosone®)	C,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G,L	clobetasol propionate 0.05% (~~**Olux®,**~~ Olux-E®, Tovet®)	F
clobetasol propionate 0.05% (Olux®)	**F**	clobetasol propionate 0.05% (Clobex®)	L**,Sh**	Clobetasol propionate 0.05% (Impeklo™)	L
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	desoximetasone 0.25% (Topicort®)	Spr
desoximetasone 0.25% (Topicort®)	C,O	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
fluocinonide 0.05%	C,O,So	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon E®)	C
fluocinonide 0.1% (Vanos®)	C	flurandrenolide tape 0.05% (Cordran®)	Tape	halobetasol propionate 0.01% (Bryhali®)	L
halobetasol propionate 0.05% (Ultravate®)	C,O	halcinonide 0.1% (Halog®)	C,O,So	halobetasol propionate 0.05%	F

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
		halobetasol propionate 0.05% (Ultravate®)	L		
		halobetasol propionate/lactic acid 0.05%/10% (Ultravate X®)	C		
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone dipropionate/calcipotriene 0.064%/0.005% (Taclonex®)	O,Spr, Sus	desoximetasone 0.05% (Topicort LP®)	C,O
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.12% (Luxiq®)	F	hydrocortisone valerate 0.2% (Westcort®)	C,O
fluticasone propionate 0.005% (Cutivate®)	O	betamethasone valerate 0.1% (Beta-Val®)	L	**triamcinolone acetonide 0.147mg/g (Kenalog®)**	**Spr**
fluticasone propionate 0.05% (Cutivate®)	C	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F		
mometasone furoate 0.1% (Elocon®)	C,L,O, So	clocortolone pivalate 0.1% (Cloderm®)	C		
triamcinolone acetonide 0.025%	O	fluocinolone acetonide 0.025% (Synalar®)	C,O		
triamcinolone acetonide 0.1%	C,L,O	fluocinonide emollient 0.05% (Lidex E®)	C		
triamcinolone acetonide 0.5%	C,O	flurandrenolide 0.05%	C,L,O		
		fluticasone propionate 0.05% (Cutivate®)	L		
		hydrocortisone butyrate 0.1%	C,L,O, So		
		hydrocortisone probutate 0.1% (Pandel®)	C		
		prednicarbate 0.1% (Dermatop®)	C,O		

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
		~~**triamcinolone acetonide 0.147mg/g (Kenalog®)**~~	~~**Spr**~~		
		triamcinolone acetonide 0.05% (Trianex®)	O		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C	alclometasone dipropionate 0.05% (Aclovate®)	O
fluocinolone acetonide 0.01% (Capex®)	Sh	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Synalar®)	C	desonide 0.05% (Desonate®)	G
hydrocortisone acetate 1%	C,O	~~**hydrocortisone 2.5% (Texacort®)**~~	~~**So**~~	**hydrocortisone 2.5% (Texacort®)**	**So**
hydrocortisone acetate 2.5%	C,L,O	hydrocortisone/pramoxine 1%/1% (Pramosone®)	C,L		
hydrocortisone/urea 1%/10% (U-Cort®)	C				
triamcinolone acetonide 0.025%	C,L				

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).
C = cream; F = foam; G = gel; L= lotion; O = ointment; Sh = shampoo; So = solution; Spr = spray; Sus = suspension

Utilization Details of Topical Corticosteroids: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
LOW POTENCY PRODUCTS						
HYDROCORTISONE CRE 2.5%	5,327	4,246	$65,777.55	$12.35	1.25	5.40%
TRIAMCINOLONE CRE 0.025%	4,304	3,480	$56,311.75	$13.08	1.24	4.63%
HYDROCORTISONE OIN 2.5%	3,598	2,507	$60,957.66	$16.94	1.44	5.01%
HYDROCORTISONE CRE 1%	853	760	$8,770.95	$10.28	1.12	0.72%
HYDROCORTISONE OIN 1%	587	530	$7,665.38	$13.06	1.11	0.63%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROCORTISONE LOT 2.5%	445	332	$12,206.94	$27.43	1.34	1.00%
TRIAMCINOLONE LOT 0.025%	120	105	$4,021.70	$33.51	1.14	0.33%
HYDROCORTISONE POW	82	65	$1,479.97	$18.05	1.26	0.12%
DESONIDE CRE 0.05%	81	76	$2,378.26	$29.36	1.07	0.20%
FLUOCINOLONE ACT SOL 0.01%	59	45	$1,710.27	$28.99	1.31	0.14%
DESONIDE OIN 0.05%	49	41	$1,659.21	$33.86	1.2	0.14%
TRIAMCINOLONE ACT POW	34	27	$686.58	$20.19	1.26	0.06%
HYDROCORTISONE POW	33	24	$383.57	$11.62	1.38	0.03%
HYDROCORTISONE MICRO POW	9	7	$168.45	$18.72	1.29	0.01%
CAPEX SHA 0.01%	1	1	$393.46	$393.46	1	0.03%
SUBTOTAL	**15,582**	**12,246**	**$224,571.70**	**$14.41**	**1.27**	**18.45%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLONE CRE 0.1%	24,521	18,779	$336,568.38	$13.73	1.31	27.65%
TRIAMCINOLONE OIN 0.1%	14,854	11,197	$235,279.81	$15.84	1.33	19.33%
TRIAMCINOLONE CRE 0.5%	2,690	2,024	$41,756.14	$15.52	1.33	3.43%
TRIAMCINOLONE OIN 0.025%	2,502	2,013	$37,913.39	$15.15	1.24	3.12%
TRIAMCINOLONE OIN 0.5%	1,316	1,010	$25,233.80	$19.17	1.3	2.07%
MOMETASONE CRE 0.1%	847	648	$19,584.82	$23.12	1.31	1.61%
BETAMETH VAL CRE 0.1%	498	373	$15,547.84	$31.22	1.34	1.28%
TRIAMCINOLONE LOT 0.1%	450	382	$13,451.23	$29.89	1.18	1.11%
FLUTICASONE CRE 0.05%	400	269	$9,887.30	$24.72	1.49	0.81%
MOMETASONE OIN 0.1%	366	226	$6,742.59	$18.42	1.62	0.55%
BETAMETH VAL OIN 0.1%	316	224	$10,087.74	$31.92	1.41	0.83%
MOMETASONE SOL 0.1%	243	158	$6,649.28	$27.36	1.54	0.55%
BETAMETH DIP LOT 0.05%	166	119	$5,330.19	$32.11	1.39	0.44%
FLUTICASONE OIN 0.005%	112	79	$3,339.90	$29.82	1.42	0.27%
SUBTOTAL	**49,281**	**37,501**	**$767,372.41**	**$15.57**	**1.31**	**63.05%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL SOL 0.05%	2,079	1,246	$51,595.28	$24.82	1.67	4.24%
CLOBETASOL CRE 0.05%	1,936	1,326	$45,495.93	$23.50	1.46	3.74%
CLOBETASOL OIN 0.05%	1,792	1,152	$42,517.98	$23.73	1.56	3.49%
AUG BETAMETH CRE 0.05%	1,010	729	$17,690.03	$17.51	1.39	1.45%
FLUOCINONIDE SOL 0.05%	599	386	$17,647.13	$29.46	1.55	1.45%
FLUOCINONIDE OIN 0.05%	353	239	$9,436.65	$26.73	1.48	0.78%
FLUOCINONIDE CRE 0.05%	270	146	$11,210.60	$41.52	1.85	0.92%
BETAMETH DIP CRE 0.05%	144	134	$4,356.77	$30.26	1.07	0.36%
CLOBETASOL EMOL CRE 0.05%	112	72	$5,447.15	$48.64	1.56	0.45%
BETAMETH DIP OIN 0.05%	83	73	$3,464.52	$41.74	1.14	0.28%
HALOBETASOL CRE 0.05%	57	40	$2,225.57	$39.05	1.43	0.18%
AUG BETAMETH OIN 0.05%	21	19	$966.57	$46.03	1.11	0.08%
HALOBETASOL OIN 0.05%	14	9	$576.90	$41.21	1.56	0.05%
FLUOCINONIDE CRE 0.1%	7	5	$152.92	$21.85	1.4	0.01%
DESOXIMETASONE CRE 0.25%	5	3	$114.86	$22.97	1.67	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DESOXIMETASONE OIN 0.25%	2	2	$51.72	$25.86	1	0.00%
FLUOCINONIDE CRE EMU 0.05%	1	1	$62.82	$62.82	1	0.01%
FLUOCINONIDE GEL 0.05%	1	1	$10.78	$10.78	1	0.00%
SUBTOTAL	**8,486**	**5,583**	**$213,024.18**	**$25.10**	**1.52**	**17.50%**
TIER-1 TOTAL	**73,349**	**55,330**	**$1,204,968.29**	**$16.43**	**1.33**	**99.00%**
TIER-2 UTILIZATION						
LOW POTENCY PRODUCTS						
FLUOCINOLONE ACT OIL 0.01%	8	3	$279.34	$34.92	2.67	0.02%
FLUOCINOLONE ACT CRE 0.01%	1	1	$82.01	$82.01	1	0.01%
SUBTOTAL	**9**	**4**	**$361.35**	**$40.15**	**2.25**	**0.03%**
MEDIUM-HIGH TO HIGH POTENCY PRODUCTS						
BETAMETH VAL LOT 0.1%	47	35	$2,073.17	$44.11	1.34	0.17%
PREDNICARBATE OIN 0.1%	1	1	$21.91	$21.91	1	0.00%
SUBTOTAL	**48**	**36**	**$2,095.08**	**$43.65**	**1.33**	**0.17%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL LOT 0.05%	74	58	$5,237.50	$70.78	1.28	0.43%
AUG BETAMETH GEL 0.05%	25	16	$3,621.27	$144.85	1.56	0.30%
CLOBETASOL GEL 0.05%	1	1	$24.20	$24.20	1	0.00%
SUBTOTAL	**100**	**75**	**$8,882.97**	**$88.83**	**1.33**	**0.73%**
TIER-2 TOTAL	**157**	**115**	**$11,339.40**	**$72.23**	**1.37**	**0.93%**
TIER-3 UTILIZATION						
LOW POTENCY PRODUCTS						
DESONATE GEL 0.05%	1	1	$385.71	$385.71	1	0.03%
SUBTOTAL	**1**	**1**	**$385.71**	**$385.71**	**1**	**0.03%**
MEDIUM-HIGH TO HIGH POTENCY PRODUCTS						
DESOXIMETASONE OIN 0.05%	1	1	$211.78	$211.78	1	0.02%
SUBTOTAL	**1**	**1**	**$211.78**	**$211.78**	**1**	**0.02%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL SHA 0.05%	9	2	$179.35	$19.93	4.5	0.01%
SUBTOTAL	**9**	**2**	**$179.35**	**$19.93**	**4.5**	**0.01%**
TIER-3 TOTAL	**11**	**4**	**$776.84**	**$70.62**	**2.75**	**0.06%**
TOTAL	**73,517**	**48,090***	**$1,217,084.53**	**$16.56**	**1.53**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = acetonide; AUG = augmented; BETAMETH = betamethasone; CRE = cream; DIP = dipropionate; EMOL = emollient; EMU = emulsified; LOT = lotion; MICRO = micronized; OINT = ointment; POW = powder; SOL = solution; SHA = shampoo; VAL = valerate

[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 07/2023. Last accessed 07/17/2023.

