OKLAHOMA
Health Care Authority

Drug Utilization Review Board

Wednesday, August 12, 2026

No live meeting is scheduled for August.
August 2026 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 12, 2026

DATE: August 5, 2026

NOTE: **No live August meeting. August 2026 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 – Appendix B

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

Annual Review of Copper Metabolism Disorder Medications and 30-Day Notice to Prior Authorize Zycubo® (Copper Histidinate) – Appendix D

Annual Review of Iron Chelating Agents – Appendix E

Annual Review of Iron Products – Appendix F

Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate) – Appendix G

Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Morphine Oral Solution Syringes, Tapentadol Tablet, Tapentadol Extended-Release (ER) Tablet, and Tapentadol Oral Solution – Appendix H

Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Amcinonide 0.1% Ointment – Appendix I

Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid) – Appendix J

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

Future Business

Adjournment

Oklahoma Health Care Authority

Drug Utilization Review Board
(DUR Board)
Packet Meeting – August 12, 2026

NOTE: ***No live August meeting. August 2026 is a packet-only meeting.***

AGENDA

Discussion and action on the following items:

Items reviewed by Dr. Haymore, Chairman:

1. **DUR Board Meeting Minutes – See Appendix A**
   A. July 8, 2026 DUR Board Meeting Minutes
   B. July 8, 2026 DUR Board Recommendations Memorandum
   C. Correspondence

Items reviewed by Dr. Wilson, Dr. Haymore, Chairman:

2. **Update on Medication Coverage Authorization Unit – See Appendix B**
   A. Pharmacy Help Desk Activity for July 2026
   B. Medication Coverage Activity for July 2026

Items reviewed by Dr. Grimes, Dr. Haymore, Chairman:

3. **U.S. Food and Drug Administration (FDA) Safety Alerts – See Appendix C**
   A. Introduction
   B. Safety Alerts

Items reviewed by Dr. Dorsey, Dr. Haymore, Chairman:

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

Items reviewed by Dr. Grimes, Dr. Haymore, Chairman:

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

Items reviewed by Dr. Wilson, Dr. Haymore, Chairman:

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

Items reviewed by Dr. Sinko, Dr. Haymore, Chairman:

7. **Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate) – See Appendix G**
   A. Current Prior Authorization Criteria
   B. Utilization of Miscellaneous Cancer Medications
   C. Prior Authorization of Miscellaneous Cancer Medications
   D. Market News and Updates
   E. Product Summaries
   F. College of Pharmacy Recommendations
   G. Utilization Details of Miscellaneous Cancer Medications

Items reviewed by Dr. Moss, Dr. Haymore, Chairman:

8. **Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Morphine Oral Solution Syringes and Tapentadol Tablet, Tapentadol Extended-Release (ER) Tablet, and Tapentadol Oral Solution – See Appendix H**
   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. Cost Comparisons
   F. College of Pharmacy Recommendations
   G. Utilization Details of Opioid Analgesics and MAT Medications

Items reviewed by Dr. O'Halloran, Dr. Haymore, Chairman:

9. **Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Amcinonide 0.1% Ointment – See Appendix I**
   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 reviewed by Dr. DeRemer, Dr. Haymore, Chairman:

10. **Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid) – See Appendix J**
    A. Current Prior Authorization Criteria
    B. Utilization of Various Systemic Antibiotics
    C. Prior Authorization of Various Systemic Antibiotics
    D. Market News and Updates
    E. Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Product Summary
    F. Cost Comparisons
    G. College of Pharmacy Recommendations
    H. Utilization Details of Various Systemic Antibiotics

Items reviewed by Dr. Wilson, Dr. Haymore, Chairman:

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

Items reviewed by Dr. Adams, Dr. Haymore, Chairman:

12. **Future Business* (Upcoming Product and Class Reviews)**
    A. Amyloidosis Medications
    B. Antihistamine Medications
    C. Benign Prostatic Hyperplasia (BPH) Medications
    D. Bladder Control Medications
    E. Breast Cancer Medications
    F. Cystic Fibrosis (CF) Medications
    G. Various Ophthalmic Medications

    *Future product and class reviews subject to change.

13. **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.

NOTE: Oklahoma Medicaid transitioned from a fee-for-service (FFS) pharmacy benefit to a managed care pharmacy benefit for most members on April 1, 2024. At that time, the majority of SoonerCare members were transitioned to one of the three managed care SoonerSelect plans: Aetna, Humana, or Oklahoma Complete Health. SoonerSelect data has been provided to the College of Pharmacy and has been used in analyses throughout this DUR Board meeting packet. The data included in this DUR Board meeting packet combines FFS and managed care utilization data. The managed care utilization and prior authorization (PA) data reported in this packet is based solely on the data provided by the SoonerSelect plans.

Appendix A

OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW (DUR) BOARD MEETING
MINUTES OF MEETING JULY 8, 2026

DUR BOARD MEMBERS:	PRESENT	ABSENT
Cassidy Blaiss, Pharm.D., BCOP	X	
Jennifer Boyett, MHS, PA-C		X
Christen Ground, D.O.	X	
Bret Haymore, M.D.; Chairman	X	
Bethany Holderread, Pharm.D.	X	
Matt John, Pharm. D., MBA	X	
T. Craig Kupiec II, M.D., MSPH	X	
Lee Muñoz, D.Ph.		X
Edna Patatanian, Pharm.D., FASHP; Vice Chairwoman	X	
Jennifer Weakley, M.D., DipABLM		X

COLLEGE OF PHARMACY STAFF:	PRESENT	ABSENT
Michyla Adams, Pharm.D.; DUR Manager	X	
Alanah Canfield Miller, Pharm.D.; Clinical Pharmacist		X
Michaela DeRemer, Pharm.D., MBA, BCIDP, BCPS; Clinical Pharmacist	X	
Darius Dorsey, Pharm.D., Pharmacy Resident	X	
Erin Ford, Pharm.D.; Clinical Pharmacist		X
Beth Galloway; Business Analyst	X	
Lezlie Grimes, Pharm.D.; Clinical Pharmacist	X	
Katrina Harris, Pharm.D.; Clinical Pharmacist		X
Robert Klatt, Pharm.D.; Clinical Pharmacist		X
Regan Moss, Pharm.D.; Clinical Pharmacist	X	
Brandy Nawaz, Pharm.D.; Clinical Pharmacist		X
Alicia O'Halloran, Pharm.D.; Clinical Pharmacist	X	
Wynn Phung, Pharm.D.; Clinical Pharmacist		X
Grant H. Skrepnek, Ph.D.; Associate Professor		X
Peggy Snyder, Pharm.D.; Clinical Pharmacist		X
Ashley Teel, Pharm.D.; Clinical Pharmacist		X
Jacquelyn Travers, Pharm.D.; Practice Facilitating Pharmacist	X	
Devin Wilcox, D.Ph.; Pharmacy Director	X	
Justin Wilson, Pharm.D.; Clinical Pharmacist	X	
PA Oncology Pharmacists: Whitney Bueno, Pharm.D., BCOP		X
Christine Hughes, Pharm.D., MBA, BCOP		X
Lauren Sinko, Pharm.D., BCOP	X	
Graduate Students: Matthew Dickson, Pharm.D.		X
Mark Wendelboe		X
Visiting Pharmacy Student(s): N/A		

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Josh Anderson, Chief of Staff		
Mark Brandenburg, M.D., MSC; Medical Director	X	
Clay Bullard; Chief Executive Officer		
Terry Cothran, D.Ph.; Pharmacy Director	X	

Bradford Eckhart, J.D.; Deputy General Counsel	X	
Melissa Miller, State Medicaid Director		X
Jill Ratterman, D.Ph.; Clinical Pharmacist	X	
Shanna Simmons, Pharm.D.; Program Integrity Pharmacist	X	
Michelle Tahah, Pharm.D.; Clinical Pharmacist	X	

OTHERS PRESENT:	
Jennifer Lauper, Bristol-Myers Squibb	Dan Calloway, Bristol-Myers Squibb
Andi Stratton, Krystal Biotech	Dominic Marchese, Krystal Biotech
Porscha Martin-Petties, Gilead	Andrew Delgado, Bristol-Myers Squibb
Courtney Walker, Novo Nordisk	David Prather, Novo Nordisk
David Mendoza, Otsuka	Deidra Williams, Humana
Laura Cordell, Sanofi	Lee Stout, Chiesi
Justin Springfield, Gilead	Kellie Vazzana, Alkermes
Kristen Winters, Centene	Bryan Steffan, Boehringer
Ashlee Waring, Organon	Scott Burns, Johnson & Johnson
Julie Rhodes, AbbVie	Andy Gorzynski, Cytokinetics
Miranda Ryzenman, Artia Solutions	Tim Melancon, Immedica
Marc Parker, VS Health Group	Kevin Chang, Sanofi
Jama Larose, Dyne Therapeutics	Wendy Lepore, MannKind
Colton Kreamer, MannKind	Irene Chung, Aetna
Lauren Ninas, MannKind	Gary Parenteau, Dexcom
Alice Chan, MannKind	Sergio Gomez, Concis
Vicky Viss, Phathom	Phillip Lohec, Viatris
Eardie Curry, Genentech	Andy Berg, Concis
Monica Mazziotti, MannKind	

PRESENT FOR PUBLIC COMMENT:	
Andrew Delgado, Bristol-Myers Squibb	Porscha Martin-Petties, Gilead
Dominic Marchese, Krystal Biotech	Courtney Walker, Novo Nordisk

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

1A: ROLL CALL

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

ACTION: NONE REQUIRED

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

2A: AGENDA ITEM NO. 7 ANDREW DELGADO
2B: AGENDA ITEM NO. 8 PORSCHA MARTIN-PETTIES
2C: AGENDA ITEM NO. 13 DOMINIC MARCHESE
2D: AGENDA ITEM NO. 15 COURTNEY WALKER

ACTION: NONE REQUIRED

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

3A: JUNE 10, 2026 DUR MINUTES

Materials included in agenda packet; presented by Dr. Haymore
Dr. Holderread moved to approve; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: **UPDATE ON MEDICATION COVERAGE AUTHORIZATION UNIT**

4A: PHARMACY HELPDESK ACTIVITY FOR JUNE 2026

4B: MEDICATION COVERAGE ACTIVITY FOR JUNE 2026

Non-presentation item; materials included in agenda packet by Dr. DeRemer

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: **CHRONIC MEDICATION ADHERENCE (CMA) PROGRAM UPDATE**

5A: CMA PRESCRIBER MAILING SUMMARY

5B: MAILING SUMMARIES

5C: STAR RATINGS

5D: PROVIDER SUMMARY REPORT

5E: CMA TRENDS

5F: CONCLUSIONS

Materials included in agenda packet; presented by Dr. Travers

ACTION: NONE REQUIRED

AGENDA ITEM NO. 6: **VOTE TO PRIOR AUTHORIZE NEREUS™ (TRADIPITANT) AND POSFREA™ (PALONOSETRON INJECTION) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTI-EMETIC MEDICATIONS**

6A: MARKET NEWS AND UPDATES

6B: NEREUS™ (TRADIPITANT) PRODUCT SUMMARY

6C: COST COMPARISON: PALONOSETRON PRODUCTS

6D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. Moss

Dr. Holderread moved to approve; seconded by Dr. Blaiss

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: **VOTE TO PRIOR AUTHORIZE BYSANTI™ (MILSAPERIDONE) AND UPDATE THE APPROVAL CRITERIA FOR THE ATYPICAL ANTIPSYCHOTIC MEDICATIONS**

7A: MARKET NEWS AND UPDATES

7B: BYSANTI™ (MILSAPERIDONE) PRODUCT SUMMARY

7C: COST COMPARISON: ATYPICAL ANTIPSYCHOTICS FOR ADJUNCT TREATMENT OF MDD

7D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

Dr. Kupiec moved to approve; seconded by Dr. Holderread

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: **VOTE TO PRIOR AUTHORIZE HEPCLUDEX® (BULEVIRTIDE-GMOD), RELENZA® (ZANAMIVIR INHALATION POWDER), AND XOFLUZA® (BALOXAVIR) AND UPDATE THE APPROVAL CRITERIA FOR THE ANTIVIRAL MEDICATIONS**

8A: MARKET NEWS AND UPDATES

8B: HEPCLUDEX® (BULEVIRTIDE-GMOD) PRODUCT SUMMARY

8C: COST COMPARISON: ORAL INFLUENZA ANTIVIRAL MEDICATIONS

8D: COLLEGE OF PHARMACY RECOMMENDATIONS

Materials included in agenda packet; presented by Dr. DeRemer

Moved to amend Sovaldi and Zepatier criteria to add "for hepatitis C treatment" to the specialist evaluation for consistency among other hepatitis C medications.

Dr. Ground moved to approve the amended criteria; seconded by Dr. Patatanian

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: **VOTE TO PRIOR AUTHORIZE PRIOR AUTHORIZE LOARGYS® (PEGZILARGINASE-NBLN) AND UPDATE THE APPROVAL CRITERIA FOR THE UREA CYCLE DISORDER (UCD) MEDICATIONS**

9A: MARKET NEWS AND UPDATES
9B: LOARGYS® PEGZILARGINASE-NBLN) PRODUCT SUMMARY
9C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 10: **VOTE TO PRIOR AUTHORIZE AVERI™ (DESOGESTREL/ETHINYL ESTRADIOL/FERROUS BISGLYCINATE), CAFERGOT® (ERGOTAMINE/CAFFEINE TABLET), DESMODA™ (DESMOPRESSIN ORAL SOLUTION), DICYCLOMINE 40MG TABLET, GRISEOFULVIN ULTRAMICROSIZE 165MG TABLET, HYDROXYZINE ORAL SOLUTION UNIT DOSE CUPS (UDCS), KHINDIVI™ (HYDROCORTISONE ORAL SOLUTION), MIGERGOT® (ERGOTAMINE/CAFFEINE SUPPOSITORY), ONTRALFY™ (TIZANIDINE ORAL SOLUTION), POKONZA™ (POTASSIUM CHLORIDE 10MEQ/15ML ORAL SOLUTION), POKONZA™ (POTASSIUM CHLORIDE 15MEQ PACKET), POTASSIUM CHLORIDE 40MEQ PACKET, QUIOFIC™ (FOLIC ACID ORAL SOLUTION), RELGAABI™ (GABAPENTIN 200MG CAPSULE), AND VYKOURA™ (LEUCOVORIN INJECTION)**

10A: INTRODUCTION
10B: PRODUCT SUMMARIES
10C: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 11: **VOTE TO PRIOR AUTHORIZE INLEXZO™ (GEMCITABINE INTRAVESICAL SYSTEM), KYXATA™ (CARBOPLATIN), LIFYORLI™ (RELACORILANT), AND ZUSDURI™ (MITOMYCIN INTRAVESICAL SOLUTION) AND UPDATE THE APPROVAL CRITERIA FOR THE GENITOURINARY AND GYNECOLOGIC CANCER MEDICATIONS**

11A: MARKET NEWS AND UPDATES
11B: PRODUCT SUMMARIES
11C: COST COMPARISON: CARBOPLATIN PRODUCTS
11D: COLLEGE OF PHARMACY RECOMMENDATIONS

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

AGENDA ITEM NO. 12: **ANNUAL REVIEW OF ANTI-ULCER MEDICATIONS**

12A: CURRENT PRIOR AUTHORIZATION CRITERIA
12B: UTILIZATION OF ANTI-ULCER MEDICATIONS
12C: PRIOR AUTHORIZATION OF ANTI-ULCER MEDICATIONS
12D: MARKET NEWS AND UPDATES
12E: COLLEGE OF PHARMACY RECOMMENDATIONS
12F: UTILIZATION DETAILS OF ANTI-ULCER MEDICATIONS

Materials included in agenda packet; presented by Dr. DeRemer
Dr. Kupiec moved to approve; seconded by Dr. Holderread
ACTION: MOTION CARRIED