Appendix F

Calendar Year 2022 Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Brixadi™ (Buprenorphine Extended-Release Injection), Nalocet® (Oxycodone/Acetaminophen Tablet), and Prolate™ (Oxycodone/Acetaminophen Tablet)

Oklahoma Health Care Authority
August 2023

Current Prior Authorization Criteria: Opioid Analgesics

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	oxycodone/APAP ER tab (Xartemis® XR)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	tramadol ER tab (Ultram ER®, Ryzolt®)	hydromorphone ER tab (Exalgo®)	
		methadone tab and oral soln (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
		morphine ER tab (Arymo™ ER)	
		morphine ER tab (MorphaBond™)	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
		oxycodone ER cap (Xtampza® ER)	
		oxycodone/ naltrexone ER cap (Troxyca® ER)	
		tapentadol ER tab (Nucynta® ER)	
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	oxymorphone IR tab (Opana®)	benzhydrocodone/ APAP tab (Apadaz®)	celecoxib 56mg/tramadol 44mg (Seglentis®)
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	tapentadol IR tab (Nucynta®)	dihydrocodeine/ APAP/caff cap (Trezix®)	levorphanol tab
codeine tab	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)	hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	tramadol 100mg tab
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	tramadol oral soln (Qdolo™)
dihydrocodeine/ ASA/caff cap (Synalgos-DC®)		oxycodone tab (Oxaydo®)	
hydrocodone/ APAP tab (Norco®)		oxycodone tab (RoxyBond™)	
hydrocodone/IBU tab 5/200mg, 7.5/200mg (Vicoprofen®, Ibudone®, Reprexain™)			
hydromorphone tab (Dilaudid®)			
morphine IR tab (MSIR®)			***Oncology Only:***
oxycodone/APAP tab (Percocet®)			fentanyl buccal film (Onsolis®)
oxycodone/ASA tab (Percodan®)			fentanyl buccal tab (Fentora®)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
oxycodone IR cap (Oxy IR®)			fentanyl nasal spray (Lazanda®)
oxycodone IR tab (Roxicodone®)			fentanyl SL spray (Subsys®)
tramadol 50mg tab (Ultram®)			fentanyl SL tab (Abstral®)
tramadol/APAP tab (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

*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).
APAP = acetaminophen; ASA = aspirin; caff = caffeine; cap = capsule; ER = extended-release; IBU = ibuprofen; IR = immediate-release; PA = prior authorization; SL = sublingual; soln = solution; tab = tablet

- Tier-1 products are covered with no prior authorization necessary.
- Members with an oncology-related diagnosis are exempt from the prior authorization process.
- Only 1 long-acting and 1 short-acting medication can be used concurrently.
- Short-acting, solid dosage formulation products are limited to a quantity of 4 units per day or a quantity of 120 units per 30 days.
- An age restriction applies on oral liquid narcotic analgesic products for all members older than 12 years of age and oral solid dosage forms for all members younger than 10 years of age.
- An age restriction applies for all tramadol and codeine products (both liquid and solid dosage formulations) for members younger than 12 years of age. Authorization consideration for members younger than 12 years of age requires a patient-specific, clinically significant reason for use of these products despite the medication being contraindicated for the member's age.

Opioid Analgesics Tier-2 Approval Criteria:

1. A documented 30-day trial/titration period with at least 1 Tier-1 medication within the last 90 days is required for a Tier-2 long-acting medication; and
2. A chronic pain diagnosis requiring time-released medication (for long-acting medications); or
3. A documented 30-day trial with at least 2 Tier-1 short-acting medications within the last 90 days is required for a Tier-2 short-acting medication; or
4. A documented allergy or contraindication(s) to all available Tier-1 medications.

Opioid Analgesics Tier-3 Approval Criteria:

1. A documented 30-day trial with at least 2 Tier-2 long-acting medications within the last 90 days is required for approval of a Tier-3 long-acting medication; or
2. A documented 30-day trial with at least 2 Tier-2 short-acting medications within the last 90 days is required for approval of a Tier-3 short-acting medication; or
3. A documented allergy or contraindication(s) to all available Tier-2 medications.

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Abstral®, Actiq®, Fentora®, Lazanda®, Onsolis®, and Subsys® are approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Hydrocodone/Acetaminophen (APAP) Unique Strengths Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) must be provided.
4. Levorphanol Tablet Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.
5. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
    b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
    c. A quantity limit of 2,400mL per 30 days will apply.
6. Seglentis® (Celecoxib 56mg/Tramadol 44mg) Approval Criteria:
    a. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and
    b. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and

c. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and
d. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
e. A quantity limit of 28 tablets for a 7-day supply will apply.

7. Tramadol 100mg Tablet Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided; and
   b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.
8. Xartemis® XR (Oxycodone/APAP ER Tablet) Approval Criteria:
   a. An acute pain condition requiring around-the-clock opioid treatment; and
   b. A patient-specific, clinically significant reason must be provided for all of the following:
      i. Why the member cannot use any other opioid medication for treatment of acute pain; and
      ii. Why the member requires a long-acting medication for an acute pain condition; and
      iii. Why the member cannot use Oxycontin® (oxycodone ER) and over-the-counter (OTC) APAP individual products in place of this combination product; and
   c. A quantity limit of 4 tablets per day will apply with a maximum approval duration of 10 days; and
   d. The member must not exceed 3,250mg of APAP per day from all sources; and
   e. Tier structure rules still apply.

Approval Criteria for Greater than 12 Claims Per Year of Hydrocodone Products:

1. Members may be approved for greater than 12 claims per year of hydrocodone products if the member has a pain contract with a single prescriber. A copy of the pain contract must be submitted with the prior authorization request. Requests outside of the plan outlined in the contract will not be approved.

2. Members with a current oncology-related diagnosis, hemophilia diagnosis, or sickle cell disease diagnosis do not require a pain contract for additional approvals.

Approval Criteria for Greater than the Opioid Morphine Milligram Equivalent (MME) Limit:

1. SoonerCare has an opioid MME limitation of 90 MME per day. Members with a daily MME >90 will require prior authorization. Each request for >90 MME per day will be evaluated on a case-by-case basis; and
2. Patient-specific, clinically significant reasoning for daily doses >90 MME must be provided; and
3. Reasoning why tapering to below the SoonerCare MME limit is not appropriate for the member must be provided; and
    a. A taper schedule, dates of an attempted taper with reason(s) for failure, or a patient-specific, clinically significant reason why a taper attempt is not appropriate for the member should be documented on the prior authorization request; and
4. For members unable to taper to below the SoonerCare MME limit or for whom tapering to below the SoonerCare MME limit is not appropriate, the prescriber must attest to all of the following:
    a. Other non-pharmacologic therapies have been ineffective (i.e., physical therapy); and
    b. Other non-opioid pharmacologic therapies have been ineffective [i.e., non-steroidal anti-inflammatory drugs (NSAIDs)]; and
    c. Risk factors for respiratory depression have been reviewed (i.e., concurrent benzodiazepine use, asthma); and
    d. Counseling on opioid overdose has been provided and a prescription for naloxone has been offered to the member; and
    e. Member has been evaluated for opioid use disorder; and
    f. Pain treatment plan has been established and includes realistic goals for pain and function; and
    g. Monitoring plan is established including random urine drug screens and review of the Oklahoma Prescription Monitoring Program (PMP); and
    h. Dose reduction has resulted in loss of pain control and/or function; and
    i. Further escalation in dose will not be allowed by provider. Authorization will only be granted at current MME; and
    j. The benefits of high-dose opioid therapy for both pain and function in the member outweigh the risks to member safety; and
5. Requests for members exceeding the 90 MME limit per day can be approved when there is documentation of pain associated with end-of-life care, palliative care, or hospice; and

6. Members with oncology, sickle cell disease, or hemophilia diagnoses are excluded from the MME limit.

Current Prior Authorization Criteria: MAT Medications

Suboxone® [Buprenorphine/Naloxone Sublingual (SL) Tablet and Film], Subutex® (Buprenorphine SL Tablet), and Zubsolv® (Buprenorphine/ Naloxone SL Tablet) Approval Criteria:

1. Generic buprenorphine/naloxone SL tablet is the preferred product. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why generic buprenorphine/naloxone SL tablets are not appropriate.
2. Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and
3. Buprenorphine products FDA approved for a diagnosis of opioid abuse/ dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and
4. Member must have an FDA approved diagnosis of opioid abuse/ dependence; and
5. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
6. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
7. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 60 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 30 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg and 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.

High-Dose Buprenorphine Medication-Assisted Treatment (MAT) Products Approval Criteria:

1. Each request for >16mg bioequivalent buprenorphine per day will be evaluated on a case-by-case basis; and
2. A taper schedule, dates of an attempted taper with reason(s) for failure, or a patient-specific, clinically significant reason why a taper attempt is not appropriate for the member should be documented on the prior authorization request; and
3. Opioid urine drug screens should be submitted with high-dose requests that plan to continue high-dose treatment longer than the duration of 1 month; and
    a. Urine drug screens must show the absence of opioid medications other than buprenorphine products for continued approval; or
    b. Prescriber must document a patient-specific reason the member should continue therapy, reason for opioid use, and document a plan for member to discontinue opioid use; and
4. Symptoms associated with withdrawal at lower doses or symptoms requiring high doses should be listed on the prior authorization request; and
5. Each approval will be for the duration of 1 month. If urine drug screen and other documentation are submitted indicating high-dose therapy is necessary, an approval can be granted for the duration of 3 months; and
6. Continued high-dose authorization after the 3-month approval will require a new (recent) urine drug screen.

Lucemyra® (Lofexidine) Approval Criteria:

1. An FDA approved indication for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults; and
2. Date of opioid discontinuation must be listed on the prior authorization request; and
3. Prescriber must verify member has been screened for hepatic and renal impairment and that dosing is appropriate for the member's degree of hepatic and renal function; and
4. Prescriber must verify member's vital signs have been monitored and that the member is capable of and has been instructed on self-monitoring for hypotension, orthostasis, bradycardia, and associated symptoms; and
5. Member must not have severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, or marked bradycardia; and
6. Member must not have congenital long QT syndrome; and

7. Prescriber must verify Lucemyra® will be used in conjunction with a comprehensive management program for the treatment of opioid use disorder; and
8. A patient-specific, clinically significant reason why clonidine tablets or patches cannot be used in place of Lucemyra® to mitigate opioid withdrawal symptoms must be provided; and
9. Approvals will be for a maximum duration of 14 days; and
10. A quantity limit of 12 tablets per day will apply.

Sublocade® [Buprenorphine Extended-Release (ER) Injection] Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder; and
2. Sublocade® must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and
3. Member must have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days; and
4. Concomitant treatment with opioids (including tramadol) will be denied; and
5. Sublocade® should only be prepared and administered by a health care provider; and
6. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual tablets) must be provided; and
7. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
8. A quantity limit of 1 dose (300mg or 100mg) per 28 days will apply.

Utilization of Opioid Analgesics and MAT Medications: Calendar Year 2022

Comparison of Calendar Years: Opioid Analgesics (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	78,664	232,421	$8,214,012.58	$35.34	$1.92	15,084,318	4,276,227
2022	104,602	305,697	$10,256,013.57	$33.55	$1.91	18,944,337	5,370,890
% Change	**33.0%**	**31.5%**	**24.9%**	**-5.1%**	**-0.5%**	**25.6%**	**25.6%**
Change	**25,938**	**73,276**	**$2,042,000.99**	**-$1.79**	**-$0.01**	**3,860,019**	**1,094,663**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: Butrans® and Belbuca® are included in the above opioid analgesics data as they are only indicated for chronic pain and are not indicated for the treatment of opioid dependence.

- Aggregate drug rebates collected during calendar year 2022 for opioid analgesics: $5,270,642.69.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

Comparison of Calendar Years: MAT Medications (Pharmacy Claims)

Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	5,795	36,239	$3,137,435.43	$86.58	$3.37	1,721,386	930,281
2022	8,435	57,470	$5,694,802.18	$99.09	$4.01	2,517,094	1,421,880
% Change	**45.6%**	**58.6%**	**81.5%**	**14.4%**	**19.0%**	**46.2%**	**52.8%**
Change	**2,640**	**21,231**	**$2,557,366.75**	**$12.51**	**$0.64**	**795,708**	**491,599**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Please note: The above MAT medications data does not include Butrans® or Belbuca® claims.

Comparison of Calendar Years: MAT Medications (Medical Claims)

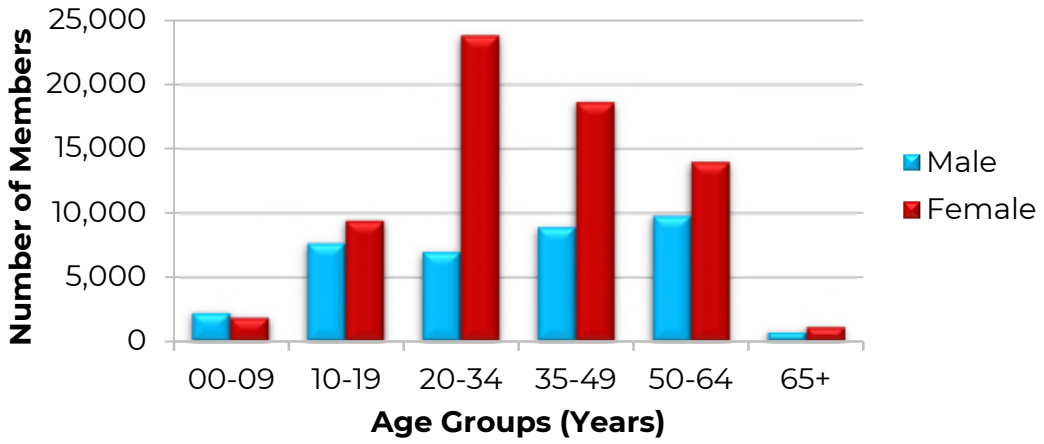
Calendar Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	2	3	$10.50	$3.50	1.5
2022	4	7	$8,318.58	$1,188.37	1.75
% Change	**100.00%**	**133.33%**	**79,124.57%**	**33,853.43%**	**16.67%**
Change	**2**	**4**	**$8,308.08**	**$1,184.87**	**0.25**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.