AGENDA ITEM NO. 13: ANNUAL REVIEW OF EPIDERMOLYSIS BULLOSA (EB) MEDICATIONS

13A: CURRENT PRIOR AUTHORIZATION CRITERIA
13B: UTILIZATION OF EB MEDICATIONS
13C: PRIOR AUTHORIZATION OF EB MEDICATIONS
13D: MARKET NEWS AND UPDATES
13E: COLLEGE OF PHARMACY RECOMMENDATIONS
13F: UTILIZATION DETAILS OF EB MEDICATIONS

Materials included in agenda packet; presented by Dr. Moss
Moved to amend the initial approval length for both Vyjuvek and Filsuvez from 3 months to 6 months based on clinical practice.
Dr. Patatanian moved to approve the amended criteria; seconded by Dr. Blaiss
ACTION: MOTION CARRIED

AGENDA ITEM NO. 14: ANNUAL REVIEW OF COLORECTAL CANCER (CRC) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE JOBEVNE™ (BEVACIZUMAB-NWGD)

14A: CURRENT PRIOR AUTHORIZATION CRITERIA
14B: UTILIZATION OF CRC MEDICATIONS
14C: PRIOR AUTHORIZATION OF CRC MEDICATIONS
14D: MARKET NEWS AND UPDATES
14E: COST COMPARISON: BEVACIZUMAB PRODUCTS
14F: COLLEGE OF PHARMACY RECOMMENDATIONS
14G: UTILIZATION DETAILS OF CRC MEDICATIONS

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

AGENDA ITEM NO. 15: ANNUAL REVIEW OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE) AND 30-DAY NOTICE TO PRIOR AUTHORIZE AWIQLI® (INSULIN ICODEC-ABAE), GLIPIZIDE 15MG TABLET, KIRSTY™ (INSULIN ASPART-XJHZ), AND LANGLARA™ (INSULIN GLARGINE-ALDY)

15A: CURRENT PRIOR AUTHORIZATION CRITERIA
15B: UTILIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
15C: PRIOR AUTHORIZATION OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)
15D: MARKET NEWS AND UPDATES
15E: AWIQLI® (INSULIN ICODEC-ABAE) PRODUCT SUMMARY
15F: COLLEGE OF PHARMACY RECOMMENDATIONS
15G: UTILIZATION DETAILS OF ANTI-DIABETIC MEDICATIONS AND KERENDIA® (FINERENONE)

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

AGENDA ITEM NO. 16: ANNUAL REVIEW OF HEART FAILURE (HF) MEDICATIONS AND 30-DAY NOTICE TO PRIOR AUTHORIZE ENBUMYST™ (BUMETANIDE NASAL SPRAY), LASIX® ONYU (FUROSEMIDE ON-BODY INFUSOR), AND MYQORZO™ (AFICAMTEN)

16A: CURRENT PRIOR AUTHORIZATION CRITERIA
16B: UTILIZATION OF HF MEDICATIONS
16C: PRIOR AUTHORIZATION OF HF MEDICATIONS
16D: MARKET NEWS AND UPDATES
16E: PRODUCT SUMMARIES
16F: COLLEGE OF PHARMACY RECOMMENDATIONS

16G: UTILIZATION DETAILS OF HF MEDICATIONS
Materials included in agenda packet; presented by Dr. Grimes
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® IQLIK™ (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: COLLEGE OF PHARMACY RECOMMENDATIONS
17F: UTILIZATION DETAILS OF ALZHEIMER'S DISEASE MEDICATIONS
Materials included in agenda packet; presented by Dr. Dorsey
ACTION: NONE REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER

AGENDA ITEM NO. 18: ANNUAL REVIEW OF TESTOSTERONE PRODUCTS
18A: CURRENT PRIOR AUTHORIZATION CRITERIA
18B: UTILIZATION OF TESTOSTERONE PRODUCTS
18C: PRIOR AUTHORIZATION OF TESTOSTERONE PRODUCTS
18D: MARKET NEWS AND UPDATES
18E: COLLEGE OF PHARMACY RECOMMENDATIONS
18F: UTILIZATION DETAILS OF TESTOSTERONE PRODUCTS
Non-presentation item; materials included in agenda packet by Dr. Wilson
ACTION: NONE REQUIRED

AGENDA ITEM NO. 19: U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTATION (DEA) UPDATES
Non-presentation item; materials included in agenda packet by Dr. DeRemer
ACTION: NONE REQUIRED

AGENDA ITEM NO. 20: FUTURE BUSINESS* (UPCOMING PRODUCT AND CLASS REVIEWS)
NO LIVE DUR MEETING IS SCHEDULED FOR AUGUST 2026. AUGUST 2026 WILL BE A PACKET ONLY MEETING
24A: COPPER METABOLISM DISORDER MEDICATIONS
24B: IRON CHELATING AGENTS
24C: IRON PRODUCTS
24D: MISCELLANEOUS CANCER MEDICATIONS
24E: OPIOID ANALGESICS AND MEDICATION-ASSISTED TREATMENT (MAT) MEDICATIONS
24F: TOPICAL CORTICOSTEROIDS
24G: VARIOUS SYSTEMIC ANTIBIOTICS
*Future product and class reviews subject to change.
Non-presentation item; materials included in agenda packet by Dr. Adams
ACTION: NONE REQUIRED

AGENDA ITEM NO. 21: ADJOURNMENT
The meeting was adjourned at 5:34pm.

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

Memorandum

Date: July 9, 2026

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 8, 2026

Recommendation 1: Update on Medication Coverage Authorization Unit

NO ACTION REQUIRED.

Recommendation 2: Chronic Medication Adherence (CMA) Program Update

NO ACTION REQUIRED.

Recommendation 3: Vote to Prior Authorize Nereus™ (Tradipitant) and Posfrea™ (Palonosetron Injection) and Update the Approval Criteria for the Anti-Emetic Medications

MOTION CARRIED by unanimous approval.

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

Nereus™ (Tradipitant) Approval Criteria:

1. An FDA approved indication for the prevention of vomiting induced by motion; and
2. Member must be 18 years of age or older; and
3. Member must have a history of vomiting induced by motion; and

4. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention of vomiting induced by motion (i.e., Dramamine®, meclizine, scopolamine) must be provided; and
5. Approval length will be based on the duration of need which must be documented on the request; and
6. Approval of the 170mg dose will require documentation of failure at the lower dose; and
7. A quantity limit of 16 capsules per 30 days will apply.

The College of Pharmacy recommends the prior authorization of Posfrea™ (palonosetron injection) with criteria similar to the criteria for palonosetron 0.25mg/5mL single-dose prefilled syringes (changes shown in red):

Palonosetron 0.25mg/5mL Single-Dose Prefilled Syringe and Posfrea™ (Palonosetron 0.25mg/5mL Injection) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic Aloxi® (palonosetron 0.25mg/5mL), which is available without a prior authorization, must be provided.

Recommendation 4: Vote to Prior Authorize Bysanti™ (Milsaperidone) 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 (changes noted in red in the following PBPA Tier chart and approval criteria):

1. Creation of a new Special Prior Authorization (PA) Tier and criteria based on net costs; and
2. Updating the trial requirements for Tier-2, Tier-3, and the Special PA Tier based on DUR Board feedback and discussion; and
3. Prior authorization of Bysanti™ (milsaperidone) and placement into the Special PA Tier with additional approval criteria; and
4. Moving Latuda® (lurasidone) from Tier-2 to Tier-1 based on net costs; and
5. Moving Lybalvi® (olanzapine/samidorphan) from Tier-3 to the Special PA Tier based on net costs and updating the Lybalvi® approval criteria based on the recommended Tier changes and clinical practice; and
6. Moving Caplyta® (lumateperone), Cobenfy™ (xanomeline/trospium), Fazaclo® (clozapine orally disintegrating tablet), Opipza™ (aripiprazole oral film), quetiapine 150mg tablet, Secuado® (asenapine transdermal system), Symbyax® (olanzapine/fluoxetine), and Versacloz® (clozapine oral suspension) from Tier-3 to the Special PA Tier based on net costs; and

7. Moving Risperdal Consta® (risperidone IM injection) and Rykindo® (risperidone IM injection) to the Special PA Tier, designating Risperdal Consta® as brand preferred, and updating the Long-Acting Injectable (LAI) Products Approval Criteria based on net costs; and
8. Updating the Atypical Antipsychotic Medications as Adjunctive Treatment of MDD Approval Criteria based on the FDA approval of Caplyta® for this indication and net costs.

Atypical Antipsychotic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
aripiprazole ODT, sol, & tab (Abilify®)¥	asenapine sublingual tab (Saphris®)	~~**aripiprazole oral film (Opipza™)⁺**~~	**aripiprazole oral film (Opipza™)⁺**
clozapine tab (Clozaril®)◊	iloperidone tab (Fanapt®)	~~**asenapine transdermal system (Secuado®)⁺**~~	**asenapine transdermal system (Secuado®)⁺**
lurasidone tab (Latuda®)	~~**lurasidone tab (Latuda®)**~~	brexpiprazole tab (Rexulti®)**~**	**clozapine ODT (Fazaclo®)⁺**
olanzapine IM inj, ODT, & tab (Zyprexa®)	paliperidone ER tab (Invega®)	cariprazine cap (Vraylar®)**~**	**clozapine oral susp (Versacloz®)⁺**
quetiapine tab (Seroquel®)		~~**clozapine ODT (Fazaclo®)⁺**~~	**lumateperone cap (Caplyta®)~**
quetiapine ER tab (Seroquel XR®)		~~**clozapine oral susp (Versacloz®)⁺**~~	**milsaperidone tab (Bysanti™)⁺**
risperidone ODT, sol, & tab (Risperdal®)		~~**lumateperone cap (Caplyta®)**~~	**olanzapine/fluoxetine cap (Symbyax®)⁺**
ziprasidone cap & IM inj (Geodon®)		~~**olanzapine/fluoxetine cap (Symbyax®)⁺~**~~	**olanzapine/samidorphan tab (Lybalvi®)ᵝ**
		~~**olanzapine/samidorphan tab (Lybalvi®)ᵝ**~~	**quetiapine 150mg tab⁺**
		~~**quetiapine 150mg tablets⁺**~~	
Unique Mechanisms of Action			
		~~**xanomeline/trospium (Cobenfy™)**~~	**xanomeline/trospium (Cobenfy™)**
Long-Acting Injectables (LAIs)^			
aripiprazole IM inj (Abilify Asimtufii®)^		~~**risperidone IM inj (Risperdal Consta®)^∞**~~	**risperidone IM inj (Risperdal Consta®)^∞**
aripiprazole IM inj (Abilify Maintena®)^		~~**risperidone IM inj (Rykindo®)^∞**~~	**risperidone IM inj (Rykindo®)^∞**
aripiprazole lauroxil IM inj (Aristada®)^			
aripiprazole lauroxil IM inj (Aristada Initio®)^			
olanzapine pamoate IM inj (Zyprexa® Relprevv™)			
paliperidone palmitate IM inj (Erzofri®)^			

Atypical Antipsychotic Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
paliperidone palmitate IM inj (Invega Hafyera®)^			
paliperidone palmitate IM inj (Invega Sustenna®)^			
paliperidone palmitate IM inj (Invega Trinza®)^			
risperidone ER sub-Q inj (Perseris®)^			
risperidone sub-Q inj (Uzedy®)^			

*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.

cap = capsule; ER = extended-release; IM = intramuscular; inj = injection; ODT = orally disintegrating tablet; sol = solution; sub-Q = subcutaneous; susp = suspension; tab = tablet

¥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.

^Use of a long-acting injectable 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 ~~in addition to tier trial requirements.~~

ᵝUnique criteria applies to Lybalvi® (olanzapine/samidorphan).

ᵒᵒUnique criteria applies to ~~Tier-3~~ Special PA long-acting injectable (LAI) products.

~Unique criteria applies for a diagnosis of adjunctive treatment of major depressive disorder (MDD).

Atypical Antipsychotic Medications Tier-2 Approval Criteria:

1. Trials of 2 Tier-1 medications ~~A Tier-1 trial at least 14 days in duration each, titrated to recommended dose,~~ that did not yield an adequate response or resulted in intolerable adverse effects; ~~and~~ or
2. Members currently stable on a Tier-2 medication may be approved for continuation of therapy.

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~~

~~2. Trials of 2 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. Trials of 3 Tier-1 and Tier-2 medications (at least 2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; or
5. Members currently stable on a Tier-3 medication may be approved for continuation of therapy.~~; and~~

~~6. 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~~

~~7. Use of Opipza™ (aripiprazole oral film) will require a patient-specific, clinically significant reason why the member cannot use the oral tablet or oral disintegrating tablet formulation; and~~

~~8. 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~~

~~9. 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~~

~~10. Use of Symbyax® (olanzapine/fluoxetine) requires a patient-specific, clinically significant reason why the member cannot use olanzapine and fluoxetine as individual components.~~

Atypical Antipsychotic Medications Special PA Approval Criteria:

~~1. Trials of 1 Tier-1 medications, 1 Tier-2 medication, and 2 Tier-3 medication at least 14 days in duration, titrated to recommended dose, which did not yield adequate response or resulted in intolerable adverse effects; or~~

~~2. Member has had at least 5 trials of Tier-1, Tier-2, and Tier-3 medications (2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; and~~

3. Trials of 4 Tier-1, Tier-2, and Tier-3 medications (at least 2 trials must be from Tier-1) that did not yield an adequate response or resulted in intolerable adverse effects; or
4. Members currently stable on a Special PA medication may be approved for continuation of therapy.
5. Use of Bysanti™ (milsaperidone) will require a patient-specific, clinically significant reason why the member cannot use Fanapt® (iloperidone). Tier structure rules continue to apply.
6. 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.

7. Use of Opipza™ (aripiprazole oral film) will require a patient-specific, clinically significant reason why the member cannot use the oral tablet or oral disintegrating tablet formulation.
8. 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.
9. 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.
10. 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 Antipsychotic Medications as Adjunctive Treatment of Major Depressive Disorder (MDD):

1. Authorization of Caplyta® (lumateperone), ~~Symbyax® (olanzapine/fluoxetine),~~ Rexulti® (brexpiprazole), 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. For Caplyta®, a patient-specific, clinically significant reason why the member cannot use Rexulti® and Vraylar® must be provided; and
3. Members currently stable on the requested medication may be approved for continuation of therapy; and
4. Tier structure rules still apply.

Long-Acting Injectable (LAI) Products ~~Tier 3~~ Special PA 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; and
2. Risperdal Consta® [risperidone intramuscular (IM) injection] is brand preferred. Requests for generic risperidone IM injection will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
3. Requests for Rykindo® (risperidone IM injection) will require a patient-specific, clinically significant reason why the member cannot use brand name Risperdal Consta®; and
4. Members currently stable on the requested medication may be approved for continuation of therapy.

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 meet 1 of the following:

a. Member has a positive clinical response to olanzapine and experienced weight gain ≥7% from baseline body weight or other metabolic complications [e.g., increased waist circumference, increased metabolic parameters, worsening diabetes (i.e., increased A1c or glucose despite optimal adherent therapy for diabetes)] after starting olanzapine (baseline and current weight must be provided or documentation of metabolic complications); or
b. Member has a trial of ~~one Tier-1 and one Tier-2~~ 2 lower-tiered medications with a lower weight gain or metabolic profile (e.g., aripiprazole, ziprasidone, lurasidone, brexpiprazole), at least 14 days in duration each, titrated to recommended dose, that did not yield adequate response or resulted in intolerable adverse effects; and

4. Member must not be taking opioids or undergoing acute opioid withdrawal; and
5. Initial approvals will be for 6 ~~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) or has had no increase or worsening in metabolic complications (documentation must be provided) while on therapy must be provided. Subsequent approvals will be for the duration of 1 year.

Recommendation 5: Vote to Prior Authorize Hepcludex® (Bulevirtide-gmod), Relenza® (Zanamivir Inhalation Powder), and Xofluza® (Baloxavir) and Update the Approval Criteria for the Antiviral Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Hepcludex® (bulevirtide-gmod) with the following criteria (shown in red):

Hepcludex® (Bulevirtide-gmod) Approval Criteria:

1. An FDA approved diagnosis of chronic hepatitis D virus (HDV) infection; and
2. Diagnosis must be confirmed by all of the following test results conducted within the last 6 months (results must be submitted with the request):
   a. Detectable serum HDV RNA level; and
   b. Elevated alanine aminotransferase (ALT) levels between 1 and 10 times the upper limit of normal; and
3. Member must not have decompensated cirrhosis or hepatocellular carcinoma (HCC); and
4. Member must be 18 years of age or older; and
5. Must be prescribed by a gastroenterologist, hepatologist, or infectious disease specialist; and
6. Prescriber must verify that underlying hepatitis B virus (HBV) infection will be managed as clinically appropriate; and

7. Prescriber must verify that the member or caregiver will be trained on the proper storage, reconstitution, and administration of Hepcludex®; and
8. A quantity limit of 30 vials per 30 days will apply; and
9. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment as indicated by all of the following (results of testing must be submitted with the request):
    a. Undetectable HDV RNA or a ≥2 $\log_{10}$ IU/mL reduction in HDV RNA from baseline; and
    b. A reduction or normalization of ALT; and
    c. Member has not developed decompensated cirrhosis or HCC; and
    d. Member has not undergone a liver transplant.

The College of Pharmacy also recommends the prior authorization of Relenza® (zanamivir inhalation powder) and Xofluza® (baloxavir) based on net costs with the following criteria (shown in red):

Relenza® (Zanamivir Inhalation Powder) and Xofluza® (Baloxavir) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Treatment of acute uncomplicated influenza in members who have been symptomatic for no more than 48 hours; or
    b. Post-exposure prophylaxis of influenza following contact with an individual who has influenza; and
2. Member must be 5 years of age or older; and
3. A patient specific, clinically significant reason (beyond convenience) why the member cannot use oseltamivir (generic Tamiflu®), which is available without prior authorization, must be provided.

The College of Pharmacy also recommends updating the Epclusa® (sofosbuvir/velpatasvir), Sovaldi® (sofosbuvir tablets and oral pellets), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), and Zepatier® (elbasvir/grazoprevir) prior authorization criteria based on clinical practice, for consistency with criteria for other Hepatitis C medications, and for clarity, including the DUR Board's recommendation for clarification of the specialist evaluation *for hepatitis C treatment* to the Sovaldi® and Zepatier® criteria for consistency (changes shown in red):

Epclusa® (Sofosbuvir/Velpatasvir) Tablets and Pellets Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) ~~genotype 1, genotype 2, genotype 3, genotype 4, genotype 5, or genotype 6;~~ and
3. All of the following test results must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 12 months; and

b. Liver fibrosis assessment (METAVIR equivalent); and
c. HCV genotype (only for members with cirrhosis or being evaluated for retreatment); and
i. Baseline resistance-associated substitution (RAS) testing for members with genotype 3 and compensated cirrhosis; and

4. For members with decompensated cirrhosis or being evaluated for retreatment, Epclusa® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and

~~5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and~~

~~6. Member has chronic HCV infection defined by:~~

~~a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or~~

~~b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~

~~i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or~~

~~ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and~~

~~7. The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:~~

~~a. Genotype 1, 2, 3, 4, 5, 6:~~

~~i. Treatment-naïve or treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A):~~

~~1. Epclusa® for 12 weeks~~

~~ii. Treatment-naïve or treatment-experienced with decompensated cirrhosis (Child-Pugh B and C):~~

~~1. Epclusa® + weight-based ribavirin for 12 weeks~~

~~b. New regimens will apply as approved by the FDA~~

8. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
9. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
10. Member must sign and submit the Hepatitis C Intent to Treat contract; and
11. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and

~~12. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and~~

13. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
14. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
15. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin users); and

~~16. Member must not be taking the following medications: H2-receptor antagonists at doses >40mg famotidine equivalent, amiodarone, omeprazole or other proton pump inhibitors, topotecan, rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, efavirenz, tenofovir disoproxil fumarate, tipranavir/ritonavir, St. John's wort, and rosuvastatin doses >10mg; and~~

~~17. If member is using antacids, they must agree to separate antacid and Epclusa® administration by 4 hours; and~~

18. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Epclusa® and agree to address interactions with concomitant medications according to package labeling; and

~~19. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and~~

20. Member must not have a limited life expectancy (<12 months) that cannot be remediated by treating ~~hepatitis C virus (~~HCV~~)~~, liver transplantation, or another direct therapy; and
21. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
        ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
        iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis

should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and

22. ~~Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.~~
23. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Sovaldi® (Sofosbuvir Tablets and Oral Pellets) Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) ~~genotype-1, genotype-2, genotype-3, or genotype-4~~; and
3. Sovaldi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and
4. Sovaldi must be used as a component of a combination regimen; and
5. ~~Member must be eligible for ribavirin (RBV) or daclatasvir therapy. Approvals will not be granted for regimens without RBV or daclatasvir; and~~
6. Member must not have decompensated cirrhosis; and
7. All of the following must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 6 months; and
    b. Liver fibrosis assessment (METAVIR equivalent); and
    c. HCV genotype testing; and
    d. For treatment experienced members, prior HCV treatment regimens; and
8. ~~Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and~~
9. ~~Member has chronic HCV infection defined by:~~
    a. ~~If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only 1 detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or~~
    b. ~~If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~
        i. ~~Positive (i.e., reactive) HCV antibody test and has a recent (within the last 3 months) detectable and quantifiable HCV RNA (>15 IU/mL); or~~
        ii. ~~Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and~~
10. ~~The following regimens and requirements based on genotype, prior treatment experience, and cirrhosis status will apply:~~

~~a. Genotype 1:~~
~~i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~a. Genotype 2:~~
~~i. Treatment-naïve, non-cirrhotic:~~
~~1. Sovaldi® with weight-based ribavirin for 12 weeks~~
~~ii. Treatment-naïve, cirrhotic:~~
~~1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks~~
~~iii. Treatment-experienced, non-cirrhotic or cirrhotic:~~
~~1. Sovaldi® with weight-based ribavirin for 12 or 16 weeks~~
~~2. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~b. Genotype 3:~~
~~i. Treatment-naïve, non-cirrhotic~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)~~
~~ii. Treatment-naïve, cirrhotic~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)~~
~~iii. Treatment-experienced, non-cirrhotic~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)~~
~~iv. Treatment-experienced, cirrhotic~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~2. Sovaldi® with weight-based ribavirin for 24 weeks (if interferon ineligible)~~
~~c. Genotype 4:~~
~~i. Treatment-naïve or experienced, non-cirrhotic or cirrhotic:~~
~~1. Sovaldi® with weight-based ribavirin and peginterferon alfa for 12 weeks~~
~~d. New regimens will apply as approved by the FDA.~~

11. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
12. Members who are older than 6 years of age and request the oral pellet formulation of Sovaldi® must provide a patient-specific, clinically significant reason for use of the oral pellet formulation in place of the tablet formulation; and

13. Member must sign and submit the Hepatitis C Intent to Treat contract; and
14. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
~~15. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and~~
16. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
17. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
18. Female members must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin members); and
~~19. Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, phenytoin, oxcarbazepine, tipranavir/ritonavir, didanosine or St. John's wort; and~~
20. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Sovaldi® and agree to address interactions with concomitant medications according to package labeling; and
~~21. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and~~
22. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
23. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
        ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
        iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a

gastroenterologist, infectious disease specialist, or transplant specialist; and

~~24. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.~~

25. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Vosevi® (Sofosbuvir/Velpatasvir/Voxilaprevir) Approval Criteria:

1. Member must be 18 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) genotype 1, genotype 2, genotype 3, genotype 4, genotype 5, or genotype 6; and
3. Vosevi® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and

~~4. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on the prior authorization request; and~~

5. Member must not have decompensated cirrhosis or moderate or severe hepatic impairment (Child-Pugh B or C); and
6. All of the following must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 6 months; and
    b. Liver fibrosis assessment (METAVIR equivalent); and
    c. HCV genotype testing; and
    d. For treatment experienced members, prior HCV treatment regimens; and

~~7. Member has chronic HCV infection defined by:~~

~~a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or~~

~~b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~

~~i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or~~

~~ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and~~

~~8. The following regimens and requirements based on treatment history will apply:~~

~~a. Adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A):~~

i. ~~Genotype 1, 2, 3, 4, 5, or 6 patients who were previously treated with an HCV regimen containing an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir): Vosevi® for 12 weeks; or~~

ii. ~~Genotype 1a or 3 patients who were previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor: Vosevi® for 12 weeks; or~~

~~b. New regimens will apply as approved by the FDA; and~~

7. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
8. Member must sign and submit the Hepatitis C Intent to Treat contract; and
9. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
10. ~~The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and~~
11. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
12. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
13. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating HCV, liver transplantation, or another directed therapy; and
14. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin users); and
15. ~~Member must not be taking the following medications: H2-receptor antagonists at doses greater than 40mg famotidine twice daily equivalent, omeprazole doses greater than 20mg daily or other proton pump inhibitors, amiodarone, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, St. John's wort, pravastatin doses greater than 40mg daily, rosuvastatin, pitavastatin, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan; and~~
16. ~~If member is using antacids they must agree to separate antacid and Vosevi® administration by four hours; and~~
17. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Vosevi® and agree to address interactions with concomitant medications according to package labeling; and
18. ~~All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia,~~

~~anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and~~

19. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
        ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
        iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and

~~20. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy; and~~

21. Approvals for treatment regimen initiation for 12 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Zepatier® (Elbasvir/Grazoprevir) Approval Criteria:

1. Member must be 12 years of age or older or weigh at least 30kg; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) genotype-1 or genotype-4; and
3. Member must not have decompensated cirrhosis or moderate-to-severe hepatic impairment (Child-Pugh B and C); and
4. Zepatier® must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist for hepatitis C therapy within the last 3 months; and

~~5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and~~

6. All of the following must be indicated on the initial prior authorization request:
    a. Detectable hepatitis C virus (HCV) RNA test within the last 6 months; and
    b. Liver fibrosis assessment (METAVIR equivalent); and
    c. HCV genotype testing; and

i. Baseline resistance-associated substitution (RAS) testing for members with genotype 1a; and

d. Prior DAA regimens; and

~~7. If the member has genotype 1a, testing results for the presence of virus with NS5A resistance-associated polymorphisms must be indicated on the prior authorization request; and~~

~~8. Member has chronic HCV infection defined by:~~

~~a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required; or~~

~~b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:~~

~~i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or~~

~~ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and~~

~~9. The following regimens and requirements based on genotype, polymorphisms, and prior treatment status will apply (all regimens apply to patients with and without cirrhosis, HIV/HCV co-infected patients, and patients with or without renal impairment):~~

~~a. Genotype 1a, treatment-naïve or peginterferon alfa + ribavirin experienced without baseline NS5A polymorphisms:~~

~~i. Zepatier® for 12 weeks~~

~~b. Genotype 1a, treatment-naïve or peginterferon alfa + ribavirin experienced with baseline NS5A polymorphisms:~~

~~i. Zepatier® with weight-based ribavirin for 16 weeks~~

~~c. Genotype 1b, treatment-naïve or peginterferon alfa + ribavirin experienced:~~

~~i. Zepatier® for 12 weeks~~

~~d. Genotype 1a or 1b, peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, teleprevir) experienced:~~

~~i. Zepatier® with weight-based ribavirin for 12 weeks~~

~~e. Genotype 4, treatment-naïve:~~

~~i. Zepatier® for 12 weeks~~

~~f. Genotype 4, treatment-experienced:~~

~~i. Zepatier® with weight-based ribavirin for 16 weeks~~

~~g. New regimens will apply as approved by the FDA~~

10. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
11. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and

12. Member must sign and submit the Hepatitis C Intent to Treat contract; and
13. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
~~14. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Viral Response (SVR-12); and~~
15. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
16. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
17. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for ribavirin users); and
~~18. The prescriber must verify that the member's ALT levels will be monitored prior to treatment initiation, at treatment week eight, and as clinically indicated thereafter (patients receiving 16 weeks of therapy should receive additional ALT levels at treatment week 12); and~~
~~19. Member must not be taking the following medications: phenytoin, carbamazepine, rifampin, St. John's wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, bosentan, etravirine, elvitegravir/cobicstat/emtricitabine/tenofovir, or modafinil; and~~
20. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Zepatier® and agree to address interactions with concomitant medications according to package labeling; and
~~21. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease, or autoimmune thyroid disease; and~~
22. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating hepatitis C virus (HCV), liver transplantation, or another directed therapy; and
23. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and

ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and

~~24. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.~~

25. Approvals for treatment regimen initiation for 12 or 16 weeks of therapy will not be granted prior to the 10th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Lastly, the College of Pharmacy recommends updating the Harvoni® (ledipasvir/sofosbuvir tablets and oral pellets) prior authorization criteria based on net costs and clinical practice and for clarity (changes shown in red):

Harvoni® (Ledipasvir/Sofosbuvir Tablets and Oral Pellets) Approval Criteria:

1. Member must be 3 years of age or older; and
2. An FDA approved diagnosis of chronic hepatitis C (CHC) genotype-1, genotype-4, genotype-5, or genotype-6; and

~~3. Request for the generic formulation will require a patient-specific, clinically significant reason the member cannot use the brand formulation; and~~

4. Harvoni must be prescribed by a gastroenterologist, infectious disease specialist, or transplant specialist or the member must have been evaluated for hepatitis C treatment by a gastroenterologist, infectious disease specialist, or transplant specialist within the last 3 months; and

~~5. Hepatitis C Virus (HCV) genotype testing must be confirmed and indicated on prior authorization request; and~~

6. All of the following test results must be indicated on the initial prior authorization request:
   a. Detectable hepatitis C virus (HCV) RNA test within the last 6 months; and
   b. Liver fibrosis assessment (METAVIR equivalent); and
   c. HCV genotype testing; and

~~7. Member has chronic HCV infection defined by:~~
   ~~a. If the member has a liver fibrosis score ≥F1 (METAVIR equivalent) then only one detectable and quantifiable HCV RNA (>15 IU/mL) test within the last 12 months is required (must be within last 3 months if requesting 8-week regimen); or~~

b. If the member has a liver fibrosis score <F1 (METAVIR equivalent) then the following must be met:
    i. Positive (i.e., reactive) HCV antibody test that is at least 6 months old and has a detectable and quantifiable HCV RNA (>15 IU/mL) test 6 months after date of positive HCV antibody test; or
    ii. Two detectable and quantifiable HCV RNA (>15 IU/mL) tests at least 6 months apart; and

8. The following regimens and requirements based on prior treatment experience, baseline viral load, and cirrhosis will apply:
    a. Genotype 1:
        i. Treatment-naïve without cirrhosis who have a pre-treatment HCV-RNA less than 6 million IU/mL:
            1. Harvoni for 8 weeks
        ii. Treatment-naïve with or without compensated cirrhosis:
            1. Treatment-naïve patients who are cirrhotic or have a pre-treatment HCV-RNA greater than 6 million IU/mL
            2. Harvoni for 12 weeks
        iii. Treatment-experienced without cirrhosis:
            1. Harvoni for 12 weeks
        iv. Treatment-experienced with compensated cirrhosis:
            1. Harvoni with weight-based ribavirin for 12 weeks
            2. Harvoni for 24 weeks
        v. Treatment-naïve or treatment-experienced with decompensated cirrhosis:
            1. Harvoni with weight-based ribavirin for 12 weeks
    b. Genotype 1 or Genotype 4:
        i. Treatment-naïve or treatment-experienced liver transplant recipients with or without compensated cirrhosis:
            1. Harvoni with weight-based ribavirin for 12 weeks
    c. Genotype 4, Genotype 5, or Genotype 6:
        ii. Treatment-naïve or treatment-experienced with or without compensated cirrhosis:
            1. Harvoni for 12 weeks
    d. New regimens will apply as approved by the FDA
9. Request must be for an FDA approved or American Association for the Study of Liver Diseases (AASLD) recommended treatment regimen; and
10. A patient specific, clinically significant reason why the member cannot use Mavyret® (glecaprevir/pibrentasvir), which is available without prior authorization, must be provided; and
11. Members who are older than 6 years of age and request the oral pellet formulation of Harvoni must provide a patient-specific, clinically significant reason for use of the oral pellet formulation in place of the tablet formulation; and