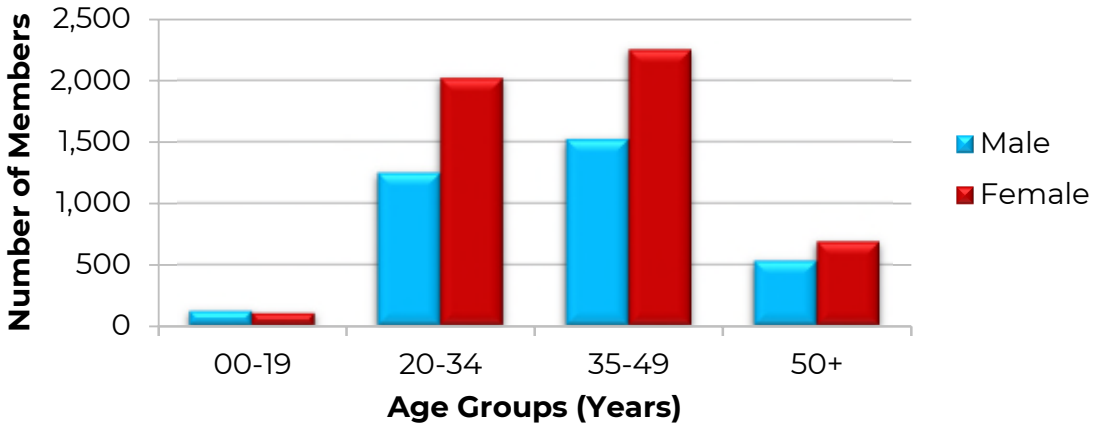
- Aggregate drug rebates collected during calendar year 2022 MAT medications: $1,106,833.20.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

[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.

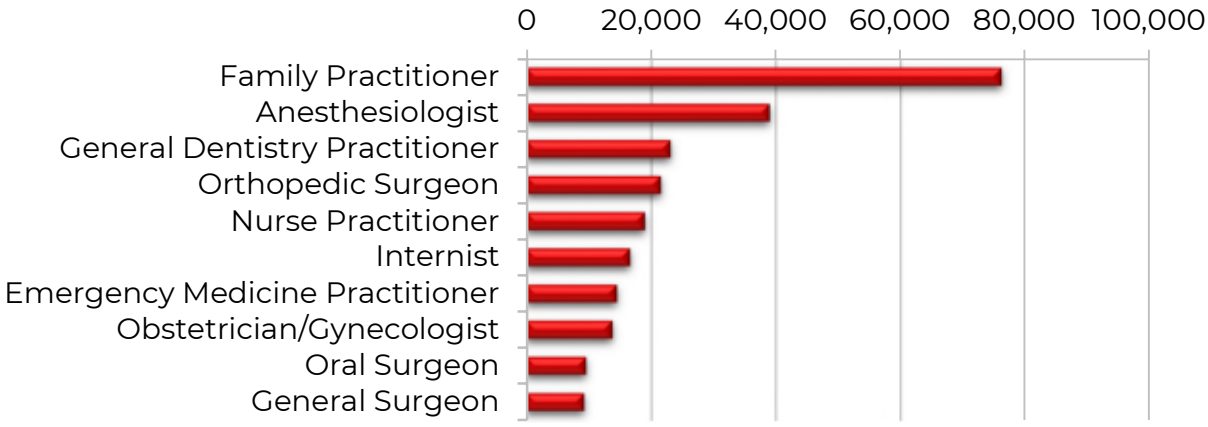
Demographics of Members Utilizing Opioid Analgesics



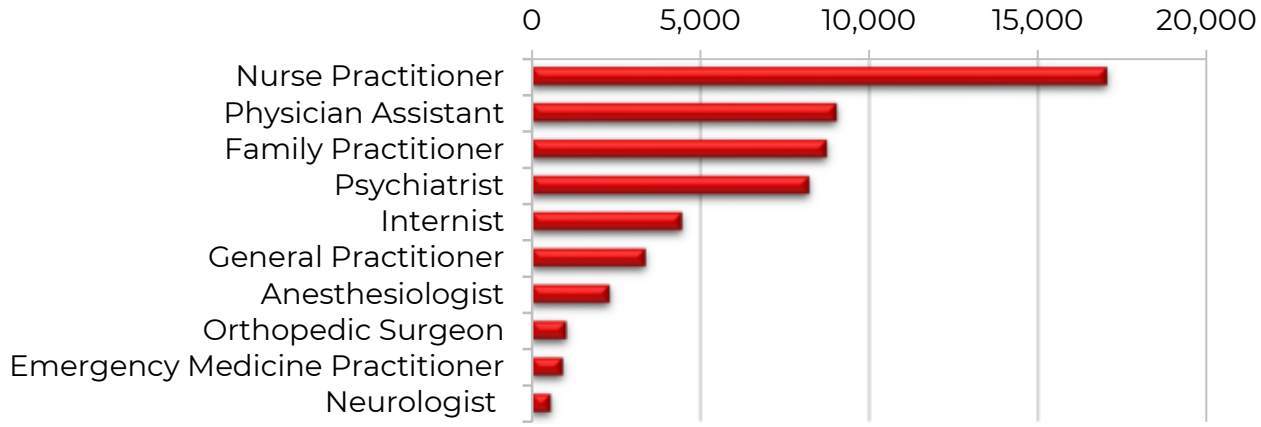
Demographics of Members Utilizing MAT Medications



Top Prescriber Specialties of Opioid Analgesics by Number of Claims



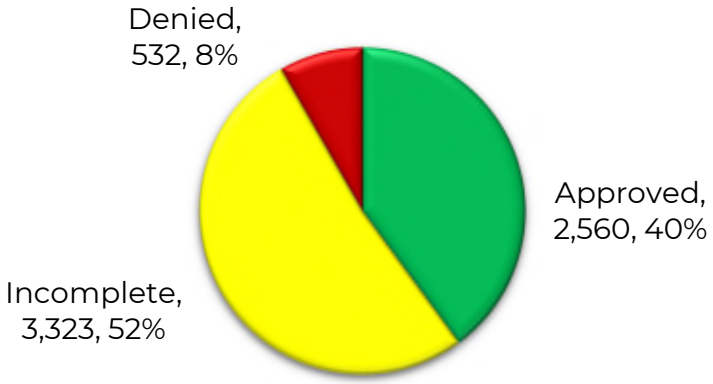
Top Prescriber Specialties of MAT Medications by Number of Claims



Prior Authorization of Opioid Analgesics and MAT Medications

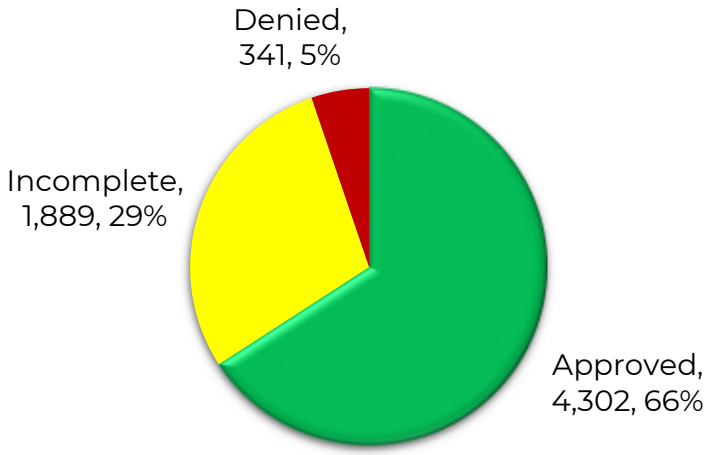
There were 6,415 prior authorization requests submitted for opioid analgesics during calendar year 2022. Computer edits are in place to detect diagnosis, quantity/day supply, and lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions: Opioid Analgesics



There were 6,532 prior authorizations submitted for MAT medications during calendar year 2022. Computer edits are in place to detect diagnosis, concomitant opioid claims, and quantity/day supply and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for calendar year 2022.

Status of Petitions: MAT Medications



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

Anticipated Patent Expiration(s):

- Oxaydo® [oxycodone immediate-release (IR) tablet]: March 2025
- Nucynta® (tapentadol IR tablet): June 2025
- Fentora® (fentanyl buccal tablet): June 2028
- MorphaBond™ [morphine extended-release (ER) tablet]: August 2028
- Nucynta® ER (tapentadol ER tablet): September 2028
- Subsys® [fentanyl sublingual (SL) spray]: April 2030
- Apadaz® [benzhydrocodone/acetaminophen (APAP) IR tablet]: February 2031
- Seglentis (celecoxib/tramadol tablet): June 2031
- Hysingla® ER (hydrocodone ER tablet): December 2031
- Lazanda® (fentanyl nasal spray): January 2032
- Brixadi™ (buprenorphine ER injection): July 2032
- Zubsolv® (buprenorphine/naloxone SL tablet): September 2032
- Belbuca® (buprenorphine ER buccal film): December 2032
- Zohydro® ER (hydrocodone ER capsule): September 2034
- Sublocade® (buprenorphine ER injection): November 2035
- Xtampza® ER (oxycodone ER capsule): September 2036
- Qdolo™ (tramadol oral solution): September 2040

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

- **May 2023:** The FDA approved Brixadi™ (buprenorphine ER injection) for the treatment of moderate-to-severe opioid use disorder (OUD) in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. Brixadi™ is an ER formulation of buprenorphine given weekly or monthly via subcutaneous (sub-Q) injection. Brixadi™

will be available through a risk evaluation and mitigation strategy (REMS) program to be administered by a health care provider in a health care setting.

Guideline Update(s):

- **November 2022:** The Centers for Disease Control and Prevention (CDC) published the *CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States*, updating the previous guidelines from 2016. These guidelines are intended to help clinicians decide when to initiate opioids, which opioids to select, how long opioids should be used, when to follow up, and risk and harm assessment. These guidelines do not apply to opioid therapy for pain due to cancer, sickle cell disease, or palliative or end-of-life care. Some notable changes include:
  - The scope of the guidelines has been expanded to include opioids used to treat acute pain (defined as a duration of <1 month), subacute pain (defined as a duration of 1-3 months), as well as chronic pain (defined as a duration >3 months). The previous guidelines were limited to recommendations for chronic pain.
  - Updated recommendations for determining opioid dosages no longer reference specific morphine milligram equivalent (MME) thresholds, and the recommendation to avoid dosages ≥90 MME has been removed. Opioids should still be prescribed at the lowest effective dosage, and clinicians should avoid increasing the dosage above levels likely to yield diminishing returns in benefits relative to risks to patients.
  - Clinicians should continue to consider a patient's total MME/day to help evaluate overdose risk; however, buprenorphine should not be counted in the MME/day calculations due to its partial agonist properties at opioid receptors, conferring a ceiling effect on respiratory depression.
  - For patients already receiving opioid therapy, if the benefits do not outweigh the risks of continued opioid use, the recommendations regarding tapering and discontinuing opioids have been expanded to clarify that opioid therapy should not be discontinued abruptly or tapered rapidly unless there are indications of a life-threatening issue such as warning signs of impending overdose. Clinicians should work with patients to gradually reduce dosages, if warranted, prior to discontinuation.

News:

- **January 2023:** The federal requirement for prescribers to qualify for a waiver and be assigned a Drug Enforcement Administration (DEA) X number to prescribe medications, such as buprenorphine, for the treatment of opioid use disorder (OUD) has been removed. Section 1262

of the 2023 Consolidated Appropriations Act, also known as the Omnibus Bill, allows all providers with a current DEA registration to prescribe Schedule III medications to now prescribe buprenorphine for the treatment of OUD if permitted by state law.