11. Member must sign and submit the Hepatitis C Intent to Treat contract; and
12. Member's pharmacy must submit the Hepatitis C Therapy Pharmacy Agreement for each member on therapy; and
~~13. The prescriber must verify that they will provide SoonerCare with all necessary labs to evaluate hepatitis C therapy efficacy including Sustained Virologic Response (SVR-12); and~~
14. Prescriber must agree to counsel members on potential harms of illicit IV drug use or alcohol use; and
15. Must have documentation of initiation of immunization with the hepatitis A and B vaccines; and
16. Female members must not be pregnant and must have a pregnancy test immediately prior to therapy initiation. Male and female members must be willing to use 2 forms of non-hormonal birth control while on therapy (and for 6 months after therapy completion for those on ribavirin); and
~~17. Member must not be taking the following medications: rifampin, rifabutin, rifapentine, carbamazepine, eslicarbazepine, phenytoin, phenobarbital, oxcarbazepine, tipranavir/ritonavir, simeprevir, rosuvastatin, St. John's wort, or elvitegravir/cobicistat/emtricitabine in combination with tenofovir disoproxil fumarate; and~~
18. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Harvoni® and agree to address interactions with concomitant medications according to package labeling; and
~~19. All other clinically significant issues must be addressed prior to starting therapy including but not limited to the following: neutropenia, anemia, thrombocytopenia, surgery, depression, psychosis, epilepsy, obesity, weight management, severe concurrent medical diseases, such as but not limited to, retinal disease or autoimmune thyroid disease; and~~
20. Member must not have a limited life expectancy (less than 12 months) that cannot be remediated by treating ~~hepatitis C virus (~~HCV~~)~~, liver transplantation, or another directed therapy; and
21. Prescribing physician must verify that they will work with the member to ensure the member remains adherent to hepatitis C therapies; and
    a. Incomplete adherence with treatment gaps longer than 7 days must be addressed by all of the following for continued approval:
        i. Provider must agree to counsel the member on the importance of adherence to treatment and about factors contributing to incomplete adherence; and
        ii. Clinical documentation describing the treatment interruption and reinitiation plan must be submitted with the request; and
        iii. Incomplete adherence in members with prior direct-acting antiviral (DAA) treatment (i.e., treatment-experienced

members), post-liver transplant, or decompensated cirrhosis should be managed by, or in consultation with, a gastroenterologist, infectious disease specialist, or transplant specialist; and

~~22. Members must be adherent for continued approval. Treatment gaps of therapy longer than 3 days/month will result in denial of subsequent requests for continued therapy.~~

23. Approvals for treatment regimen initiation for 8 or 12 weeks of therapy will not be granted prior to the 10th of a month, and for 24 weeks of therapy prior to the 15th of a month in order to prevent prescription limit issues from affecting the member's compliance.

Recommendation 6: Vote to Prior Authorize Loargys® (Pegzilarginase-nbln) and Update the Approval Criteria for the Urea Cycle Disorder (UCD) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Loargys® (pegzilarginase-nbln) with the following criteria (shown in red):

Loargys® (Pegzilarginase-nbln) Approval Criteria:

1. An FDA approved diagnosis of arginase 1 deficiency (ARG1-D); and
    a. Diagnosis of ARG1-D must be confirmed by 1 of the following (results of the selected test must be submitted with the request):
        i. Persistently elevated plasma arginine levels; or
        ii. Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the *ARG1* gene; or
        iii. Diminished erythrocyte ARG1 activity; and
2. Member must be 2 years of age or older; and
3. Loargys® must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of ARG1-D; and
4. Loargys® must be administered under the ~~direct~~ supervision of a health care provider; and
5. Active management with a protein restricted diet; and
6. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the package labeling; and
7. The maximum approvable dose of Loargys® is 0.2mg/kg once weekly; and
8. Initial approvals will be for 6 months. Subsequent approvals for the duration of 1 year will be approved if the prescriber documents the member is responding to treatment (i.e., reduction or normalization in plasma arginine levels); and
9. A quantity limit of 12mL per 28 days will apply. For members who require doses exceeding this quantity limit, a quantity limit override

may be approved with the submission of supporting clinical documentation.

Additionally, the College of Pharmacy recommends updating the approval criteria for Carbaglu® (carglumic acid) based on clinical practice (changes shown in red):

Carbaglu® (Carglumic Acid) Approval Criteria:

1. An indication of the treatment of acute or chronic hyperammonemia due to 1 of the following:
   a. N-acetylglutamate synthase (NAGS) deficiency; or
   b. Propionic acidemia (PA) or methylmalonic acidemia (MMA); and
2. ~~An FDA approved indication of 1 of the following:~~
   ~~a. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; or~~
   ~~b. Maintenance therapy for the treatment of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency; or~~
   ~~c. Adjunctive therapy to the standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA); and~~
3. Carbaglu® must be prescribed by a geneticist or in consultation with a geneticist; and
4. Carbaglu® is brand preferred; use of generic carglumic acid will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
5. For a diagnosis of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency:
   a. Documentation of active management with a low protein diet; and
   b. Initial approvals will be for the duration of 1 year. After that time, reauthorization will require the prescriber to verify the member is responding to therapy; or
6. ~~For a diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA):~~
   ~~a. Documentation the member's plasma ammonia level is ≥50micromol/L; and~~
   ~~b. Prescriber must confirm Carbaglu® is being used concurrently with other ammonia-lowering therapies [e.g., intravenous (IV) glucose, insulin, L-carnitine, protein restriction, dialysis]; and~~
   ~~c. Number of days Carbaglu® was received while hospitalized must be provided; and~~
   ~~d. Approvals will be for no longer than 7 days total (including treatment days while hospitalized) as there is currently no evidence to support the use of Carbaglu® for acute hyperammonemia due to~~

~~propionic acidemia (PA) or methylmalonic acidemia (MMA) beyond 7 days.~~

7. For a diagnosis of hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA):
   a. Prescriber must confirm Carbaglu® is being used concurrently with standard of care treatment (e.g., L-carnitine, metronidazole, protein-restricted diet); and
   b. Initial approvals will be for the duration of 6 months. Subsequent approvals, for the durations of 1 year, may be granted if the prescriber attests that the member is tolerating and responding well to therapy.

Lastly, the College of Pharmacy recommends updating the approval criteria for Olpruva® (sodium phenylbutyrate pellets for oral suspension) and Pheburane® (sodium phenylbutyrate oral pellets) based on clinical practice and recommends updating the approval criteria for Ravicti® (glycerol phenylbutyrate) based on clinical practice and net cost (changes shown in red):

Olpruva® (Sodium Phenylbutyrate Pellets for Oral Suspension) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. Olpruva® must be prescribed by, or in consultation with, a geneticist; and
4. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
6. A maximum daily dose of 20g of sodium phenylbutyrate will apply.

Pheburane® (Sodium Phenylbutyrate Oral Pellets) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. Pheburane® must be prescribed by, or in consultation with, a geneticist; and
4. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
5. A maximum daily dose of 20g sodium phenylbutyrate will apply; and

6. A quantity limit of 1,218g of pellets (equivalent to 588g of sodium phenylbutyrate) per 29 days will apply.

Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Active management with a protein restricted diet; and
3. ~~A patient-specific, clinically significant reason why member cannot use Buphenyl (sodium phenylbutyrate) must be provided; and~~
4. ~~A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and~~
5. Ravicti® must be prescribed by, or in consultation with, a geneticist; and
6. Ravicti® is brand preferred; use of generic glycerol phenylbutyrate will require a patient-specific, clinically significant reason why the member cannot use the brand formulation; and
7. A maximum daily dose of 17.5mL (19g) of glycerol phenylbutyrate will apply; and
8. A quantity limit of 525mL per 30 days will apply.

Recommendation 7: Vote to Prior Authorize Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Cafergot® (Ergotamine/Caffeine Tablet), Desmoda™ (Desmopressin Oral Solution), Dicyclomine 40mg Tablet, Griseofulvin Ultramicrosize 165mg Tablet, Hydroxyzine Oral Solution Unit Dose Cups (UDCs), Khindivi™ (Hydrocortisone Oral Solution), Migergot® (Ergotamine/Caffeine Suppository), Ontralfy™ (Tizanidine Oral Solution), PoKonza™ (Potassium Chloride 10mEq/15mL Oral Solution), PoKonza™ (Potassium Chloride 15mEq Packet), Potassium Chloride 40mEq Packet, Quiofic™ (Folic Acid Oral Solution), Relgaabi™ (Gabapentin 200mg Capsule), and Vykoura™ (Leucovorin Injection) and Update the Approval Criteria for the Various Special Formulations

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the prior authorization of Averi™ (desogestrel/ethinyl estradiol/ferrous sulfate) with criteria similar to Femlyv™ [norethindrone acetate/ethinyl estradiol orally disintegrating tablet (ODT)], Nextstellis® (drospirenone/estetrol tablet) and Slynd® (drospirenone tablet) with the following criteria (shown in red):

Averi™ (Desogestrel/Ethinyl Estradiol/Ferrous Bisglycinate), Femlyv™ [Norethindrone Acetate and Ethinyl Estradiol Orally Disintegrating Tablet (ODT)], Nextstellis® (Drospirenone/Estetrol Tablet), and Slynd® (Drospirenone Tablet) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all alternative formulations of hormonal contraceptives available without prior authorization must be provided.

The College of Pharmacy recommends the prior authorization of Cafergot® (ergotamine/caffeine tablets) and Migergot® (ergotamine/caffeine suppository) with placement into the Special Prior Authorization (PA) Tier of the Anti-Migraine Product Based Prior Authorization (PBPA) category with the following additional criteria (changes shown in red):

Anti-Migraine Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
eletriptan tablet (Relpax®)	frovatriptan tablet (Frova®)	almotriptan tablet (Axert®)	DHE autoinjector (Brekiya®)
naratriptan tablet (Amerge®)	sumatriptan/ naproxen tablet (Treximet®)	DHE nasal spray (Migranal®)	DHE injection (D.H.E. 45®)
rizatriptan tablet, ODT (Maxalt®, Maxalt MLT®)		sumatriptan autoinjector pen and vial (Imitrex®)	ergotamine sublingual tablet (Ergomar®)
sumatriptan tablet (Imitrex®)		sumatriptan nasal spray (Imitrex®)	**ergotamine/caffeine suppository (Migergot®)**
zolmitriptan tablet, ODT (Zomig®, Zomig-ZMT®)			**ergotamine/caffeine tablet (Cafergot®)**
			lasmiditan tablet (Reyvow®)
			meloxicam/rizatriptan (Symbravo®)
			rimegepant ODT (Nurtec® ODT)
			sumatriptan injection (Imitrex® STATdose System)
			sumatriptan injection (Zembrace® SymTouch®)
			sumatriptan nasal spray (Tosymra®)
			ubrogepant tablet (Ubrelvy®)
			zavegepant nasal spray (Zavzpret™)
			zolmitriptan nasal spray (Zomig® nasal spray)

*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).
DHE = dihydroergotamine; ODT = orally disintegrating tablet; PA = prior authorization

Anti-Migraine Medications Special Prior Authorization Approval Criteria:

1. Use of Cafergot® (ergotamine/caffeine tablets), Ergomar® (ergotamine sublingual tablets), and Migergot® (ergotamine/caffeine suppository) will require a patient-specific, clinically significant reason why the member cannot use lower-tiered triptan medications; and
   a. Member must not have any of the contraindications for use of Cafergot®, Ergomar®, and Migergot® (e.g., coadministration with a potent CYP3A4 inhibitor, women who are or may become

pregnant, peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic or renal function, sepsis, hypersensitivity to any of the components); and

b. The following ~~A~~ quantity limits ~~of 20 tablets per 28 days~~ will apply~~.~~:
   i. Cafergot®: 40 tablets per 28 days; or
   ii. Ergomar®: 20 tablets per 28 days; or
   iii. Migergot®: 20 suppositories per 28 days.

2. Use of Brekiya® [dihydroergotamine (DHE) autoinjector] or D.H.E. 45® (DHE injection) will require a patient-specific, clinically significant reason why the member cannot use Migranal® (DHE nasal spray) and lower-tiered triptan medications.
3. Nurtec® ODT (rimegepant) Approval Criteria [Migraine Diagnosis (Acute Treatment)]⁺:
   a. Member must have failed therapy with at least 2* triptan medications or a patient-specific, clinically significant reason why a triptan is not appropriate for the member must be provided; and
   b. Nurtec® ODT will not be approved for concurrent use with a prophylactic CGRP inhibitor; and
   c. A quantity limit of 8 orally disintegrating tablets (ODTs) per 30 days will apply.

   *The manufacturer of Nurtec® ODT has currently provided a supplemental rebate to require a trial with 2 triptan medications and to be the preferred CGRP product for acute treatment over Reyvow®, Ubrelvy®, and Zavzpret™; however, Nurtec® ODT will follow the same criteria as Reyvow®, Ubrelvy®, and Zavzpret™ if the manufacturer chooses not to participate in supplemental rebates.
   ⁺Nurtec® ODT approval criteria for the preventive treatment of episodic migraines can be found with the Qulipta® and Vyepti® approval criteria.
4. Use of Reyvow® (lasmiditan) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
   a. Reyvow® will not be approved for concurrent use with a prophylactic calcitonin gene-related peptide (CGRP) inhibitor
5. Use of Symbravo® (meloxicam/rizatriptan) will require a patient-specific, clinically significant reason why the member cannot use Treximet® (sumatriptan/naproxen) and a different combination of a lower-tiered triptan medication in combination with a non-steroidal anti-inflammatory drug (NSAID) (i.e., rizatriptan with ibuprofen).
6. Use of Ubrelvy® (ubrogepant) or Zavzpret™ (zavegepant nasal spray) will require a patient-specific, clinically significant reason why the member cannot use triptan medications and Nurtec® ODT (rimegepant); and
   a. Ubrelvy® and Zavzpret™ will not be approved for concurrent use with a prophylactic CGRP inhibitor.
7. Use of Imitrex® STATdose System (sumatriptan injection), Tosymra® (sumatriptan nasal spray), or Zembrace® SymTouch® (sumatriptan

injection) will require a patient-specific, clinically significant reason why the member cannot use all available generic formulations of sumatriptan (tablets, nasal spray, and injection) and lower-tiered triptan medications.
8. Use of any non-oral zolmitriptan formulation will require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation and lower-tiered triptan medications.

The College of Pharmacy recommends the prior authorization of Desmoda™ (desmopressin oral solution) with the following criteria (shown in red):

Desmoda™ (Desmopressin Oral Solution) Approval Criteria:

1. An FDA approved diagnosis of arginine vasopressin deficiency (AVP-D), also known as central diabetes insipidus; and
2. A patient specific, clinically significant reason why the member cannot use desmopressin nasal spray and desmopressin oral tablets, even when tablets are crushed, which are both available without a prior authorization, must be provided.

The College of Pharmacy recommends the prior authorization of dicyclomine 40mg tablet with the following criteria (shown in red):

Dicyclomine 40mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient specific, clinically significant reason why the member cannot use the 20mg tablet, which is available without a prior authorization, to achieve the dose must be provided.