- **April 2023:** Forte BioPharma, the current manufacturer of Nalocet® and Prolate® (oxycodone/APAP) products, began participating in the federal Medicaid Drug Rebate Program (MDRP) in April 2023.
- **April 2023:** The FDA issued a Drug Safety Communication regarding several updates to be made to the *Prescribing Information* for opioid pain medications. The communication noted that there has been a decrease in the number of dispensed prescriptions for opioids, however overdose deaths involving prescription opioids have remained steady. The *Prescribing Information* for all opioid products, including IR, ER, and long-acting (LA) formulations, will be updated to state that the risk of overdose increases as the dose increases. Additionally, IR opioid formulations will include a statement that these products should not be used for an extended period unless the pain remains severe enough to require them and alternative treatments continue to be inadequate. The approved use for ER/LA opioid products will be updated to recommend they be reserved for severe and persistent pain that requires an extended treatment period with a daily opioid and for which alternative treatment options are inadequate. A new warning regarding opioid-induced hyperalgesia (OIH) will also be added for all opioid products.

Brixadi™ (Buprenorphine ER Injection) Product Summary[7]

Therapeutic Class: Partial opioid agonist

Indication(s): Treatment of moderate-to-severe OUD in patients who have started treatment with a transmucosal buprenorphine product or who are already being treated with buprenorphine

- Brixadi™ should be used as part of a complete treatment plan that includes counseling and psychosocial support.

How Supplied: Pre-filled single-dose syringe in the following strengths:

- Weekly Injections: 8mg/0.16mL, 16mg/0.32mL, 24mg/0.48mL, and 32mg/0.64mL
- Monthly Injections: 64mg/0.18mL, 96mg/0.27mL, and 128mg/0.36mL

Dosing and Administration:

- Should be administered as a single sub-Q injection into the buttock, thigh, abdomen, or upper arm
- Should be administered in a health care setting by a health care professional

- Brixadi™ (weekly) should be administered in 7-day intervals.
- Brixadi™ (monthly) should be administered in 28-day intervals.
- Refer to package labeling for specific dosing recommendations for patients not currently receiving buprenorphine treatment, patients switching from transmucosal buprenorphine-containing products, and patients transitioning between Brixadi™ weekly and Brixadi™ monthly.

Cost Comparison:

Product	Cost Per Unit	Cost Per 28 Days*
Brixadi™ (buprenorphine ER inj) 128mg/0.36mL	**$4,430.56**	**$1,595.00**
Brixadi™ (buprenorphine ER inj) 32mg/0.64mL	**$648.44**	**$1,660.01**
Sublocade® (buprenorphine ER inj) 300mg/1.5mL	$1,280.33	$1,920.50
buprenorphine/naloxone SL tablet 8/2mg (generic)	$1.04	$62.40

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 28 days based on 1 injection for Brixadi™ 128mg and Sublocade® 300mg, 4 weekly injections for Brixadi™ 32mg, or 2 tablets per day for buprenorphine/naloxone SL tablet
Unit = mL or tablet
ER = extended-release; inj = injection; SL = sublingual

Nalocet® and Prolate® (Oxycodone/APAP) Product Summary[8,9,10]

Therapeutic Class: Opioid agonist (oxycodone); analgesic/antipyretic (APAP)

Indication(s): Management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate

How Supplied:
- Nalocet®: Oxycodone/APAP 2.5mg/300mg oral tablets
- Prolate®: Oxycodone/APAP 10mg/300mg/5mL oral solution and 5mg/300mg, 7.5mg/300mg, 10mg/300mg tablets

Dosing and Administration:
- Usual adult dose:
  - Nalocet®: 1 to 2 tablets every 6 hours
  - Prolate® Tablet: 1 tablet every 6 hours
  - Prolate® Oral Solution: 5mL every 6 hours
  - Total daily dose of APAP should not exceed 4g

Cost Comparison:

Product	Cost Per Unit	Cost Per Day*
Nalocet® (oxycodone/APAP) 2.5/300mg tablet	**$31.73**	**$126.92**
Prolate® (oxycodone/APAP) 5/300mg tablet	**$27.76**	**$111.04**
Prolate® (oxycodone/APAP) 10/300mg/5mL oral solution	**$10.94**	**$218.80**

oxycodone/APAP 5/325mg tablet (generic)	$0.08	$0.32

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 day based on 1 tablet or 5mL every 6 hours.
Unit = mL or tablet
APAP = acetaminophen

Recommendations

The College of Pharmacy recommends the following changes to the Opioid Analgesics Product Based Prior Authorization (PBPA) category (changes noted in red in the following Tier chart and approval criteria):

1. Adding Nalocet® and Prolate® to Tier-3 of the Short-Acting Opioid Analgesics category based on net costs; and
2. Moving Nucynta® and Nucynta® ER 50mg to Tier-1 based on net costs; and
3. Moving Nucynta® ER 100mg, 150mg, 200mg, and 250mg to Tier-2 based on net costs and morphine milligram equivalent (MME); and
4. Removing Arymo™ ER, Lazanda®, MorphaBond™, Subsys®, Synalgos-DC®, Troxyca® ER, and Xartemis® XR due to product discontinuations.

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
Long-Acting			
buprenorphine patch (Butrans®) – **Brand Preferred**	fentanyl patch (Duragesic®)	buprenorphine ER buccal film (Belbuca®)	~~**oxycodone/APAP ER tab (Xartemis® XR)**~~
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tapentadol ER tab 50mg (Nucynta® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER)	tramadol ER cap (ConZip®)
	tapentadol ER tab 100mg, 150mg, 200mg, 250mg (Nucynta® ER)	hydromorphone ER tab (Exalgo®)	
	tramadol ER tab (Ultram ER®, Ryzolt®)	methadone tab and oral soln (Dolophine®)	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
		morphine ER cap (Avinza®, Kadian®)	
		~~**morphine ER tab (Arymo™ ER)**~~	
		~~**morphine ER tab (MorphaBond™)**~~	
		oxycodone ER cap (Xtampza® ER)	
		~~**oxycodone/ naltrexone ER cap (Troxyca® ER)**~~	
		~~**tapentadol ER tab (Nucynta® ER)**~~	
Short-Acting			
APAP/butalbital/ caff/codeine cap (Fioricet® with Codeine)	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)	benzhydrocodone/ APAP tab (Apadaz®)	levorphanol tab
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)	dihydrocodeine/ APAP/caff cap (Trezix®)	tramadol 100mg tab
codeine tab	~~**tapentadol IR tab (Nucynta®)**~~	hydrocodone/ APAP oral soln (Zamicet®, Liquicet®)	tramadol oral soln (Qdolo™)
codeine/APAP tab (Tylenol® with Codeine)		hydrocodone/ APAP tab (Xodol®)	celecoxib 56mg/tramadol 44mg (Seglentis®)
~~**dihydrocodeine/ ASA/caff cap (Synalgos-DC®)**~~		**oxycodone/APAP tab (Nalocet®)**	
hydrocodone/ APAP tab (Norco®)		**oxycodone/APAP tab and oral soln (Prolate®)**	

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®, Ibudone®, Reprexain™)		oxycodone tab (Oxaydo®)	
hydromorphone tab (Dilaudid®)		oxycodone tab (RoxyBond™)	
morphine IR tab (MSIR®)			
oxycodone/APAP tab (Percocet®)			***Oncology Only:***
oxycodone/ASA tab (Percodan®)			fentanyl buccal film (Onsolis®)
oxycodone IR cap (Oxy IR®)			fentanyl buccal tab (Fentora®)
oxycodone IR tab (Roxicodone®)			~~**fentanyl nasal spray (Lazanda®)**~~
tapentadol IR (Nucynta®)			~~**fentanyl SL spray (Subsys®)**~~
tramadol 50mg tab (Ultram®)			fentanyl SL tab (Abstral®)
tramadol/APAP (Ultracet®)			fentanyl transmucosal lozenge (Actiq®)

*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).
APAP = acetaminophen; ASA = aspirin; caff = caffeine; cap = capsule; ER = extended-release; IBU = ibuprofen; IR = immediate-release; PA = prior authorization; SL = sublingual; soln = solution; tab = tablet

Opioid Analgesics Special Prior Authorization (PA) Approval Criteria:

1. Abstral®, Actiq®, Fentora®, ~~Lazanda®,~~ and Onsolis®~~, and Subsys®~~ are approved for oncology-related diagnoses only.
2. ConZip® [Tramadol Extended-Release (ER) Capsule] Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use the ER tablet formulation must be provided. Tier structure rules apply.
3. Hydrocodone/Acetaminophen (APAP) Unique Strengths Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) must be provided.
4. Levorphanol Tablet Approval Criteria:

a. A patient-specific, clinically significant reason why the member cannot use alternative treatment options for pain (e.g., non-opioid analgesics, lower-tiered opioid analgesics) must be provided.

5. Qdolo™ (Tramadol 5mg/mL Oral Solution) Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use tramadol 50mg tablets, even when tablets are crushed, must be provided; and
   b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the prescriber must provide patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
   c. A quantity limit of 2,400mL per 30 days will apply.
6. Seglentis® (Celecoxib 56mg/Tramadol 44mg) Approval Criteria:
   a. An FDA approved indication of acute pain in adults that is severe enough to require an opioid analgesic; and
   b. A patient-specific, clinically significant reason why the member cannot use any other opioid medication for treatment of acute pain must be provided; and
   c. A patient-specific, clinically significant reason why the member cannot use celecoxib and tramadol individual products in place of Seglentis® must be provided; and
   d. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age; and
   e. A quantity limit of 28 tablets for a 7-day supply will apply.
7. Tramadol 100mg Tablet Approval Criteria:
   a. A patient-specific, clinically significant reason why the member cannot use 2 tramadol 50mg tablets to achieve a 100mg dose must be provided; and
   b. An age restriction will apply for members younger than 12 years of age. For members younger than 12 years of age, the provider must submit patient-specific, clinically significant information supporting the use of tramadol despite the medication being contraindicated for the member's age.

~~8. Xartemis® XR (Oxycodone/APAP ER Tablet) Approval Criteria:~~
   ~~a. An acute pain condition requiring around-the-clock opioid treatment; and~~
   ~~b. A patient-specific, clinically significant reason must be provided for all of the following:~~
      ~~i. Why the member cannot use any other opioid medication for treatment of acute pain; and~~

~~ii. Why the member requires a long-acting medication for an acute pain condition; and~~

~~iii. Why the member cannot use Oxycontin® (oxycodone ER) and over-the-counter (OTC) APAP individual products in place of this combination product; and~~

~~c. A quantity limit of 4 tablets per day will apply with a maximum approval duration of 10 days; and~~

~~d. The member must not exceed 3,250mg of APAP per day from all sources; and~~

~~e. Tier structure rules still apply.~~

The College of Pharmacy also recommends the following changes to the MAT medications approval criteria (changes noted in red in the following criteria):

1. The prior authorization of Brixadi™ with criteria similar to Sublocade®; and
2. Updating the approval criteria for Sublocade®, Suboxone®, Subutex®, and Zubsolv® to remove the DEA X requirement based on the 2023 Consolidated Appropriations Act.

Brixadi™ [Buprenorphine Extended-Release (ER) Injection] and Sublocade® (Buprenorphine ER Injection) Approval Criteria:

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder; and
2. ~~Sublocade® must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and~~
3. For Sublocade®, member must have initiated treatment with a transmucosal buprenorphine-containing product for a minimum of 7 days; ~~and~~ or
4. For Brixadi™, member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
5. Concomitant treatment with opioids (including tramadol) will be denied; and
6. ~~Sublocade®~~ Medication should only be prepared and administered by a health care provider; and
7. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual tablets) must be provided; and
8. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and

9. A quantity limit of 1 monthly dose ~~(300mg or 100mg)~~ per 28 days or 4 weekly doses per 28 days will apply.

Suboxone® [Buprenorphine/Naloxone Sublingual (SL) Tablet and Film], Subutex® (Buprenorphine SL Tablet), and Zubsolv® (Buprenorphine/ Naloxone SL Tablet) Approval Criteria:

1. Generic buprenorphine/naloxone SL tablet is the preferred product. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why generic buprenorphine/naloxone SL tablets are not appropriate.
2. Subutex® (buprenorphine) 2mg and 8mg SL tablets will only be approved if the member is pregnant or has a documented serious allergy or adverse reaction to naloxone; and
3. ~~Buprenorphine products FDA approved for a diagnosis of opioid abuse/ dependence must be prescribed by a licensed practitioner who qualifies for a waiver under the Drug Addiction Treatment Act (DATA) and has notified the Center for Substance Abuse Treatment of the intention to treat addiction patients and has been assigned a Drug Enforcement Agency (DEA) X number; and~~
4. Member must have an FDA approved diagnosis of opioid abuse/ dependence; and
5. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
6. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
7. The following limitations will apply:
    a. Suboxone® 2mg/0.5mg and 4mg/1mg SL tablets and films: A quantity limit of 90 SL units per 30 days will apply.
    b. Suboxone® 8mg/2mg SL tablets and films: A quantity limit of 60 SL units per 30 days will apply.
    c. Suboxone® 12mg/3mg SL films: A quantity limit of 30 SL films per 30 days will apply.
    d. Subutex® 2mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    e. Subutex® 8mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    f. Zubsolv® 0.7mg/0.18mg, 1.4mg/0.36mg, and 2.9mg/0.71mg SL tablets: A quantity limit of 90 SL tablets per 30 days will apply.
    g. Zubsolv® 5.7mg/1.4mg SL tablets: A quantity limit of 60 SL tablets per 30 days will apply.
    h. Zubsolv® 8.6mg/2.1mg and 11.4mg/2.9mg SL tablets: A quantity limit of 30 SL tablets per 30 days will apply.