The College of Pharmacy recommends the prior authorization of griseofulvin ultramicrosize 165mg tablet with the following criteria (shown in red):

Griseofulvin Ultramicrosize 165mg Tablet Approval Criteria:

1. An FDA approved indication for the treatment of ringworm infections of the skin, hair, and nails; and
2. The infection must be caused by 1 or more of the genera of fungi listed in the package labeling; and
3. A patient specific, clinically significant reason why the member cannot use other formulations of griseofulvin available without a prior authorization (i.e., griseofulvin microsize 500mg tablet, griseofulvin 125mg/5mL suspension, and griseofulvin ultramicrosize 125mg and 250mg tablets) must be provided.

The College of Pharmacy also recommends the prior authorization of hydroxyzine oral solution UDCs with the following criteria (shown in red):

Hydroxyzine 10mg/5mL and 50mg/25mL Oral Solution Unit-Dose Cups (UDCs) Approval Criteria:

1. A patient-specific, clinically significant reason why the member requires the UDCs in place of the bulk solution, which is available without a prior authorization, must be provided.

The College of Pharmacy recommends the prior authorization of Khindivi™ (hydrocortisone oral solution) with criteria similar to Alkindi Sprinkle® (hydrocortisone oral granule) (changes shown in red):

Alkindi Sprinkle® (Hydrocortisone Oral Granule) and Khindivi™ (Hydrocortisone Oral Solution) Approval Criteria:

1. An FDA approved indication of replacement therapy in pediatric members with adrenocortical insufficiency; and
2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use hydrocortisone tablets, even when tablets are crushed or split, which are available without prior authorization, must be provided (e.g., clinically indicated dose cannot be achieved with available tablet formulation); and
3. For Khindivi™, a patient-specific, clinically significant reason why the member cannot use Alkindi Sprinkle® must be provided.

The College of Pharmacy also recommends the prior authorization of Ontralfy™ (tizanidine oral solution) with placement into the Special PA Tier of the Muscle Relaxant Medications PBPA category with the following additional criteria (changes shown in red):

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
baclofen 10mg, 20mg (Lioresal®)	metaxalone 800mg tabs (Skelaxin®)	baclofen 5mg (Lioresal®)
chlorzoxazone 500mg (Parafon Forte®)		baclofen oral granules (Lyvispah®)
cyclobenzaprine (Flexeril®)		baclofen 5mg/5mL oral soln (Ozobax®)
methocarbamol (Robaxin®)		baclofen 10mg/5mL oral soln (Ozobax® DS)
orphenadrine (Norflex®)		baclofen 25mg/5mL oral susp (Fleqsuvy®)
tizanidine tabs (Zanaflex®)		carisoprodol 250mg (Soma®)
		carisoprodol 350mg (Soma®)
		chlorzoxazone 250mg tabs
		chlorzoxazone 375mg, 750mg (Lorzone®)
		cyclobenzaprine 7.5mg tabs (Fexmid®)
		cyclobenzaprine ER caps (Amrix®)
		metaxalone 400mg tabs (Skelaxin®)
		metaxalone 640mg tabs

Muscle Relaxant Medications*		
Tier-1	**Tier-2**	**Special PA**
		methocarbamol 1,000mg tabs (Tanlor®)
		methocarbamol oral susp (Atmeksi®)
		orphenadrine/ASA/caffeine tabs (Norgesic®, Norgesic® Forte, Orphengesic® Forte)
		tizanidine caps (Zanaflex®)
		tizanidine oral soln (Ontralfy™)

*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

Ontralfy™ (Tizanidine Oral Solution) Approval Criteria:

1. An FDA approved indication for the treatment of spasticity; and
2. A patient-specific, clinically significant reason why the member cannot use Tier-1 tizanidine tablets, even when tablets are crushed or split, which are available without prior authorization, must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use generic tizanidine 2mg, 4mg, or 6mg capsules to achieve the requested dose, even when the capsules are opened and sprinkled on applesauce, must be provided.

The College of Pharmacy also recommends the prior authorization of PoKonza™ 10mEq/15mL solution, PoKonza™ 15mEq packet, and potassium chloride 40mEq packet with criteria similar to the other potassium chloride products (changes shown in red):

Klor-Con® (Potassium Chloride 20mEq Packet), ~~and~~ PoKonza™ (Potassium Chloride ~~10mEq~~ Oral Solution and Packet), and Potassium Chloride 40mEq Packet Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use all the following must be provided:
   a. Potassium chloride tablet; and
   b. Potassium chloride extended-release (ER) dispersible tablet; and
   c. Potassium chloride ER sprinkle capsule; and
   d. Potassium chloride oral solution.

The College of Pharmacy recommends the prior authorization of Quiofic™ (folic acid solution) with the following criteria (shown in red):

Quiofic™ (Folic Acid Oral Solution) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the tablet formulation, even when the tablets are crushed, which is available without prior authorization, must be provided; and
2. A quantity limit of 150mL per 30 days will apply.

The College of Pharmacy recommends the prior authorization Relgaabi™ (gabapentin 200mg capsule) with the following criteria (shown in red):

Relgaabi™ (Gabapentin 200mg Capsule) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use 2 of the 100mg gabapentin capsules, which are available without prior authorization, to achieve the 200mg dose must be provided; and
2. A quantity limit of 270 capsules per 30 days will apply.

The College of Pharmacy also recommends the prior authorization of Vykoura™ (leucovorin injection) with criteria similar to Khapzory® (levoleucovorin injection) approval criteria (changes shown in red):

Khapzory® (Levoleucovorin Injection) and Vykoura™ (Leucovorin Injection) Approval Criteria:

1. An FDA approved indication; and ~~of 1 of the following:~~
   ~~a. Rescue after high-dose methotrexate (MTX) therapy in members with osteosarcoma; or~~
   ~~b. Diminishing the toxicity associated with overdosage of folic acid antagonists or impaired MTX elimination; or~~
   ~~c. Treatment of members with metastatic colorectal cancer in combination with fluorouracil; and~~
2. A patient-specific, clinically significant reason why the member cannot use generic leucovorin injection or generic levoleucovorin calcium injection, which are both available without prior authorization, must be provided.

Finally, the College of Pharmacy recommends the prior authorization of Annovera™ (segesterone acetate/ethinyl estradiol vaginal system) based on net cost with the following criteria (shown in red):

Annovera™ (Segesterone Acetate/Ethinyl Estradiol Vaginal System) Approval Criteria:

1. An FDA approved indication to prevent pregnancy in women; and
2. A patient-specific, clinically significant reason why the member cannot use NuvaRing® (etonogestrel/ethinyl estradiol vaginal ring) and all other available formulations of estrogen/progestin contraception available without prior authorization must be provided; and
3. A quantity limit of 1 vaginal system per year will apply.

Recommendation 8: Vote to Prior Authorize Inlexzo™ (Gemcitabine Intravesical System), Kyxata™ (Carboplatin), Lifyorli™ (Relacorilant), and Zusduri™ (Mitomycin Intravesical Solution) 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 Inlexzo™ (gemcitabine intravesical system), Lifyorli™ (relacorilant), and Zusduri™ (mitomycin intravesical solution) with the following criteria (shown in red):

Inlexzo™ (Gemcitabine Intravesical System) 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. Disease is unresponsive to Bacillus Calmette-Guérin (BCG) treatment; and
3. Member must be 18 years of age or older; and
4. Used for intravesical administration only; and
5. Initial approvals will be for 6 months for 8 doses administered every 3 weeks; and
6. Subsequent approvals will be for 6 months for 2 doses administered every 12 weeks; and
7. Approval will be limited to a maximum total of 14 doses.

Lifyorli™ (Relacorilant) Approval Criteria [Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2. Disease is platinum resistant; and
3. Member has received a prior systemic treatment regimen that included bevacizumab; and
4. Used in combination with nab-paclitaxel; and
5. Member must be 18 years of age or older.

Zusduri™ (Mitomycin Intravesical Solution) Approval Criteria [Non-Muscle Invasive Bladder Cancer (NMIBC) Diagnosis]:

1. Diagnosis of NMIBC; and
2. Disease is low-grade, intermediate-risk; and
3. Disease is recurrent; and
4. Administered by intravesical instillation only; and
5. Member must be 18 years of age or older; and
6. Approval will be limited to a total of 6 weekly instillations.

The College of Pharmacy also recommends the prior authorization of Kyxata™ (carboplatin) based on net costs with the following criteria (shown in red):

Kyxata™ (Carboplatin; J9278) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason the member cannot use generic carboplatin products (J9045), which are available without prior authorization, must be provided.

Next, the College of Pharmacy recommends updating the approval criteria for Padcev® (enfortumab vedotin-ejfv) and Welireg® (belzutifan) based on recent FDA approvals (changes and new criteria noted in red):

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

1. Diagnosis of muscle invasive bladder cancer (MIBC); and
    a. Used as neoadjuvant treatment and continued as adjuvant treatment after cystectomy; and
    b. Used in combination with pembrolizumab; and
    c. Member is ineligible for cisplatin-containing chemotherapy; or
2. Diagnosis of locally advanced or metastatic urothelial cancer; and
    a. Used in 1 of the following settings:
        i. 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
        ii. As a single agent and member has received at least 1 prior therapy and is ineligible for cisplatin-containing chemotherapy; or
        iii. Used in combination with pembrolizumab.

Welireg® (Belzutifan) Approval Criteria [Renal Cell Carcinoma (RCC) Diagnosis]:

1. Diagnosis of advanced RCC with a clear cell component; and
    a. Member has received at least 2 lines of systemic therapy, including a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI); and
    b. As a single agent; or
2. Diagnosis of RCC with a clear cell component; and
    a. Disease is intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions; and
    b. Used in combination with pembrolizumab; and
    c. Approval will be for a maximum of 54 weeks.

Next, the College of Pharmacy recommends updating the approval criteria for Akeega® (niraparib/abiraterone acetate) based on recent FDA approvals and National Comprehensive Cancer Network (NCCN) recommendations (changes and new criteria noted in red):

Akeega® (Niraparib/Abiraterone Acetate) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC with high-volume metastasis; and

    a. High-volume defined as presence of visceral metastasis or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis; and
2. Presence of deleterious or suspected deleterious *BRCA2* mutation based upon an FDA-approved test; and
3. Used in conjunction with prednisone; and
4. Used in conjunction with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

Next, the College of Pharmacy recommends updating the Afinitor® (everolimus), Xtandi® (enzalutamide), Yonsa® (abiraterone acetate), Zejula® (niraparib), and Zytiga® (abiraterone) approval criteria based on NCCN guideline recommendations and net cost (changes shown in red):

Afinitor® (Everolimus) Approval Criteria [Neuroendocrine Tumors (NET) of Pancreatic (PNET), Gastrointestinal, or Lung Origin Diagnosis]:

1. Diagnosis of unresectable, locally advanced, or metastatic NET of pancreatic (PNET), gastrointestinal, or lung origin; and
2. ~~Progressive disease from a previous treatment.~~
3. Member does not have functional carcinoid tumor.

Xtandi® (Enzalutamide) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of non-metastatic CRPC; and
    a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
    b. PSA doubling time (PSADT) is ≤10 months; or
2. Diagnosis of metastatic CRPC; and
    a. Concomitant treatment with a GnRH analog or prior history of bilateral orchiectomy; and
    b. If disease is homologous recombination repair (HRR) gene-mutated, must be used in combination with talazoparib.

Xtandi® (Enzalutamide) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC; ~~or~~ and
    a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; or
2. Diagnosis of non-metastatic CSPC with biochemical recurrence at high risk for metastasis (high-risk BCR).

Yonsa® (Abiraterone Acetate) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Abiraterone must be used in combination with ~~a corticosteroid~~ methylprednisolone; and

3. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. A patient-specific, clinically significant reason why the member cannot use generic abiraterone tablets must be provided.

Zejula® (Niraparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

1. Diagnosis of metastatic CRPC; and
2. Presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
3. Used in combination with abiraterone and prednisone or abiraterone acetate and methylprednisolone; and
4. Used in combination with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

Zejula® (Niraparib) Approval Criteria [Castration-Sensitive Prostate Cancer (CSPC) Diagnosis]:

1. Diagnosis of metastatic CSPC with high-volume metastases; and
   a. High-volume defined as presence of visceral metastasis or ≥4 bone lesions with ≥1 beyond the vertebral bodies and pelvis; and
2. Presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
3. Used in combination with abiraterone and prednisone or abiraterone acetate and methylprednisolone; and
4. Used in combination with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
5. Member has not progressed on prior abiraterone therapy.

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. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. 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. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
4. If used in combination with niraparib, member has presence of deleterious or suspected deleterious *BRCA* mutation based upon an FDA-approved test; and
5. Use of the 500mg tablet will require a patient-specific, clinically significant reason why the member cannot use generic abiraterone 250mg tablets.

Lastly, the College of Pharmacy recommends removing the prior authorization requirement for Camcevi® (leuprolide) and updating the Orgovyx® (relugolix) approval criteria based on net cost (changes shown in red):

~~**Camcevi® (Leuprolide) Approval Criteria [Prostate Cancer Diagnosis]:**~~

~~1. Diagnosis of advanced prostate cancer; and~~
~~2. A patient-specific, clinically significant reason why the member cannot use Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication].~~

Orgovyx® (Relugolix) Approval Criteria [Prostate Cancer Diagnosis]:

1. Diagnosis of advanced prostate cancer; and
2. A patient-specific, clinically significant reason why the member cannot use Camcevi® (leuprolide), Eligard® (leuprolide acetate), Firmagon® (degarelix), and Lupron Depot® (leuprolide acetate) must be provided [reason(s) must address each medication]; and
3. A quantity limit of 30 tablets per 30 days will apply. Upon meeting approval criteria, a quantity limit override will be approved for the day 1 loading dose of 360mg.

Recommendation 9: Fiscal Year 2025 Annual Review of Anti-Ulcer Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends the following changes to the Anti-Ulcer Medications Product Based Prior Authorization (PBPA) Tier chart and additional criteria (changes shown in red):

1. Adding Tagamet® (cimetidine) solution and Pepcid® (famotidine) tablets and injection, which are available without prior authorization, to Tier-1 for clarity; and

2. No longer designating Prevacid® orally disintegrating tablet (ODT) (lansoprazole ODT) as brand preferred based on net cost; and
3. Updating the Anti-Ulcer Medications Tier-2 and Tier-3 Approval Criteria to allow for a patient-specific, clinically significant reason why a member cannot use lower-tiered products instead of requiring a 14-day trial based on DUR Board input; and
4. Rephrasing criteria regarding age restrictions for clarity; and
5. Updating the Talicia® (omeprazole/amoxicillin/rifabutin) criteria based on clinical practice.

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
cimetidine (Tagamet® soln)	dexlansoprazole (Dexilant® caps) – **Brand Preferred**	esomeprazole inj (Nexium® I.V.)	bismuth subcitrate potassium/metronidazole/ tetracycline (Pylera® caps)
esomeprazole (Nexium® caps)	pantoprazole (Protonix® I.V.)	omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)
esomeprazole (Nexium® packet) – **Brand Preferred**		pantoprazole (Protonix® susp)	esomeprazole kit (ESOMEP-EZS™)
famotidine (Pepcid® tabs, inj)			famotidine (Pepcid® susp)
lansoprazole (Prevacid® caps**, ODT**)			glycopyrrolate (Glycate® tabs)
~~**lansoprazole ODT (Prevacid® ODT) – Brand Preferred**~~			glycopyrrolate ODT (Dartisla® ODT)
omeprazole (Prilosec® caps)			lansoprazole/amoxicillin/ clarithromycin (PrevPac®)
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/amoxicillin/ rifabutin (Talicia® caps)
sucralfate (Carafate® tabs)			omeprazole/sodium bicarbonate (Konvomep® for oral suspension)
			omeprazole/sodium bicarbonate (Zegrid® caps & pack)
			pantoprazole in 0.9% NaCl for IV inj
			sucralfate (Carafate® susp)
			vonoprazan (Voquezna® tabs)
			vonoprazan fumarate/ amoxicillin trihydrate (Voquezna® Dual Pak®)
			vonoprazan fumarate/ amoxicillin trihydrate/ clarithromycin (Voquezna® Triple Pak®)

*Special formulations including ODTs, granules, suspension, sprinkle capsules, and solution for IV require special reasoning for use.
+Individual criteria specific to each product applies.
caps = capsules; inj = injection; IV = intravenous; ODT = orally disintegrating tablet; NaCl = sodium chloride; PA = prior authorization; soln = solution; susp = suspension; tabs = tablet

Anti-Ulcer Medications Tier-2 Approval Criteria:

1. ~~A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that resulted in inadequate relief of symptoms or intolerable adverse effects; or~~
2. ~~Contraindication(s) to all available Tier-1 medications; or~~
3. A patient-specific clinically significant reason why all Tier-1 products for the requested route of administration, titrated to the recommended dose, are not appropriate for the member must be provided; or
4. An indication not covered by lower tiered medications.