Utilization Details of Opioid Analgesics: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SHORT-ACTING OPIOID ANALGESICS					
IMMEDIATE-RELEASE HYDROCODONE PRODUCTS					
HYDROCOD/APAP TAB 5-325MG	51,415	36,229	$638,408.13	$12.42	1.42
HYDROCOD/APAP TAB 10-325MG	49,619	8,996	$1,002,730.97	$20.21	5.52
HYDROCOD/APAP TAB 7.5-325MG	47,426	23,468	$718,119.04	$15.14	2.02
HYDROCOD/APAP SOL 7.5-325MG	4,647	4,227	$100,993.14	$21.73	1.1
HYDROCOD/IBU TAB 7.5-200MG	250	63	$5,811.09	$23.24	3.97
HYDROCOD/IBU TAB 10-200MG	73	11	$23,579.33	$323.00	6.64
HYDROCOD/IBU TAB 5-200MG	22	12	$3,380.17	$153.64	1.83
SUBTOTAL	**153,452**	**73,006**	**$2,493,021.87**	**$16.25**	**2.1**
IMMEDIATE-RELEASE OXYCODONE PRODUCTS					
OXYCOD/APAP TAB 10-325MG	21,163	4,014	$512,140.82	$24.20	5.27
OXYCOD/APAP TAB 5-325MG	18,929	13,059	$241,704.40	$12.77	1.45
OXYCOD/APAP TAB 7.5-325MG	11,318	4,629	$190,214.36	$16.81	2.45
OXYCODONE TAB 5MG	8,441	6,248	$99,924.48	$11.84	1.35
OXYCODONE TAB 10MG	6,086	1,433	$117,041.67	$19.23	4.25
OXYCODONE TAB 15MG	5,798	940	$120,452.47	$20.77	6.17
OXYCODONE SOL 5MG/5ML	1,650	1,476	$28,282.92	$17.14	1.12
OXYCODONE TAB 20MG	1,607	277	$43,327.19	$26.96	5.8
OXYCODONE TAB 30MG	570	114	$17,281.66	$30.32	5
OXYCODONE CAP HCL 5MG	122	107	$2,443.22	$20.03	1.14
OXYCODONE CAP 5MG	115	97	$2,200.45	$19.13	1.19
ENDOCET TAB 10-325MG	59	16	$1,438.39	$24.38	3.69
ENDOCET TAB 7.5-325MG	30	8	$625.47	$20.85	3.75
ENDOCET TAB 5-325MG	20	14	$255.52	$12.78	1.43
OXYCODONE CONC 100MG/5ML	15	11	$1,407.45	$93.83	1.36
OXYCOD/APAP TAB 2.5-325MG	10	8	$264.48	$26.45	1.25
OXYCOD/APAP SOL 5-325MG/5ML	2	2	$203.73	$101.87	1
SUBTOTAL	**75,935**	**32,453**	**$1,379,208.68**	**$18.16**	**2.34**
IMMEDIATE-RELEASE TRAMADOL PRODUCTS					
TRAMADOL HCL TAB 50MG	35,251	13,901	$382,396.06	$10.85	2.54
TRAMADOL/APAP TAB 37.5-325MG	304	227	$3,924.05	$12.91	1.34
TRAMADOL HCL TAB 100MG	1	1	$85.32	$85.32	1
SUBTOTAL	**35,556**	**14,129**	**$386,405.43**	**$10.87**	**2.52**
CODEINE PRODUCTS					
APAP/CODEINE TAB 300-30MG	12,536	7,932	$155,364.47	$12.39	1.58
APAP/CODEINE TAB 300-60MG	7,152	2,019	$169,010.87	$23.63	3.54
BUT/APAP/CAF/COD CAP 50/325/40/30MG	333	98	$17,297.80	$51.95	3.4
APAP/CODEINE TAB 300-15MG	212	159	$2,649.68	$12.50	1.33
BUT/ASA/CAF/COD CAP 50/325/40/30MG	101	27	$8,479.84	$83.96	3.74

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ASCOMP/COD CAP 30MG	49	11	$5,502.52	$112.30	4.45
CODEINE SULF TAB 30MG	34	9	$1,150.55	$33.84	3.78
CODEINE SULF TAB 60MG	20	4	$2,011.68	$100.58	5
APAP/CODEINE SOL 120-12MG/5ML	18	4	$369.54	$20.53	4.5
BUT/ASA/CAF/COD CAP 50/325/40/30MG	4	3	$231.67	$57.92	1.33
CODEINE SULF TAB 15MG	1	1	$26.79	$26.79	1
SUBTOTAL	**20,460**	**10,267**	**$362,095.41**	**$17.70**	**1.99**
IMMEDIATE-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG	1,304	336	$37,875.87	$29.05	3.88
MORPHINE SULF TAB 30MG	322	74	$14,506.21	$45.05	4.35
MORPHINE SULF SOL 100MG/5ML	79	53	$2,361.09	$29.89	1.49
MORPHINE SULF SOL 10MG/5ML	52	34	$1,152.48	$22.16	1.53
MORPHINE SULF SOL 20MG/5ML	24	16	$686.35	$28.60	1.5
SUBTOTAL	**1,781**	**513**	**$56,582.00**	**$31.77**	**3.47**
IMMEDIATE-RELEASE HYDROMORPHONE PRODUCTS					
HYDROMORPHONE TAB 4MG	741	169	$12,328.78	$16.64	4.38
HYDROMORPHONE TAB 2MG	608	298	$7,917.32	$13.02	2.04
HYDROMORPHONE TAB 8MG	87	28	$2,975.16	$34.20	3.11
HYDROMORPHONE LIQ 1MG/ML	17	4	$5,126.11	$301.54	4.25
HYDROMORPHONE POW	4	3	$859.72	$214.93	1.33
HYDROMORPHONE INJ 2MG/ML	1	1	$106.45	$106.45	1
HYDROMORPHONE INJ 1MG/ML	1	1	$47.79	$47.79	1
SUBTOTAL	**1,459**	**504**	**$29,361.33**	**$20.12**	**2.89**
MEPERIDINE PRODUCTS					
MEPERIDINE SOL 50MG/5ML	195	149	$1,464.55	$7.51	1.31
MEPERIDINE TAB 50MG	8	7	$178.56	$22.32	1.14
SUBTOTAL	**203**	**156**	**$1,643.11**	**$8.09**	**1.3**
PENTAZOCINE PRODUCTS					
PENTAZ/NALOX TAB 50-0.5MG	101	30	$14,169.26	$140.29	3.37
SUBTOTAL	**101**	**30**	**$14,169.26**	**$140.29**	**3.37**
IMMEDIATE-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG	69	9	$3,112.70	$45.11	7.67
OXYMORPHONE TAB 5MG	16	2	$456.51	$28.53	8
SUBTOTAL	**85**	**11**	**$3,569.21**	**$41.99**	**7.73**
IMMEDIATE-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA TAB 50MG	14	4	$10,823.94	$773.14	3.5
NUCYNTA TAB 75MG	2	1	$1,212.20	$606.10	2
SUBTOTAL	**16**	**5**	**$12,036.14**	**$752.26**	**3.2**
SHORT-ACTING SUBTOTAL	**289,048**	**131,074**	**$4,738,092.44**	**$16.39**	**2.21**
LONG-ACTING OPIOID ANALGESICS					
BUPRENORPHINE PAIN PRODUCTS					
BUTRANS DIS 20MCG/HR	1,414	255	$1,231,653.85	$871.04	5.55
BUTRANS DIS 10MCG/HR	1,282	567	$638,104.03	$497.74	2.26

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUTRANS DIS 15MCG/HR	1,010	331	$715,438.35	$708.35	3.05
BUTRANS DIS 5MCG/HR	512	292	$168,902.49	$329.89	1.75
BUTRANS DIS 7.5MCG/HR	274	138	$126,912.79	$463.19	1.99
BELBUCA MIS 450MCG	164	40	$128,928.39	$786.15	4.1
BELBUCA MIS 900MCG	157	23	$143,905.18	$916.59	6.83
BELBUCA MIS 300MCG	141	46	$80,415.00	$570.32	3.07
BELBUCA MIS 600MCG	101	21	$80,401.13	$796.05	4.81
BELBUCA MIS 150MCG	99	44	$37,053.18	$374.27	2.25
BELBUCA MIS 750MCG	95	15	$83,899.31	$883.15	6.33
BELBUCA MIS 75MCG	22	15	$7,721.94	$351.00	1.47
BUPRENORPHINE DIS 20MCG/HR	3	2	$1,226.38	$408.79	1.5
SUBTOTAL	**5,274**	**1,789**	**$3,444,562.02**	**$653.12**	**2.95**
EXTENDED-RELEASE MORPHINE PRODUCTS					
MORPHINE SULF TAB 15MG ER	2,769	524	$55,308.80	$19.97	5.28
MORPHINE SULF TAB 30MG ER	1,487	285	$40,636.18	$27.33	5.22
MORPHINE SULF TAB 60MG ER	248	54	$10,397.23	$41.92	4.59
MORPHINE SULF CAP 10MG ER	56	12	$5,623.54	$100.42	4.67
MORPHINE SULF TAB 100MG ER	35	7	$2,329.95	$66.57	5
MORPHINE SULF CAP 20MG ER	23	7	$3,549.39	$154.32	3.29
MORPHINE SULF CAP 30MG ER	22	4	$3,756.56	$170.75	5.5
MORPHINE SULF CAP 50MG ER	18	4	$1,752.77	$97.38	4.5
MORPHINE SULF CAP 100MG ER	1	1	$250.13	$250.13	1
SUBTOTAL	**4,659**	**898**	**$123,604.55**	**$26.53**	**5.19**
EXTENDED-RELEASE OXYCODONE PRODUCTS					
OXYCONTIN TAB 10MG ER	1,671	319	$371,527.98	$222.34	5.24
OXYCONTIN TAB 20MG ER	718	148	$322,688.98	$449.43	4.85
OXYCONTIN TAB 15MG ER	575	110	$206,530.26	$359.18	5.23
OXYCONTIN TAB 30MG ER	330	56	$223,591.25	$677.55	5.89
OXYCONTIN TAB 40MG ER	176	36	$147,898.70	$840.33	4.89
OXYCONTIN TAB 60MG ER	88	18	$116,747.75	$1,326.68	4.89
XTAMPZA ER CAP 9MG	87	16	$28,637.28	$329.16	5.44
OXYCONTIN TAB 80MG ER	60	8	$93,101.85	$1,551.70	7.5
XTAMPZA ER CAP 13.5MG	47	8	$20,470.39	$435.54	5.88
XTAMPZA ER CAP 18MG	42	8	$21,105.26	$502.51	5.25
XTAMPZA ER CAP 36MG	42	5	$61,315.33	$1,459.89	8.4
XTAMPZA ER CAP 27MG	17	3	$14,339.21	$843.48	5.67
SUBTOTAL	**3,853**	**735**	**$1,627,954.24**	**$422.52**	**5.24**
EXTENDED-RELEASE TRAMADOL PRODUCTS					
TRAMADOL TAB 200MG ER 24HR	548	113	$27,887.93	$50.89	4.85
TRAMADOL TAB 100MG ER 24HR	459	125	$16,998.34	$37.03	3.67
TRAMADOL TAB 300MG ER 24HR	133	26	$8,014.99	$60.26	5.12
TRAMADOL TAB 200MG BIPHASIC	22	5	$1,794.28	$81.56	4.4
TRAMADOL TAB 100MG BIPHASIC	16	4	$939.94	$58.75	4