Anti-Ulcer Medications Tier-3 Approval Criteria:

1. ~~A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or~~
2. ~~Contraindication(s) to all available Tier-1 and Tier-2 medications; or~~
3. A patient-specific clinically significant reason why all Tier-1 and Tier-2 products for the requested route of administration, titrated to the recommended dose, are not appropriate for the member must be provided; or
4. An indication not covered by lower tiered medications; and
5. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and intravenous (IV) solutions require special reasoning for use.

~~Proton Pump Inhibitors for Pediatric Members Approval Criteria:~~

1. ~~A recent 14-day trial of a histamine type 2 receptor (H2) antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or~~
2. ~~Recurrent or severe disease such as:~~
   a. ~~Gastrointestinal (GI) bleed; or~~
   b. ~~Zollinger-Ellison Syndrome or similar disease; and~~
3. ~~Tier structure rules still apply.~~

Anti-Ulcer Medications Special Prior Authorization (PA) Approval Criteria:

1. Axid® (Nizatidine Capsule) Approval Criteria:
   a. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.
2. Axid® (Nizatidine Solution) Approval Criteria:
   a. A previous 14-day trial of famotidine suspension or a patient-specific, clinically significant reason why famotidine suspension is not appropriate for the member must be provided; and

b. Nizatidine solution (Axid®) will ~~have an age restriction of~~ be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

3. Carafate® (Sucralfate Suspension) Approval Criteria:
   a. A patient specific, clinically significant reason why the member cannot use the tablet formulation, which is available without prior authorization, must be provided.
4. Dartisla® ODT [Glycopyrrolate Orally Disintegrating Tablet (ODT)] Approval Criteria:
   a. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 18 years of age and older; and
   b. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided; and
   c. A quantity limit of 120 tablets per 30 days will apply.
5. Esomep-EZS™ (Esomeprazole Kit) Approval Criteria:
   a. A previous 14-day trial of esomeprazole magnesium and a patient-specific, clinically significant reason why other lower tiered proton pump inhibitors (PPIs), including omeprazole and esomeprazole, along with over-the-counter (OTC) pill swallowing spray are not appropriate for the member must be provided; and
   b. Current Tier structure rules will also apply.
6. Glycate® (Glycopyrrolate Tablet) Approval Criteria:
   a. An FDA approved indication of adjunctive therapy in the treatment of peptic ulcer disease (PUD) in members 12 years of age and older; and
   b. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided.
7. Konvomep® (Omeprazole/Sodium Bicarbonate for Oral Suspension) and Zegerid® (Omeprazole/Sodium Bicarbonate Capsule) Approval Criteria:
   a. Member must be 18 years of age or older; and
   b. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided; and
   c. For Konvomep®, requests for the 90mL or 150mL package will require a patient-specific, clinically significant reason why the member cannot use the 300mL package size.
8. Pantoprazole in 0.9% NaCl for Intravenous (IV) Injection Approval Criteria:

a. A patient-specific, clinically significant reason why the member cannot use Tier-2 Protonix® I.V. (pantoprazole) must be provided.

9. Pepcid® (Famotidine Suspension) Approval Criteria**:**
   a. Famotidine suspension will ~~have an age restriction of~~ be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age will require a patient-specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.
10. PrevPac® (Lansoprazole/Amoxicillin/Clarithromycin) Approval Criteria:
    a. An FDA approved indication for the eradication of *Helicobacter pylori* (*H. pylori*) infection and reduce the risk of duodenal ulcer recurrence; and
    b. A patient-specific, clinically significant reason why the member cannot use the individual components, which are available without prior authorization must be provided; and
    c. A quantity limit of 112 tablets/capsules per 14 days will apply.
11. Pylera® (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline Capsule) Approval Criteria:
    a. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
    b. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
    ~~c. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori infection* (e.g., omeprazole, amoxicillin, and rifabutin), which are available without prior authorization, must be provided; and~~
    d. A quantity limit of 120 capsules per 10 days will apply.
12. Tagamet® (Cimetidine Tablet) Approval Criteria:
    a. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.
13. Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsule) Approval Criteria:
    a. An FDA approved indication for the treatment of *Helicobacter pylori* (*H. pylori*) infection; and
    b. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
    ~~c. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and rifabutin),~~

~~which are available without prior authorization, must be provided; and~~

d. A patient-specific, clinically significant reason why the member cannot use the individual components of potassium-competitive acid blocker (PCAB) dual therapy (e.g., vonoprazan fumarate and amoxicillin) must be provided; and
e. A quantity limit of 168 capsules per 14 days will apply

14. Voquezna® (Vonoprazan Fumarate) Approval Criteria [Erosive and Non-Erosive Gastroesophageal Reflux Disease (GERD) Diagnosis]:
    a. An FDA approved diagnosis; and
    b. Member must be 18 years of age or older; and
    c. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
    d. A quantity limit of 30 tablets per 30 days will apply.
15. Voquezna® (Vonoprazan Fumarate), Voquezna® Dual Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate), and Voquezna® Triple Pak® (Vonoprazan Fumarate/Amoxicillin Trihydrate/Clarithromycin) Approval Criteria [*Helicobacter pylori* (*H. pylori*) Diagnosis]:
    a. An FDA approved indication for the treatment of *H. pylori* infection; and
    b. Member must be 18 years of age or older; and
    c. A patient-specific, clinically significant reason why the member cannot use the individual components of bismuth quadruple therapy [e.g., bismuth subsalicylate, metronidazole, proton pump inhibitor (PPI), tetracycline] must be provided; and
    ~~d. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and rifabutin), which are available without prior authorization, must be provided; and~~
    e. For the Voquezna® Dual Pak® and Voquezna® Triple Pak®, a patient-specific, clinically significant reason why the member cannot use the individual components of the product requested must be provided; and
    f. A quantity limit of 112 tablets/capsules per 14 days will apply.

Recommendation 10: Fiscal Year 2025 Annual Review of Epidermolysis Bullosa (EB) Medications

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends updating the prior authorization criteria for Vyjuvek® (beremagene geperpavec-svdt) based on the FDA approved label updates and clinical practice, including amending criteria #12

to allow for initial approvals for 6 months as recommended by and approved unanimously by the DUR Board (changes shown in red):

Vyjuvek® (Beremagene Geperpavec-svdt) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members ~~6 months of age and older~~ with dystrophic epidermolysis bullosa (DEB); and
2. Diagnosis must be confirmed by a mutation in the collagen type VII alpha 1 chain (*COL7A1*) gene (results of genetic testing must be submitted); and
3. Vyjuvek® must be prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB); and
4. Pharmacy or prescriber must confirm Vyjuvek® will be prepared by a pharmacist trained in the preparation of Vyjuvek® prior to dispensing and must confirm Vyjuvek® will be shipped to the administering ~~provider~~ location (i.e., member's home, clinic) via cold chain supply and adhere to the storage and handling requirements in the Vyjuvek® package labeling; and
5. Vyjuvek® must be administered by a health care professional (HCP) or member/caregiver trained in the administration of Vyjuvek®. ~~Approvals will not be granted for self-administration.~~ Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health, member's home); and
    a. If member or caregiver is administering Vyjuvek®, the prescriber must attest that they will be trained on the dosing, administration, and storage of Vyjuvek®; and
6. Prescriber must attest that Vyjuvek® gel will be dosed per package labeling and applied to the same wound(s) until closed before selecting new wound(s) to treat, and that they will prioritize weekly treatment to previously treated wounds if they re-open; and
7. Prescriber must attest member or caregiver(s) have been counseled on the precautions prior to and during treatment with Vyjuvek® that are listed in the package labeling, including avoiding direct contact with treated wounds and dressings ~~for 24 hours~~ until the next dressing change following administration; and
8. Female members must not be pregnant and must have a negative pregnancy test immediately prior to therapy initiation. Female members of reproductive potential must be willing to use effective contraception while on therapy; and
9. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and

10. Vyjuvek® will not be approved for ~~concomitant~~ use on wounds currently treated with Filsuvez® (birch triterpenes 10% topical gel) or for use on wounds treated with Zevaskyn® (prademagene zamikeracel); and
11. A maximum approval quantity of 1 carton (2.5mL) per week will apply; and
12. Initial approvals will be for ~~3~~ 6 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Vyjuvek® will not be applied to closed wounds; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with every request documenting the member's response to treatment and ongoing treatment plan; and
    b. Vyjuvek® must continue to be administered by an HCP or a trained member/caregiver. ~~Approvals will not be granted for self-administration.~~ Prior authorization requests must indicate who will administer Vyjuvek® and in what setting (i.e., treatment facility, HCP office, home health, member's home).

The College of Pharmacy also recommends updating the prior authorization criteria for Filsuvez® based on clinical practice, including amending criteria #11 to allow for initial approvals for 6 months as recommended by and approved unanimously by the DUR Board (changes shown in red):

Filsuvez® (Birch Triterpenes 10% Topical Gel) Approval Criteria:

1. An FDA approved indication for the treatment of wounds in members 6 months of age and older with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB); and
2. Diagnosis must be confirmed by a pathogenic variant in the *COL7A1* gene for DEB or biallelic pathogenic variants in the *COL17A1*, *ITGA3*, *ITGA6*, *ITGB4*, *LAMA3*, *LAMB3*, or *LAMC2* genes for JEB (results of genetic testing must be submitted); and
3. Filsuvez® must be prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB or JEB (or an advanced care practitioner with a supervising physician who is a dermatologist or other specialist with expertise in the treatment of DEB or JEB); and
4. Member must have the presence of open partial-thickness wounds associated with DEB or JEB for ≥21 days; and
5. Filsuvez® must be applied to open partial-thickness wounds at dressing changes at least once every 4 days or up to once daily; and
6. Prescriber must attest that member and/or caregiver has been counseled on the appropriate administration and storage of Filsuvez® based on package labeling including that each sterile tube is for one-time use only; and

7. Member and/or caregiver has been advised on possible hypersensitivity reactions with Filsuvez® and to discontinue use and contact the prescriber if symptoms of a hypersensitivity reaction develop; and
8. Clinical documentation (i.e., recent office notes) must be submitted with the request documenting the member's treatment plan; and
9. Filsuvez® will not be approved for ~~concomitant~~ use on wounds currently treated with Vyjuvek® (beremagene geperpavec-svdt) or for use on wounds treated with Zevaskyn® (prademagene zamikeracel); and
10. A maximum approval quantity of 1 tube (23.4 grams) per day or 702 grams per 30 days will apply; and
    a. A quantity limit override will be considered for approval of quantities greater than 1 tube per day if the provider documents the number and size of wounds being treated to justify the need for a larger quantity; and
11. Initial approvals will be for ~~3~~ 6 months. Subsequent approvals will be for 1 year and may be granted if the prescriber documents the member is responding well to treatment as indicated by the presence of wound healing and the prescriber must confirm Filsuvez® will not be applied to closed wounds; and
    a. Clinical documentation (i.e., recent office notes) must be submitted with every request documenting the member's response to treatment and ongoing treatment plan.

Recommendation 11: Fiscal Year 2025 Annual Review of Colorectal Cancer (CRC) Medications and 30-Day Notice to Prior Authorize Jobevne™ (Bevacizumab-nwgd)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2026.

Recommendation 12: Fiscal Year 2025 Annual Review of Anti-Diabetic Medications and Kerendia® (Finerenone) and 30-Day Notice to Prior Authorize Awiqli® (Insulin Icodec-abae), Glipizide 15mg Tablet, Kirsty™ (Insulin Aspart-xjhz), and Langlara™ (Insulin Glargine-aldy)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2026.

Recommendation 13: Fiscal Year 2025 Annual Review of Heart Failure (HF) Medications and 30-Day Notice to Prior Authorize Enbumyst™ (Bumetanide Nasal Spray), Lasix® ONYU (Furosemide On-Body Infusor), and Myqorzo™ (Aficamten)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2026.

Recommendation 14: Fiscal Year 2025 Annual Review of Alzheimer's Disease Medications and 30-Day Notice to Prior Authorize Leqembi® Iqlik™ (Lecanemab-irmb)

NO ACTION REQUIRED; WILL BE AN ACTION ITEM IN SEPTEMBER 2026.

Recommendation 15: Fiscal Year 2025 Annual Review of Testosterone Products

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

- There is not a live DUR Board meeting scheduled for August 2026. August 2026 will be a packet-only meeting.

NO ACTION REQUIRED.

MENTAL HEALTH ASSOCIATION OKLAHOMA

5330 East 31st Street, Suite 1000
Tulsa, Oklahoma 74135
918.585.1213

915 North Robinson Avenue
Oklahoma City, Oklahoma 73102
405.943.3700

June 30, 2026

Drug Utilization Review (DUR) Board
Oklahoma Health Care Authority
4345 N Lincoln Boulevard
Oklahoma City, OK 73105

To members of the Drug Utilization Review Board:

I am writing on behalf of Mental Health Association Oklahoma, a nonprofit organization serving individuals in Tulsa, Oklahoma City, and Norman who are living at the intersection of mental illness and homelessness.

Each day, our Street Outreach and Street Medicine teams meet people where they are—on sidewalks, in encampments, and under bridges. Many are living with serious mental illnesses like schizophrenia. For these individuals, access to the right medication is often the first step toward stability. Without effective treatment, it becomes nearly impossible to engage in housing, employment, healthcare, or recovery.

The proposal to move Cobenfy to the Special Prior Authorization Tier would create another significant barrier to care for some of Oklahoma's most vulnerable residents.

Requiring four documented medication failures—a process that would take a minimum of 56 days under ideal circumstances—is challenging even for someone with stable housing, reliable transportation, and consistent access to healthcare. For individuals experiencing homelessness, that timeline is often unrealistic. Missed appointments, lack of transportation, difficulty storing medication, and limited communication can extend the process for months while they remain on medications that are ineffective or produce intolerable side effects.

MENTAL HEALTH ASSOCIATION OKLAHOMA

5330 East 31st Street, Suite 1000
Tulsa, Oklahoma 74135
918.585.1213

915 North Robinson Avenue
Oklahoma City, Oklahoma 73102
405.943.3700

Our Street Medicine providers have cared for patients whose previous medications left them emotionally numb, caused substantial weight gain, or intensified the very challenges that make recovery difficult. For people already struggling with food insecurity, unstable housing, and profound distrust of healthcare systems, these side effects can lead them to stop treatment altogether.

Debbi McCullock, DNP, APRN, a Family Nurse Practitioner with our Street Medicine team through a partnership with OU Health, provides direct patient care to individuals experiencing unsheltered homelessness in Oklahoma City. She has expressed serious concerns that requiring patients to experience repeated treatment failures before accessing the medication they truly need unnecessarily exposes them to significant risks associated with first- and second-generation antipsychotics. These include extrapyramidal symptoms (EPS) and irreversible tardive dyskinesia (TD), and metabolic complications such as substantial weight gain, increased appetite, hyperglycemia, diabetes, and excessive sedation. For many patients, these side effects are not simply uncomfortable—they can be life-altering and create additional barriers to recovery.

An additional concern for patients experiencing homelessness is that a treatment failure must be documented to satisfy prior authorization requirements. When patients lose contact with providers because of transportation barriers, lack of communication, or the realities of living unsheltered, those treatment trials often cannot be verified and must be repeated. This prolongs the time before patients can access an effective medication, increases the likelihood of lapses in treatment, and raises the risk of worsening symptoms and cognitive decline. Every additional failed medication trial increases the chance that a patient will disengage from care before receiving the treatment their clinician believes is most appropriate.

MENTAL HEALTH ASSOCIATION OKLAHOMA

5330 East 31st Street, Suite 1000
Tulsa, Oklahoma 74135
918.585.1213

915 North Robinson Avenue
Oklahoma City, Oklahoma 73102
405.943.3700

Delaying access to effective treatment does not reduce costs—it shifts them. When schizophrenia goes untreated or undertreated, the consequences include increased psychiatric hospitalizations, greater involvement with the criminal justice system, prolonged homelessness, and higher costs for emergency services. Research has shown that prior authorization requirements for antipsychotic medications are associated with a 23% increase in inpatient hospitalization costs, a 22% increase in the likelihood of incarceration, and a greater likelihood of homelessness.

Healthcare decisions should be guided by clinical judgment and the needs of individual patients—not by policies that require unnecessary suffering before effective treatment becomes available.

On behalf of the thousands of Oklahomans we serve each year, I respectfully urge you to vote against moving Cobenfy to the Special Prior Authorization Tier. Individuals living with schizophrenia deserve timely access to the medications their healthcare providers determine are most appropriate, without additional barriers that delay recovery and put them at greater risk.

Thank you for your consideration and your commitment to improving the health of Oklahomans.

With gratitude,

Carrie Blumert
Chief Executive Officer
Mental Health Association Oklahoma

Dear Members of the Oklahoma Health Care Authority Drug Utilization Review Board,

At NAMI Oklahoma, we hear every day from individuals living with serious mental illness and from the families who walk alongside them. We know firsthand how difficult the journey to finding an effective treatment can be. For many people living with schizophrenia, that journey is marked by repeated medication changes, frustrating setbacks, and uncertainty. When someone finally finds a treatment that works, it can mean the difference between stability and crisis.

The proposed changes would move Cobenfy from the current Tier 3 category into a new Special Prior Authorization tier, requiring additional medication trials before a patient could even be considered for approval. At a minimum, these criteria would require four sequential medication trials over at least 56 days before a prior authorization request could be submitted. In reality, the process would often take much longer once medication titration, follow-up appointments, monitoring for effectiveness and side effects, and prior authorization processing are taken into account.

Our concern is not simply about the length of time. It is about what that delay can mean for someone whose symptoms are not adequately controlled. Every additional barrier can prolong the time before a person receives the treatment that is right for them. During that time, individuals may experience worsening symptoms, psychiatric hospitalization, disruptions to work or school, increased strain on family members and caregivers, or other setbacks that make recovery more difficult.

We are also aware that Cobenfy represents a meaningful advancement in the treatment of schizophrenia. For some individuals who have not responded to, or have been unable to tolerate, existing treatment options, a different approach may provide an important opportunity for symptom improvement. Requiring patients to exhaust additional medications with similar mechanisms before accessing a treatment that works differently may unintentionally delay clinically appropriate and clinically necessary care.

NAMI Oklahoma is especially concerned about individuals who are already stable on Cobenfy. For people living with schizophrenia, maintaining stability is often hard won. Once someone has found a medication that allows them to live independently, remain employed, continue their education, or reconnect with family and community, preserving that progress should be a priority. We encourage the Board to ensure that patients who are currently benefiting from Cobenfy can continue their treatment without unnecessary interruption.

We respectfully ask the Board to maintain Cobenfy's placement within the current Tier 3 prior authorization structure. If additional utilization management is deemed necessary, we

also encourage preserving a meaningful clinical exception process that allows treating providers to request access when, in their professional judgment, Cobenfy is the most appropriate option for an individual patient.

Sincerely,

Lorna Palmer

Executive Director

NAMI Oklahoma

Lorna Palmer

Executive Director

E: lorna@namioklahoma.org

P: 405-601-8283 | **D:** 405-488-0544

Physical Address:

3009 NW 63rd, Suite 2A

Oklahoma City, OK 73116

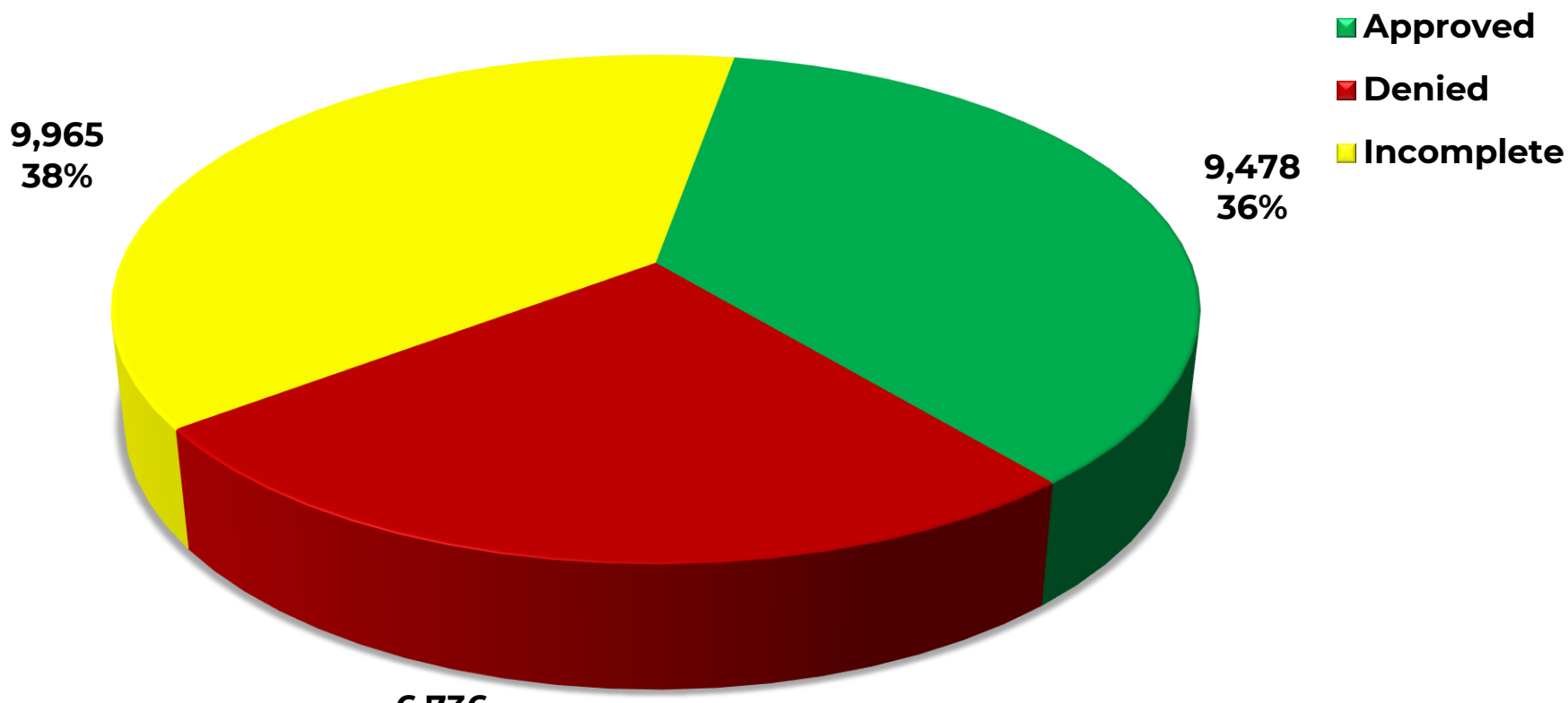
Mailing Address:

PO Box 1306, El Reno, OK 73036

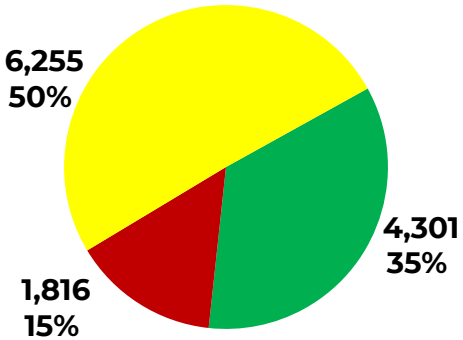
www.namioklahoma.org

Appendix B

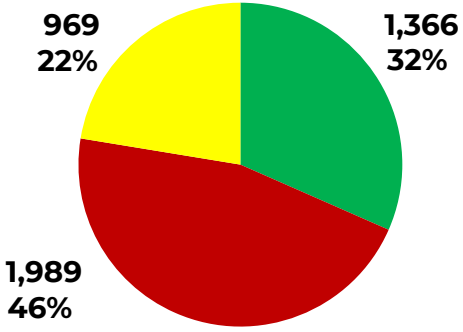
PRIOR AUTHORIZATION (PA) ACTIVITY REPORT: JULY 2026



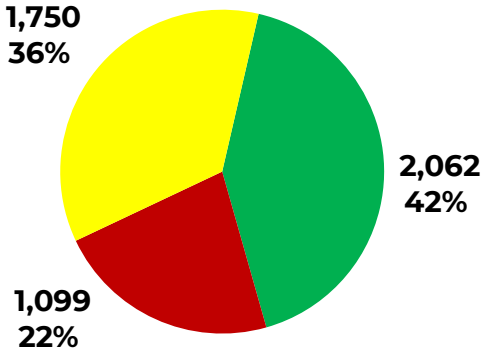
SoonerCare FFS



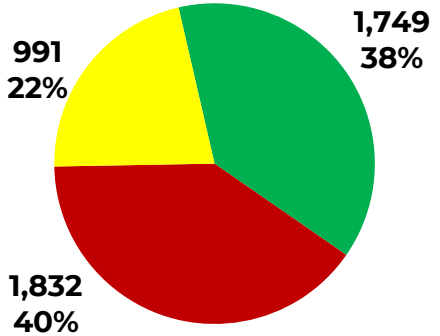
SoonerSelect Aetna



SoonerSelect Humana

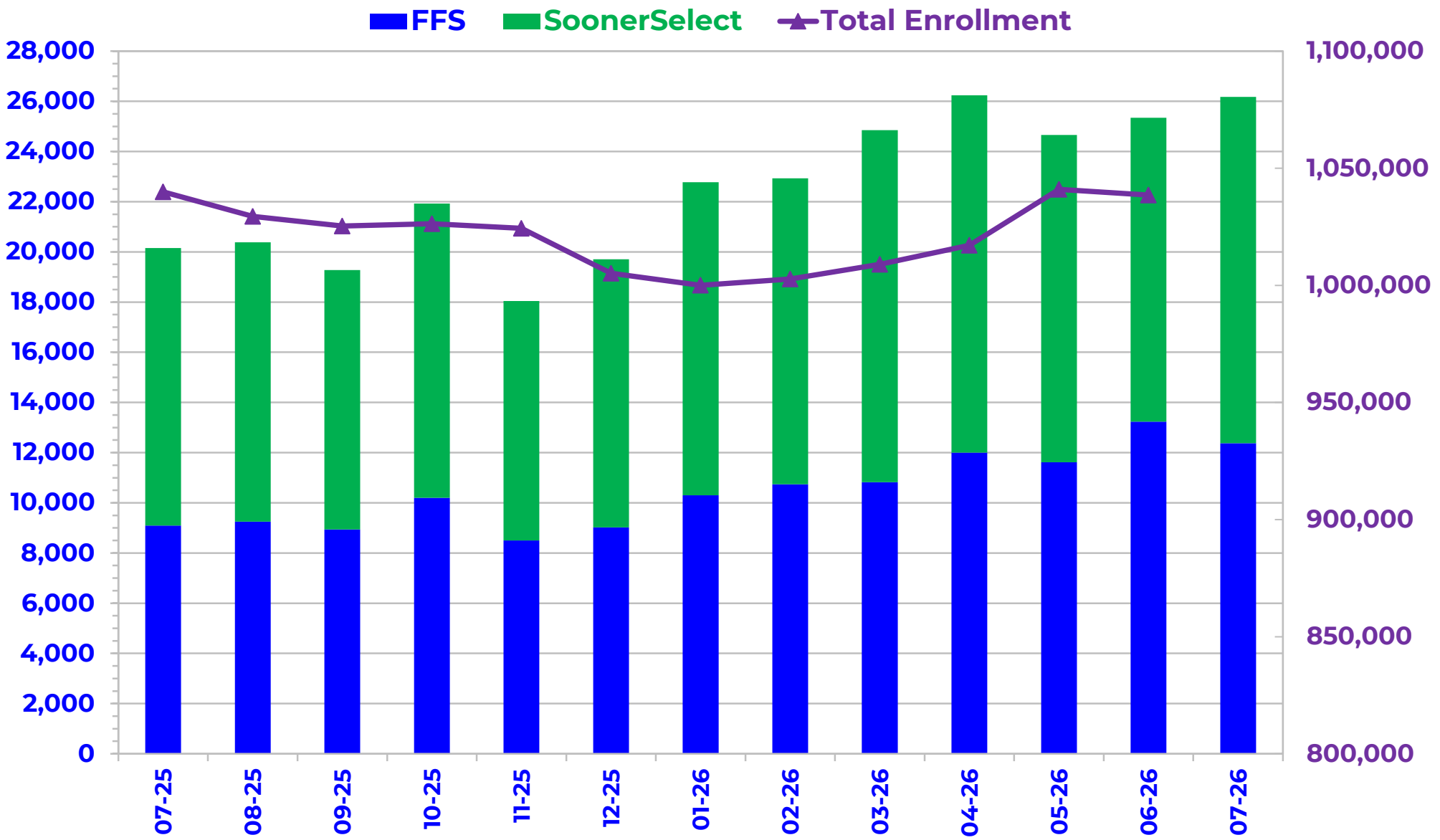


SoonerSelect OK Complete Health



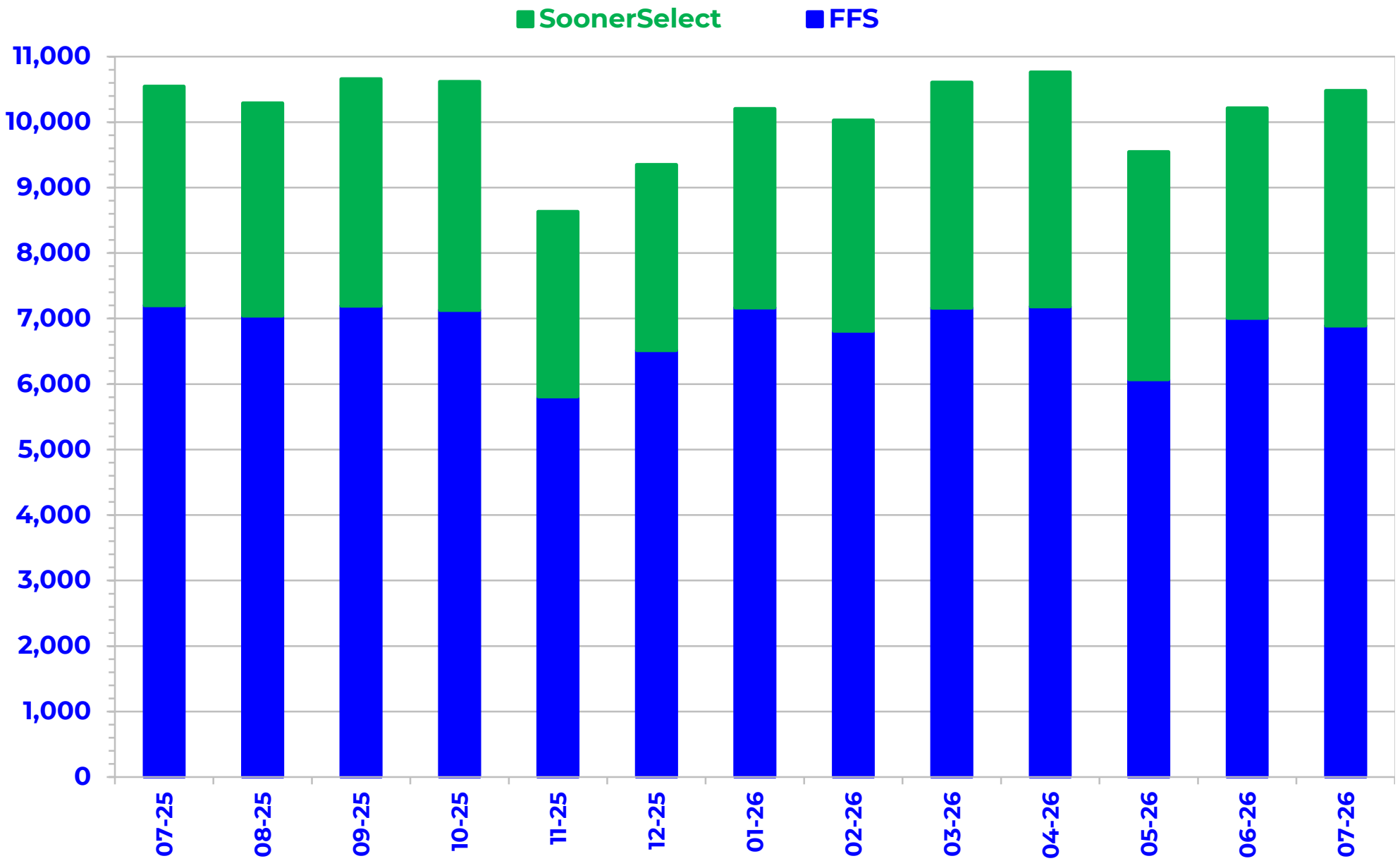
PA totals include approved/denied/incomplete/overrides; SoonerSelect totals are based on data provided to the College of Pharmacy from the SoonerSelect plans.