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TRAMADOL TAB 300MG BIPHASIC	4	2	$467.70	$116.93	2
TRAMADOL HCL CAP ER 200MG	2	1	$620.58	$310.29	2
TRAMADOL HCL CAP ER 300MG	1	1	$399.84	$399.84	1
SUBTOTAL	**1,185**	**277**	**$57,123.60**	**$48.21**	**4.28**
EXTENDED-RELEASE FENTANYL PRODUCTS					
FENTANYL DIS 25MCG/HR	425	125	$16,371.43	$38.52	3.4
FENTANYL DIS 12MCG/HR	237	57	$18,250.82	$77.01	4.16
FENTANYL DIS 50MCG/HR	182	61	$10,322.94	$56.72	2.98
FENTANYL DIS 75MCG/HR	79	22	$6,907.97	$87.44	3.59
FENTANYL DIS 37.5MCG/HR	63	9	$26,744.00	$424.51	7
FENTANYL DIS 100MCG/HR	62	19	$5,613.68	$90.54	3.26
SUBTOTAL	**1,048**	**293**	**$84,210.84**	**$80.35**	**3.58**
METHADONE PRODUCTS					
METHADONE TAB 10MG	173	25	$3,267.41	$18.89	6.92
METHADONE TAB 5MG	86	17	$1,463.37	$17.02	5.06
METHADONE SOL 10MG/5ML	51	28	$823.74	$16.15	1.82
SUBTOTAL	**310**	**70**	**$5,554.52**	**$17.92**	**4.43**
EXTENDED-RELEASE HYDROCODONE PRODUCTS					
HYSINGLA ER TAB 40MG	85	11	$52,829.34	$621.52	7.73
HYSINGLA ER TAB 30MG	66	8	$29,996.46	$454.49	8.25
HYSINGLA ER TAB 20MG	62	7	$19,448.32	$313.68	8.86
HYSINGLA ER TAB 60MG	40	4	$34,484.50	$862.11	10
HYSINGLA ER TAB 80MG	13	1	$15,070.77	$1,159.29	13
HYDROCODONE CAP 10MG ER	9	1	$3,472.59	$385.84	9
HYDROCODONE TAB 30MG ER	5	2	$1,755.10	$351.02	2.5
HYDROCODONE TAB 20MG ER	3	2	$729.84	$243.28	1.5
HYDROCODONE CAP 15MG ER	3	2	$1,074.34	$358.11	1.5
HYDROCODONE CAP 30MG ER	1	1	$262.80	$262.80	1
HYDROCODONE TAB 40MG ER	1	1	$472.17	$472.17	1
SUBTOTAL	**288**	**40**	**$159,596.23**	**$554.15**	**7.2**
EXTENDED-RELEASE OXYMORPHONE PRODUCTS					
OXYMORPHONE TAB 10MG ER	15	1	$4,804.37	$320.29	15
OXYMORPHONE TAB 20MG ER	13	1	$8,270.40	$636.18	13
SUBTOTAL	**28**	**2**	**$13,074.77**	**$466.96**	**14**
EXTENDED-RELEASE TAPENTADOL PRODUCTS					
NUCYNTA ER TAB 50MG	4	2	$2,240.36	$560.09	2
SUBTOTAL	**4**	**2**	**$2,240.36**	**$560.09**	**2**
LONG-ACTING SUBTOTAL	**16,649**	**4,106**	**$5,517,921.13**	**$331.43**	**4.05**
OPIOID TOTAL	**305,697**	**104,602**	**$10,256,013.57**	**$33.55**	**2.92**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
APAP = acetaminophen; ASA = aspirin; BUT = butalbital; CAF = caffeine; CAP = capsule; COD = codeine; CONC = concentrate; DIS = patch; ER = extended-release; HCL = hydrochloride; HYDROCOD = hydrocodone; IBU = ibuprofen; INJ = injection; LIQ = liquid; MIS = film; NALOX = naloxone; OXYCOD = oxycodone; PENTAZ = pentazocine; POW = powder; SOL = solution; SULF = sulfate; TAB = tablet

Utilization Details of MAT Medications: Calendar Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BUPRENORPHINE MAT PRODUCTS					
BUPREN/NALOX SUB 8-2MG	36,531	4,785	$1,998,496.71	$54.71	7.63
BUPRENORPHIN SUB 8MG	6,573	824	$317,503.81	$48.30	7.98
BUPREN/NALOX SUB 2-0.5MG	2,276	440	$95,253.50	$41.85	5.17
BUPREN/NALOX MIS 8-2MG	1,555	202	$315,350.62	$202.80	7.70
BUPRENORPHIN SUB 2MG	599	131	$17,664.85	$29.49	4.57
SUBLOCADE INJ 300/1.5	451	176	$828,895.41	$1,837.91	2.56
SUBLOCADE INJ 100/0.5	250	77	$460,027.90	$1,840.11	3.25
ZUBSOLV SUB 5.7-1.4MG	132	18	$52,607.60	$398.54	7.33
SUBOXONE MIS 8-2MG	109	12	$99,208.69	$910.17	9.08
ZUBSOLV SUB 8.6-2.1MG	58	6	$61,461.84	$1,059.69	9.67
BUPREN/NALOX MIS 12-3MG	41	5	$13,413.84	$327.17	8.20
BUPREN/NALOX MIS 2-0.5MG	16	4	$1,327.29	$82.96	4
BUPREN/NALOX MIS 4-1MG	11	3	$1,526.04	$138.73	3.67
ZUBSOLV SUB 0.7-0.18MG	5	1	$374.26	$74.85	5
ZUBSOLV SUB 1.4-0.36MG	4	1	$510.94	$127.74	4
SUBOXONE MIS 4-1MG	2	1	$1,573.68	$786.84	2
ZUBSOLV SUB 2.9-0.71MG	1	1	$515.82	$515.82	1
SUBTOTAL	**48,614**	**6,687**	**$4,265,712.80**	**$87.75**	**7.27**
NALTREXONE PRODUCTS					
NALTREXONE TAB 50MG	8,053	2,516	$279,606.13	$34.72	3.2
VIVITROL INJ 380MG	803	262	$1,149,483.25	$1,431.49	3.06
SUBTOTAL	**8,856**	**2,778**	**$1,429,089.38**	**$161.37**	**3.19**
MAT TOTAL	**57,470**	**8,435***	**$5,694,802.18**	**$99.09**	**6.81**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BUPREN = buprenorphine; INJ = injection; MAT = medication-assisted treatment; MIS = film; NALOX = naloxone; SUB = sublingual tablet; TAB = tablet

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	CLAIMS/ MEMBER	COST/ CLAIM
J2315 NALTREXONE INJ 1MG (VIVITROL)	3	3	$1,344.66	1	$448.22
Q9991 BUPRENORPHINE INJ 100MG (SUBLOCADE)	2	1	$3,486.96	2	$1,743.48
Q9992 BUPRENORPHINE INJ 300MG (SUBLOCADE)	2	1	$3,486.96	2	$1,743.48
TOTAL	**7**	**4**	**$8,318.58**	**1.75**	**$1,188.37**

Costs do not reflect rebated prices or net costs.
†Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection

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[9] Prolate® (Oxycodone/Acetaminophen Tablet) Prescribing Information. Forte Bio-Pharma LLC. Available online at: https://fortebiopharma.com/wp-content/uploads/2021/09/Revised-PI-1143C00-06-21-Prolate.pdf. Last revised 06/2021. Last accessed 07/26/2023.
[10] Prolate® OS (Oxycodone/Acetaminophen Solution) Prescribing Information. Forte Bio-Pharma LLC. Available online at: https://fortebiopharma.com/wp-content/uploads/2021/09/Revised-PI-1172A00-05-21-Prolate-Oral-Solution.pdf. Last revised 05/202. Last accessed 07/26/2023.

Appendix G

30-Day Notice to Prior Authorize Cuvrior™ (Trientine Tetrahydrochloride)

Oklahoma Health Care Authority
August 2023

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

Wilson's disease is a rare, progressive, genetic disorder that is characterized by excess copper accumulation in various body tissues, most commonly in the liver, brain, and corneas of the eyes. A mutation in the *ATP7B* gene prevents the body from removing excess copper from the liver to the bile to be excreted from the body and eventually leads to the accumulation of copper. If left untreated, Wilson's disease can lead to liver disease, central nervous system dysfunction, and psychiatric disturbances.

The prevalence of Wilson's disease is estimated to be about 1 in 30,000 to 40,000 people worldwide with an estimated 2,000-3,000 cases in the United States. Most patients' symptoms will vary and although Wilson's disease is present at birth, symptoms will not start to develop until the copper builds up in the body, typically beginning with liver dysfunction by 6 years of age. Wilson's disease is typically diagnosed by using medical and family history, physical exams, blood tests, liver biopsy, genetic testing, and/or urine collection tests. Additionally, scoring systems such as the Leipzig scoring system can also be used to assist providers in the diagnosis.

Treatment of Wilson's disease includes reducing the amount of copper in the body with chelating agents, such as penicillamine and trientine hydrochloride, or zinc to prevent absorption of copper in the intestines. Currently, penicillamine is the first line option for Wilson's disease; however, about one-third of patients become intolerant to penicillamine, leading to a change of therapy to trientine hydrocholoride. In May 2022, the U.S. Food and Drug Administration (FDA) approved Cuvrior™ (trientine tetrahydrochloride) for adults with stable Wilson's disease who are de-coppered and tolerant to penicillamine. Cuvrior™ was launched in the United States in April 2023 through PantherRx Rare.

Cuvrior™ (Trientine Tetrahydrochloride) Product Summary[6]

Therapeutic Class: Copper chelator

Indication(s): Treatment of adults with stable Wilson's disease who are de-coppered and tolerant to penicillamine

How Supplied: 300mg functionally scored oral tablets

Dosing and Administration:

- The starting total daily dosage of Cuvrior™ is 300mg up to 3,000mg taken in divided doses (twice daily). The total daily dosage of Cuvrior™ should not exceed 3,000mg.
- If the number of Cuvrior™ tablets prescribed per day cannot be equally divided among doses, then the total daily dosage should be divided such that the higher number of tablets is taken with the first daily dose.
- Cuvrior™ should be swallowed without crushing, chewing, or dissolving and should be taken on an empty stomach.
- Cuvrior™ is not substitutable on a milligram-per-milligram basis with other trientine products.
- Refer to the package labeling for the recommended conversion table when switching from penicillamine or other trientine products to Cuvrior™.

Cost Comparison:

Product	Cost Per Unit	Cost Per Month
Cuvrior™ (trientine tetrahydrochloride) 300mg tablet	**$191.00**	**$57,300.00***
penicillamine 250mg capsule (generic)	$80.42^	$19,300.80±
penicillamine 250mg tablet (generic)	$46.53	$11,167.20±
trientine hydrocholoride 250mg capsule (generic)	$18.87^	$4,528.80+
Galzin® (zinc acetate) 50mg capsule	$3.46	$311.40β

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
Unit = tablet or capsule
*Cuvrior™ cost is based on the maximum FDA recommended dose of 3,000mg daily.
±Penicillamine cost is based on the maximum FDA recommended dose of 2,000mg daily.
+Trientine hydrocholoride cost is based on the maximum FDA recommended dose of 2,000mg daily.
βGalzin® cost is based on the maximum FDA recommended dose of 50mg 3 times daily.
^Cost per capsule varies per NDC.

Recommendations

The College of Pharmacy recommends the prior authorization of Cuvrior™ (trientine tetrahydrochloride) with the following criteria:

Cuvrior™ (Trientine Tetrahydrochloride) Approval Criteria:

1. An FDA approved diagnosis of Wilson's disease; and
   a. Diagnosis must be confirmed by a Leipzig score ≥4; and
2. Member must be 18 years of age or older; and
3. Cuvrior must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or other specialist with expertise in the treatment of Wilson's disease (or an advanced care practitioner with a supervising physician who is gastroenterologist, hepatologist, or other specialist with expertise in the treatment of Wilson's disease); and

4. Member must be clinically stable, de-coppered, and tolerant to penicillamine as indicated by 1 of the following:
    a. Serum non-ceruloplasmin copper (NCC) level 25-150mcg/L; or
    b. Urinary copper excretion (UCE) level 200-500mcg/24 hours; and
5. Prescriber must verify the member will discontinue therapy with penicillamine or other copper chelating agents prior to starting therapy with Cuvrior™; and
6. A patient-specific, clinically significant reason why the member cannot use penicillamine, generic trientine hydrocholoride, and Galzin® (zinc acetate), which are available without a prior authorization, must be provided; and
7. A quantity limit of 288 tablets per 28 days will apply.

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[1] Schilsky M, Roberts E, Bronstein J, et al. A Multidisciplinary Approach to the Diagnosis and Management of Wilson Disease: 2022 Practice Guidance on Wilson disease from the American Association for the Study of Liver Diseases. *Hepatology* 2022. doi: 10.1002/hep.32801.
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[4] Orphalan SA. Orphalan Announces FDA Approval of Cuvrior™ for the Treatment of Adult Patients with Stable Wilson's Disease who are De-coppered and Tolerant to Penicillamine. Available online at: https://www.orphalan.com/orphalan-announces-fda-approval-of-cuvrior/. Issued 05/02/2022. Last accessed 07/19/2023.
[5] PantherRx® Rare. PantherRx® Rare Announces Release of Cuvrior™ (Trientine Tetrahydrochloride) to Treat Wilson Disease. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/pantherx-rare-announces-release-of-cuvrior-trientine-tetrahydrochloride-to-treat-wilson-disease-301802534.html. Issued 04/19/2023. Last accessed 07/19/2023.
[6] Cuvrior™ (Trientine Tetrahydrochloride) Prescribing Information. Orphalan SA. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215760s000lbl.pdf. Last revised 04/2022. Last accessed 07/19/2023.

Appendix H

Calendar Year 2022 Annual Review of Camzyos® (Mavacamten)

Oklahoma Health Care Authority
August 2023

Current Prior Authorization Criteria

Camzyos® (Mavacamten) Approval Criteria:

1. An FDA approved diagnosis of obstructive hypertrophic cardiomyopathy (HCM); and
2. Member must be 18 years of age or older; and
3. Member must have New York Heart Association (NYHA) class II to III heart failure; and
4. Camzyos® must be prescribed by, or in consultation with, a cardiologist (or an advanced care practitioner with a supervising physician who is a cardiologist); and
5. Member must have left ventricular ejection fraction (LVEF) ≥55%; and
6. Member must be on current treatment with or have a documented failure, contraindication, or intolerance to beta blockers or nondihydropyridine calcium channel blockers; and
7. Member must not be taking concurrent moderate to strong CYP2C19 inhibitors (e.g., proton pump inhibitors, clopidogrel, voriconazole, fluvoxamine), strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, ritonavir), moderate to strong CYP2C19 inducers (e.g., rifampicin, carbamazepine), or moderate to strong CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin); and
8. Member must not be taking or planning to take disopyramide, ranolazine, or a combination of a beta blocker and a calcium channel blocker concomitantly with Camzyos®; and
9. Female members of reproductive potential must have a negative pregnancy test prior to initiation of therapy and must agree to use effective contraception during treatment and for 4 months after the final dose of Camzyos®; and
10. Prescriber, pharmacy, and member must be enrolled in the Camzyos® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
11. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment; and
12. Subsequent approvals will be for the duration of 1 year.

Utilization of Camzyos® (Mavacamten): Calendar Year 2022

There was no SoonerCare utilization of Camzyos® (mavacamten) during calendar year 2022.

Prior Authorization of Camzyos® (Mavacamten)

There were 2 prior authorization requests submitted for 2 unique members for Camzyos® (mavacamten) during calendar year 2022, both of which were incompleted for more information.

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Camzyos® (mavacamten): June 2034

News:

- **June 2023:** The U.S. Food and Drug Administration (FDA) accepted a supplemental New Drug Application (sNDA) to add new positive data to the Camzyos® *Prescribing Information*. The new data showed that treatment with Camzyos® significantly reduced the composite endpoint of guideline-based eligibility for septal reduction therapy (SRT) at week 16 or to proceed with SRT prior to or at week 16. The approval of the sNDA did not lead to a change in the current approved indication for Camzyos® of obstructive hypertrophic cardiomyopathy (HCM).

Recommendations

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 07/2023. Last accessed 07/17/2023.

[2] Bristol Myers Squibb. U.S. Food and Drug Administration Approves Addition of Positive Data from Phase 3 VALOR-HCM Study to Camzyos® (Mavacamten) Label. Available online at: https://news.bms.com/news/details/2023/U.S.-Food-and-Drug-Administration-Approves-Addition-of-Positive-Data-from-Phase-3-VALOR-HCM-Study-to-CAMZYOS-mavacamten-Label. Issued 06/15/2023. Last accessed 07/17/2023.

Appendix I

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: July 28, 2023

FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product

The FDA approved RiVive™ (naloxone hydrochloride 3mg nasal spray) for over-the-counter (OTC), nonprescription use for the emergency treatment of known or suspected opioid overdose. This is the second nonprescription naloxone product the FDA has approved, helping increase consumer access to naloxone without a prescription. The timeline for availability and the price of this nonprescription product will be determined by the manufacturer.

Drug overdose persists as a major public health issue in the United States. In the 12-month period ending in February 2023, more than 105,000 reported fatal overdoses occurred which were primarily driven by synthetic opioids like illicit fentanyl. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose.

The approval of RiVive™ nasal spray for nonprescription use was supported by data from a study submitted by the manufacturer that showed similar levels of RiVive™ reach the bloodstream as an approved prescription naloxone product. The drug has been demonstrated to be safe and effective for use as directed in its labeling. The manufacturer also provided data that showed consumers can understand how to use the drug safely and effectively without the supervision of a health care professional.

The use of RiVive™ nasal spray in individuals who are dependent on opioids may result in severe opioid withdrawal characterized by body aches, diarrhea, tachycardia, fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

The FDA has taken a series of steps to help facilitate access to opioid overdose reversal products and to decrease unnecessary exposure to opioids and prevent new cases of addiction. The FDA approved the first nonprescription naloxone nasal spray product in March 2023, the first generic nonprescription naloxone nasal spray product in July 2023, and over the last year has undertaken new efforts to expand opioid disposal options in an effort to reduce opportunities for nonmedical use, accidental exposure, and overdose.

Through the FDA Overdose Prevention Framework, the FDA remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose, and death in the United States. The framework's priorities include supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.

The FDA granted the nonprescription approval of RiVive™ to Harm Reduction Therapeutics.

FDA NEWS RELEASE

For Immediate Release: July 21, 2023

FDA Provides Update Regarding Storm Damage at Pfizer Facility in North Carolina

The FDA is working closely with Pfizer to assess the impact of the damage at Pfizer's Rocky Mount, North Carolina, facility. Over the next few days, the FDA will complete a more extensive assessment of the products that may be impacted and the current available supply of those products. This assessment also will evaluate what is in Pfizer's other warehouses and what is stocked by wholesalers and distributors, if those companies are willing to share that information with the FDA.

Importantly, the FDA does not expect there to be any immediate significant impacts on supply given the products are currently at hospitals and in the distribution system, but this is a dynamic situation and FDA staff are in frequent communication with Pfizer and other manufacturers. The FDA will work closely with partners in government, industry, and the broader health care system to minimize impact on patient care.

Notably, while Pfizer has one third of the total sterile injectable drug market for hospitals in the United States, this facility only makes 25% of Pfizer's total product for this market – not the entire market. This means 8% of United States consumption is supplied by this site. While disclosure laws prevent the FDA from providing a complete list of products made at the facility, there is redundancy in the supply chain due to other manufacturers. The FDA's initial analysis has identified less than 10 drugs for which Pfizer's North Carolina plant is the sole source for the United States market; however, a number of these are specific formulations for which there should be substitutes or for which many weeks' worth of stock should be available in Pfizer's other warehouses.

For those products produced at this facility that are already in, or may be, at risk of shortage, the FDA has initiated mitigation steps, such as looking for additional sources and asking other manufacturers to prepare to ramp up production, if needed.

To have equitable distribution of the products and ensure availability to those in most need, as well as to avoid hoarding, Pfizer has put the inventory of many products on strict allocation. These allocation measures could lead to localized supply disruptions depending on contractual relationships for supplies. Health care systems that have trouble obtaining a particular drug should contact their distributor or Pfizer directly.

More broadly, this incident underscores that a robust, resilient, and safe drug supply chain is essential for public health and national security. Redundancy of manufacturing locations, which can include domestic locations, and of suppliers is important to mitigate risks to supply that can occur from natural disasters, geopolitical conflicts, or other less predictable events.

The FDA remains committed to partnering across government, academia, and industry to strengthen and diversify the supply chain and ensure Americans continue to have access to drugs that are high quality, safe, and effective.

FDA NEWS RELEASE

For Immediate Release: July 17, 2023

FDA Approves New Drug to Prevent RSV in Babies and Toddlers

The FDA approved Beyfortus™ (nirsevimab-alip) for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

RSV is a virus that causes acute respiratory infection in individuals of all age groups. While most infants and young children experience mild, cold-like symptoms, some

infants, especially with their first infection, develop lower respiratory tract disease such as pneumonia and bronchiolitis, that often leads to an emergency department or physician office visit. Premature infants, and those with chronic lung disease (CLD) of prematurity or significant congenital heart disease (CHD), are at highest risk for severe RSV disease. Approximately 1% to 3% of children younger than 12 months of age in the United States are hospitalized each year due to RSV, according to the American Academy of Pediatrics.

Beyfortus™ is a monoclonal antibody with activity against RSV. One dose of Beyfortus™, administered as a single intramuscular (IM) injection prior to or during RSV season, may provide protection during the RSV season. The safety and efficacy of Beyfortus™ were supported by 3 clinical trials (Trials 03, 04, and 05). The key measure of efficacy was the incidence of medically attended RSV lower respiratory tract infection (MA RSV LRTI), evaluated during the 150 days after Beyfortus™ administration. MA RSV LRTI included all health care provider visits (physician office, urgent care, emergency room visits, and hospitalization) for lower respiratory tract disease with worsening clinical severity and a positive RSV test. Trials 03 and 04 were randomized, double-blind, placebo-controlled, multicenter clinical trials.

Trial 03 included 1,453 preterm infants (born at ≥29 weeks of gestational age up to <35 weeks of gestation) who were born during or entering their first RSV season. Of the 1,453 preterm infants in the trial, 969 received a single dose of Beyfortus™ and 484 received placebo. Among infants who were treated with Beyfortus™, 25 (2.6%) experienced MA RSV LRTI compared with 46 (9.5%) infants who received placebo. Beyfortus™ reduced the risk of MA RSV LRTI by approximately 70% relative to placebo.

For Trial 04, the primary analysis group within the trial included 1,490 term and late preterm infants (born at ≥35 weeks in gestational age), 994 of whom received a single dose of Beyfortus™ and 496 of whom received placebo. Among infants who were treated with Beyfortus™, 12 (1.2%) experienced MA RSV LRTI compared with 25 (5.0%) infants who received placebo. Beyfortus™ reduced the risk of MA RSV LRTI by approximately 75% relative to placebo.

Trial 05, a randomized, double-blind, active (palivizumab)-controlled, multicenter trial, supported the use of Beyfortus™ in in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The trial enrolled 925 preterm infants and infants with CLD of prematurity or CHD. The safety and pharmacokinetic data from Trial 05 provided evidence for the use of Beyfortus™ to prevent MA RSV LRTI in this population.

Possible side effects of Beyfortus™ include rash and injection site reactions. Beyfortus™ should not be given to infants and children with a history of serious hypersensitivity reactions to Beyfortus™' active ingredients or any of its excipients. Beyfortus™ comes with warnings and precautions about serious hypersensitivity reactions, including anaphylaxis, which have been observed with other human IgG1 monoclonal antibodies. Beyfortus™ should be given with caution to infants and children with clinically significant bleeding disorders.

Beyfortus™ received a Fast Track designation for this indication. The FDA granted this approval to AstraZeneca.

FDA NEWS RELEASE

For Immediate Release: July 13, 2023

FDA Approves First Nonprescription Daily Oral Contraceptive

The FDA approved Opill® (norgestrel) tablet for nonprescription use to prevent pregnancy – the first daily oral contraceptive approved for use in the United States

without a prescription. Approval of this progestin-only oral contraceptive pill provides an option for consumers to purchase oral contraceptive medicine without a prescription at drug stores, convenience stores, and grocery stores, as well as online.

The timeline for availability and price of this nonprescription product is determined by the manufacturer. Other approved formulations and dosages of other oral contraceptives will remain available by prescription only.

Nonprescription availability of Opill® may reduce barriers to access by allowing individuals to obtain an oral contraceptive without the need to first see a health care provider. Almost half of the 6.1 million pregnancies in the United States each year are unintended. Unintended pregnancies have been linked to negative maternal and perinatal outcomes, including reduced likelihood of receiving early prenatal care and increased risk of preterm delivery, with associated adverse neonatal, developmental, and child health outcomes. Availability of nonprescription Opill® may help reduce the number of unintended pregnancies and their potential negative impacts.

The contraceptive efficacy of norgestrel was established with the original approval for prescription use in 1973. HRA Pharma applied to switch norgestrel from a prescription to an over-the-counter product. For approval of a product for use in the nonprescription setting, the FDA requires that the applicant demonstrate that the product can be used by consumers safely and effectively, relying only on the nonprescription drug labeling without any assistance from a health care professional. Studies showed that consumer understanding of information on the Opill® Drug Facts label was high overall and that a high proportion of consumers understood the label instructions, supporting their ability to properly use the drug when it is available as an over-the-counter product. When properly used, Opill® is safe and effective.

Opill® should be taken at the same time every day; adherence to daily use at the same time of day is important for the effectiveness of Opill®. Using medications that interact with Opill® can result in decreased efficacy of Opill® or the other medication, or both, potentially resulting in unintended pregnancy.

The most common side effects of Opill® include irregular bleeding, headaches, dizziness, nausea, increased appetite, abdominal pain, cramps, or bloating.

Opill® should not be used by those who have or have ever had breast cancer. Consumers who have any other form of cancer should ask a doctor before use. Opill® also should not be used together with another hormonal birth control product such as another oral contraceptive tablet, a vaginal ring, a contraceptive patch, a contraceptive implant, a contraceptive injection, or an intra-uterine device (IUD).

Use of Opill® may be associated with changes in vaginal bleeding patterns, such as irregular spotting and prolonged bleeding. Consumers should inform a health care provider if they develop repeated vaginal bleeding after sex, or prolonged episodes of bleeding or amenorrhea. Individuals who miss 2 periods (or have missed a single period and have missed doses of Opill®) or suspect they may be pregnant should take a pregnancy test. Consumers should discontinue Opill® if pregnancy is confirmed.

Opill® is not for use as emergency contraception and does not prevent pregnancy after unprotected sex. Oral contraceptives do not protect against transmission of HIV, AIDS, and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis. Condoms should be used to prevent sexually transmitted diseases. The FDA granted the approval to Laboratoire HRA Pharma, recently acquired by Perrigo Company plc.

FDA NEWS RELEASE

For Immediate Release: July 6, 2023

FDA Converts Novel Alzheimer's Disease Treatment to Traditional Approval

The FDA converted Leqembi® (lecanemab-irmb), indicated to treat adult patients with Alzheimer's Disease, to traditional approval following a determination that a confirmatory trial verified clinical benefit. Leqembi® is the first amyloid beta-directed antibody to be converted from an accelerated approval to a traditional approval for the treatment of Alzheimer's disease. The drug works by reducing amyloid plaques that form in the brain, a defining pathophysiological feature of the disease.

Leqembi® was approved in January under the Accelerated Approval pathway. This pathway allows the FDA to approve drugs for serious conditions where there is an unmet medical need, based on clinical data demonstrating the drug's effect on a surrogate endpoint—in the case of Leqembi®, reducing amyloid plaques in the brain—that is reasonably likely to predict a clinical benefit to patients. As a postmarketing requirement of the accelerated approval, the FDA required the applicant to conduct a clinical trial, often referred to as a confirmatory study, to verify the anticipated clinical benefit of Leqembi®. Efficacy of Leqembi® was evaluated using the results of Study 301 (CLARITY AD), a Phase 3 randomized, controlled clinical trial.

Study 301 was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study that enrolled 1,795 patients with Alzheimer's disease. Treatment was initiated in patients with mild cognitive impairment or mild dementia stage of disease and confirmed presence of amyloid beta pathology. Patients were randomized in a 1:1 ratio to receive placebo or Leqembi® at a dose of 10mg/kg, once every 2 weeks. Leqembi® demonstrated a statistically significant and clinically meaningful reduction of decline from baseline to 18 months on the primary endpoint, the Clinical Dementia Rating Scale Sum of Boxes score, compared to placebo. Statistically significant differences between treatment groups were also demonstrated on all secondary endpoints, which included the Alzheimer's Disease Assessment Scale Cognitive Subscale 14, and the Alzheimer's Disease Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment.

On June 9, the FDA convened the Peripheral and Central Nervous System Drugs Advisory Committee to discuss whether Study 301 provided evidence of clinical benefit of Leqembi® for the treatment of Alzheimer's disease. All committee members voted affirmatively that the results of the study verified the clinical benefit of Leqembi® for the indicated use.

The most common side effects of Leqembi® were headache, infusion-related reactions, and amyloid-related imaging abnormalities (ARIA), a side effect known to occur with the class of antibodies targeting amyloid. ARIA most commonly presents as temporary swelling in areas of the brain seen on imaging studies that usually resolves over time and may be accompanied by small spots of bleeding in or on the surface of the brain. Although ARIA is often not associated with any symptoms, symptoms can occur and include headache, confusion, dizziness, vision changes, and nausea. ARIA can also infrequently present with serious and life-threatening brain edema that can be associated with seizures and other severe neurological symptoms. Intracerebral hemorrhages can occur in patients treated with this class of medications and can be fatal. A boxed warning is included in the prescribing information to alert patients and caregivers to the potential risks associated with ARIA.

Patients treated with Leqembi® who are homozygous for the ApoE ε4 allele have a higher incidence of ARIA, including symptomatic, serious, and severe ARIA, compared to heterozygotes and noncarriers. The prescribing information states that testing for ApoE

ε4 status should be performed before starting treatment with Leqembi® to inform the risk of developing ARIA.

Use of anticoagulant medication was associated with an increased number of intracerebral hemorrhages in patients taking Leqembi® compared to placebo. The prescribing information recommends caution when considering use of Leqembi® in patients taking anticoagulants or with other risk factors for intracerebral hemorrhage.

Leqembi® is contraindicated in patients with serious hypersensitivity to lecanemab-irmb or to any of its inactive ingredients. Adverse reactions may include angioedema and anaphylaxis.

Leqembi® should be initiated in patients with mild cognitive impairment or mild dementia stage of Alzheimer's disease, the population in which treatment was studied in clinical trials. The labeling states that there are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. The approval of Leqembi® was granted to Eisai Inc.

Current Drug Shortages Index (as of July 26, 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.

0.9% Sodium Chloride Irrigation	***Currently in Shortage***
Albuterol Sulfate Inhalation Solution, 0.5%	***Currently in Shortage***
Alprostadil (Muse) Suppository	***Currently in Shortage***
Amifostine Injection	***Currently in Shortage***
Amino Acids	***Currently in Shortage***
Amoxapine Tablets	***Currently in Shortage***
Amoxicillin Oral Powder for Suspension	***Currently in Shortage***
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine for Injection	***Currently in Shortage***
Azithromycin (Azasite) Ophthalmic Solution 1%	***Currently in Shortage***
Bacteriostatic 0.9% Sodium Chloride Injection	***Currently in Shortage***
Bacteriostatic Water for Injection	***Currently in Shortage***
Belatacept (Nulojix) Lyophilized Powder for Injection	***Currently in Shortage***
Belladonna and Opium Suppositories	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride and Epinephrine Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Calcium Gluconate Injection	***Currently in Shortage***
Capecitabine Tablets	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefixime Oral Capsules	***Currently in Shortage***
Cefotaxime Sodium Injection	***Currently in Shortage***
Cefotetan Disodium Injection	***Currently in Shortage***

Chloramphenicol Sodium Succinate Injection	***Currently in Shortage***
Chloroprocaine Hydrochloride Injection	***Currently in Shortage***
Chlorothiazide Oral Suspension	***Currently in Shortage***
Cisplatin Injection	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablets	***Currently in Shortage***
Collagenase Ointment	***Currently in Shortage***
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container	***Currently in Shortage***
Conjugated Estrogens/Bazedoxifene (Duavee) Tablet, Film Coated	***Currently in Shortage***
Cyclopentolate Ophthalmic Solution	***Currently in Shortage***
Cytarabine Injection	***Currently in Shortage***
Dacarbazine Injection	***Currently in Shortage***
Desmopressin Acetate Nasal Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Injection	***Currently in Shortage***
Dextrose 10% Injection	***Currently in Shortage***
Dextrose 25% Injection	***Currently in Shortage***
Dextrose 5% Injection	***Currently in Shortage***
Dextrose 50% Injection	***Currently in Shortage***
Diazepam Rectal Gel	***Currently in Shortage***
Diflunisal Tablets	***Currently in Shortage***
Difluprednate Ophthalmic Emulsion	***Currently in Shortage***
Digoxin Injection	***Currently in Shortage***
Diltiazem Hydrochloride Injection	***Currently in Shortage***
Dimercaprol (Bal in Oil) Injection	***Currently in Shortage***
Disopyramide Phosphate (Norpace) Capsules	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Dulaglutide (Trulicity) Injection	***Currently in Shortage***
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution	***Currently in Shortage***
Edetate Calcium Disodium Injection	***Currently in Shortage***
Enalaprilat Injection	***Currently in Shortage***
Epinephrine Injection, 0.1mg/mL	***Currently in Shortage***
Erythromycin Ophthalmic Ointment	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate (Sublimaze) Injection	***Currently in Shortage***
Fludarabine Phosphate Injection	***Currently in Shortage***
Fluorescein Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsules	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Gentamicin Sulfate Injection	***Currently in Shortage***
Guanfacine Hydrochloride Tablets	***Currently in Shortage***
Heparin Sodium and Sodium Chloride 0.9% Injection	***Currently in Shortage***

Hydrocortisone Sodium Succinate Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert	***Currently in Shortage***
Ibutilide Fumarate Injection	***Currently in Shortage***
Indigotindisulfonate Sodium Injection	***Currently in Shortage***
Isoniazid Injection	***Currently in Shortage***
Isoniazid Tablets	***Currently in Shortage***
IV Fat Emulsion	***Currently in Shortage***
Ketamine Injection	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Leucovorin Calcium Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Viscous) Oral Topical Solution	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection	***Currently in Shortage***
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsules	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Lutetium Lu 177 Vipivotide Tetraxetan (Pluvicto) Injection	***Currently in Shortage***
Mannitol Injection	***Currently in Shortage***
Mepivacaine Hydrochloride Injection	***Currently in Shortage***
Methamphetamine Hydrochloride Tablets	***Currently in Shortage***
Methotrexate Injection	***Currently in Shortage***
Methotrexate Tablets	***Currently in Shortage***
Methyldopa Tablets	***Currently in Shortage***
Methylphenidate Hydrochloride Extended Release Tablets	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Multi-Vitamin Infusion (Adult and Pediatric)	***Currently in Shortage***
Neomycin Sulfate Tablets	***Currently in Shortage***
Nizatidine Capsules	***Currently in Shortage***
Oxybutynin Chloride Syrup	***Currently in Shortage***
Oxytocin Injection	***Currently in Shortage***
Palifermin (Kepivance) Lyophilized Powder for Injection	***Currently in Shortage***
Pantoprazole Sodium for Injection	***Currently in Shortage***
Parathyroid Hormone Injection	***Currently in Shortage***
Penicillin G Benzathine Injectable Suspension	***Currently in Shortage***
Physostigmine Salicylate Injection	***Currently in Shortage***
Potassium Acetate Injection	***Currently in Shortage***
Potassium Chloride Concentrate Injection	***Currently in Shortage***
Quinapril and Hydrochlorothiazide Tablets	***Currently in Shortage***

Quinapril Hydrochloride Tablets	***Currently in Shortage***
Remifentanil Injection	***Currently in Shortage***
Rifampin Capsules	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablets	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Semaglutide (Ozempic) Injection	***Currently in Shortage***
Semaglutide (Wegovy) Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sodium Chloride 0.9% Injection Bags	***Currently in Shortage***
Sodium Chloride 14.6% Injection	***Currently in Shortage***
Sodium Chloride 23.4% Injection	***Currently in Shortage***
Sodium Chloride Injection, 0.9% Vials and Syringes	***Currently in Shortage***
Sodium Phosphates Injection	***Currently in Shortage***
Somatropin Injection	***Currently in Shortage***
Sterile Water for Injection	***Currently in Shortage***
Sterile Water for Irrigation	***Currently in Shortage***
Streptozocin (Zanosar) Sterile Powder	***Currently in Shortage***
Sucralfate Tablets	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Sulfasalazine Tablets	***Currently in Shortage***
Technetium TC-99M Mebrofenin Injection	***Currently in Shortage***
Tirzepatide Injection	***Currently in Shortage***
Triamcinolone Acetonide Injectable Suspension	***Currently in Shortage***
Triamcinolone Hexacetonide Injectable suspension	***Currently in Shortage***
Trimethobenzamide Hydrochloride Capsules	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***
Vecuronium Bromide for Injection	***Currently in Shortage***