PRIOR AUTHORIZATION (PA) REPORT: JULY 2025 – JULY 2026



PA totals include approved/denied/incomplete/overrides

CALL VOLUME MONTHLY REPORT: JULY 2025 – JULY 2026



SoonerCare FFS Prior Authorization Activity

7/1/2026 Through 7/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc	3	0	1	2	0
Amebicides	3	1	0	2	18
Amphetamines	919	515	53	351	356
Analgesics - Anti-Inflammatory	276	90	43	143	322
Analgesics - Nonnarcotic	16	1	5	10	179
Analgesics - Opioid	367	140	33	194	142
Androgens - Anabolic	72	3	19	50	360
Anorectal and Related Products	8	3	0	5	119
Anorexiants Non-Amphetamine	1	0	1	0	0
Antacids	6	4	0	2	345
Anthelmintics	30	7	7	16	9
Anti-Infective Agents - Misc.	37	10	4	23	152
Anti-Obesity Agents	559	110	225	224	95
Antianxiety Agents	39	4	4	31	360
Antiarrhythmics	3	0	1	2	0
Antiasthmatic and Bronchodilator Agents	598	106	76	416	493
Antibiotics	50	17	1	32	241
Anticoagulants	16	2	0	14	360
Anticonvulsants	303	124	18	161	434
Antidepressants	413	107	40	266	516
Antidiabetics	2,048	567	339	1,142	364
Antidotes and Specific Antagonists	1	0	0	1	0
Antiemetics	30	2	2	26	19
Antifungals	13	5	1	7	99
Antihistamines	27	5	7	15	298
Antihyperlipidemics	113	21	22	70	311
Antihypertensives	63	19	6	38	674
Antimalarials	3	0	0	3	0
Antineoplastics and Adjunctive Therapies	279	157	19	103	186
Antiparkinson and Related Therapy Agents	19	5	2	12	945
Antipsychotics/antimanic Agents	492	183	32	277	389
Antivirals	28	7	4	17	28
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	346	207	28	111	1,000
Beta Blockers	26	4	1	21	1,114
Calcium Channel Blockers	11	3	0	8	361
Cardiovascular Agents - Misc.	143	74	12	57	358
Chemicals	1	0	1	0	0
Contraceptives	80	36	8	36	534
Corticosteroids	18	2	1	15	223
Dermatologicals	649	182	142	325	247
Diagnostic Products	58	18	3	37	224
Digestive Aids	3	1	0	2	360
Diuretics	22	9	2	11	806

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	6	0	3	3	0
Emergency PA	0	0	0	0	0
Endocrine and Metabolic Agents - Misc.	210	82	24	104	303
Estrogens	9	0	1	8	0
Gastrointestinal Agents - Misc.	495	119	107	269	272
Genitourinary Agents - Misc.	7	1	2	4	361
Gout Agents	12	3	2	7	293
Hematological Agents - Misc.	13	3	1	9	256
Hematopoietic Agents	51	20	11	20	123
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	0	1	0
Hypnotics/Sedatives/Sleep Disorder Agents	63	6	13	44	329
Laxatives	36	13	3	20	225
Medical Devices and Supplies	443	67	99	277	312
Migraine Products	434	98	106	230	258
Minerals and Electrolytes	18	6	0	12	241
Miscellaneous Therapeutic Classes	83	30	10	43	305
Mouth/Throat/Dental Agents	2	0	0	2	0
Multivitamins	2	1	0	1	360
Musculoskeletal Therapy Agents	49	5	9	35	359
Nasal Agents - Systemic and Topical	20	3	2	15	360
Neuromuscular Agents	85	37	23	25	359
Nutrients	4	0	1	3	0
Ophthalmic Agents	83	11	13	59	185
Other*	65	38	3	24	205
Otic Agents	96	49	7	40	38
Passive Immunizing and Treatment Agents	17	6	1	10	329
Pharmaceutical Adjuvants	1	1	0	0	360
Progestins	11	2	4	5	224
Psychotherapeutic and Neurological Agents - Misc.	310	90	52	168	279
Respiratory Agents - Misc.	49	31	2	16	255
Stimulants - Misc.	262	126	30	106	356
Thyroid Agents	8	1	0	7	1,091
Ulcer Drugs/Antispasmodics/Anticholinergics	148	26	25	97	709
Urinary Antispasmodics	54	9	10	35	603
Vaccines	2	2	0	0	238
Vaginal and Related Products	12	0	1	11	0
Vitamins	50	1	48	1	360
Total	**11,403**	**3,638**	**1,776**	**5,989**	
Overrides					
Brand	19	8	1	10	476
Compound	32	20	1	11	13
Dosage Change	156	147	0	9	15
IHS-Brand	1	1	0	0	9
Lost/Broken Rx	71	62	4	5	20
MAT Override	9	5	2	2	85

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
NDC vs Age	91	55	5	31	434
NDC vs Sex	10	5	2	3	359
Nursing Home Issue	51	44	2	5	14
Opioid MME Limit	43	13	2	28	165
Opioid Quantity	24	12	0	12	179
Other	49	27	7	15	22
Prescriber Temp Unlock	1	1	0	0	358
Quantity vs Days Supply	342	223	12	107	316
STBS/STBSM	21	11	2	8	79
Step Therapy Exception	1	0	0	1	0
Stolen	2	1	0	1	7
Third Brand Request	46	28	0	18	14
Overrides Total	**969**	**663**	**40**	**266**	
Total Regular PAs + Overrides	**12,372**	**4,301**	**1,816**	**6,255**	

Denial Reasons	
Unable to verify required trials.	5,739
Does not meet established criteria.	1,877
Lack required information to process request.	668
Other PA Activity	
Duplicate Requests	1,680
Letters	62,255
No Process	2
Helpdesk Initiated Prior Authorizations	407
PAs Missing Information	302
Pharmacotherapy	162
Changes to Existing PAs	702

*Includes missing and invalid NDCs, unspecified HCPCS, and CPT codes.

SoonerSelect Aetna Prior Authorization Activity

7/1/2026 Through 7/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	355	219	116	20	364
Analgesics - Anti-Inflammatory	123	71	26	26	351
Analgesics - Nonnarcotic	12	0	9	3	0
Analgesics - Opioid	112	47	36	29	109
Androgens - Anabolic	58	0	58	0	0
Anorectal and Related Products	2	0	1	1	0
Anorexiants Non-Amphetamine	3	0	2	1	0
Anthelmintics	6	0	6	0	0
Antianginal Agents	8	0	0	8	0
Antianxiety Agents	75	14	19	42	278
Antiasthmatic and Bronchodilator Agents	174	31	93	50	311
Antibiotics	24	2	10	12	47
Anticoagulants	10	3	1	6	184
Anticonvulsants	80	17	36	27	414
Antidepressants	275	60	106	109	472
Antidiabetics	591	161	321	109	314
Antiemetics	38	15	4	19	48
Antifungals	4	3	0	1	40
Antihistamines	42	20	20	2	530
Antihyperlipidemics	44	12	15	17	305
Antihypertensives	43	2	8	33	731
Anti-Infective Agents - Misc.	7	2	1	4	19
Antineoplastics and Adjunctive Therapies	75	51	3	21	164
Anti-Obesity Agents	283	55	217	11	146
Antiparkinson and Related Therapy Agents	8	0	1	7	0
Antipsychotics/Antimanic Agents	188	39	95	54	311
Antivirals	3	1	2	0	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	93	66	20	7	733
Beta Blockers	16	1	2	13	365
Calcium Channel Blockers	14	0	0	14	0
Cardiovascular Agents - Misc.	29	8	16	5	289
Contraceptives	24	2	21	1	365
Corticosteroids	31	15	16	0	183
Dermatologicals	333	122	156	55	235
Diagnostic Products	37	26	4	7	541
Digestive Aids	5	2	0	3	365
Diuretics	28	3	0	25	184
Endocrine and Metabolic Agents - Misc.	39	18	19	2	254
Estrogens	26	3	6	17	365
Gastrointestinal Agents - Misc.	111	31	72	8	223
General Anesthetics	3	0	3	0	0
Genitourinary Agents - Misc.	2	1	1	0	365
Gout Agents	4	2	1	1	365

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hematological Agents - Misc.	8	1	0	7	365
Hematopoietic Agents	10	5	3	2	223
Histamine H3-Receptor Antagonist/Inverse Agonists	2	0	2	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	35	3	20	12	184
Laxatives	7	1	3	3	7
Local Anesthetics-Parenteral	10	0	10	0	0
Medical Devices and Supplies	87	29	45	13	562
Migraine Products	224	73	143	8	229
Minerals and Electrolytes	22	1	9	12	61
Miscellaneous Therapeutic Classes	8	6	1	1	329
Multivitamins	1	1	0	0	365
Musculoskeletal Therapy Agents	54	2	18	34	69
Nasal Agents - Systemic and Topical	14	1	5	8	184
Neuromuscular Agents	16	9	3	4	365
Ophthalmic Agents	39	8	15	16	283
Other	17	0	0	17	0
Otic Agents	35	2	27	6	24
Progestins	1	0	1	0	0
Psychotherapeutic and Neurological Agents - Misc.	30	10	18	2	266
Respiratory Agents - Misc.	2	2	0	0	229
Stimulants - Misc.	86	57	24	5	358
Thyroid Agents	5	0	0	5	0
Ulcer Drugs/Antispasmodics/Anticholinergics	86	24	30	32	356
Urinary Antispasmodics	21	2	8	11	365
Vaccines	1	1	0	0	31
Vaginal and Related Products	1	0	1	0	0
Vitamins	64	3	60	1	229
****Total**	**4,324**	**1,366**	**1,989**	**969**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Overrides					
Other	969	0	0	969	0
Quantity Level Limit	33	33	0	0	331
Step Therapy Met	2	2	0	0	30
Vacation Override	1	1	0	0	30
Overrides Total	**1,005**	**36**	**0**	**969**	

Denial Reason	
Benefit	167
Experimental/Investigational	185
Lack Required Infomation to Process Request	109
Medical Necessity	1,499
Other	12
Other PA Activity	
Duplicate Requests	33
Letters	5,343
No Process	328
Changes to existing PAs	0
PAs missing info	18

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Humana Prior Authorization Activity

7/1/2026 Through 7/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Amphetamines	18	5	2	11	596
Analgesics - Anti-Inflammatory	94	69	4	21	358
Analgesics - Nonnarcotic	2	2	0	0	365
Analgesics - Opioid	115	52	37	26	278
Androgens - Anabolic	75	14	48	13	139
Anorectal and Related Products	5	0	0	5	0
Anthelmintics	8	1	0	7	52
Antianginal Agents	1	0	1	0	0
Antianxiety Agents	4	0	0	4	0
Antiasthmatic and Bronchodilator Agents	110	51	32	27	257
Antibiotics	10	0	0	10	0
Anticoagulants	3	0	0	3	0
Anticonvulsants	23	12	3	8	365
Antidepressants	75	31	18	26	250
Antidiabetics	492	171	188	133	228
Antidiarrheal/Probiotic Agents	1	1	0	0	365
Antiemetics	23	2	2	19	365
Antifungals	3	0	0	3	0
Antihyperlipidemics	30	13	7	10	268
Antihypertensives	2	1	0	1	365
Anti-Infective Agents - Misc.	3	0	0	3	0
Antineoplastics and Adjunctive Therapies	91	52	0	39	223
Anti-Obesity Agents	325	78	106	141	64
Antiparkinson and Related Therapy Agents	1	1	0	0	365
Antipsychotics/Antimanic Agents	6	1	1	4	502
Antivirals	3	3	0	0	84
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	19	9	1	9	1,004
Beta Blockers	5	2	0	3	243
Calcium Channel Blockers	2	0	0	2	0
Cardiovascular Agents - Misc.	52	20	7	25	560
Chemicals	1	1	0	0	365
Contraceptives	27	6	12	9	98
Corticosteroids	7	0	1	6	0
Dermatologicals	248	139	43	66	245
Diagnostic Products	19	11	2	6	449
Digestive Aids	2	1	0	1	365
Diuretics	5	1	1	3	365
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	2	0	1	1	0
Endocrine and Metabolic Agents - Misc.	56	38	3	15	310
Estrogens	5	2	0	3	365
Gastrointestinal Agents - Misc.	98	44	27	27	254
Gout Agents	3	3	0	0	365
Hematological Agents - Misc.	2	1	0	1	365
Hematopoietic Agents	31	9	2	20	174

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Hypnotics/Sedatives/Sleep Disorder Agents	15	2	11	2	214
Laxatives	6	1	3	2	183
Medical Devices and Supplies	22	8	1	13	1,491
Migraine Products	166	109	42	15	172
Minerals and Electrolytes	1	0	0	1	0
Miscellaneous Therapeutic Classes	24	16	0	8	287
Multivitamins	6	4	0	2	365
Musculoskeletal Therapy Agents	25	4	6	15	365
Nasal Agents - Systemic and Topical	1	0	1	0	0
Neuromuscular Agents	39	29	4	6	259
Ophthalmic Agents	35	11	12	12	281
Other	3	2	0	1	184
Otic Agents	1	0	0	1	0
Passive Immunizing and Treatment Agents	4	0	0	4	0
Psychotherapeutic and Neurological Agents - Misc.	38	20	7	11	288
Respiratory Agents - Misc.	14	14	0	0	365
Stimulants - Misc.	16	10	1	5	365
Thyroid Agents	2	1	0	1	365
Ulcer Drugs/Antispasmodics/Anticholinergics	29	12	9	8	256
Urinary Antispasmodics	8	0	3	5	0
Vaginal and Related Products	1	0	0	1	0
Vitamins	81	7	0	74	39
Total	**2,644**	**1,097**	**649**	**898**	
Overrides					
Dosage Change	170	67	74	29	132
Ingredient Duplication	188	98	57	33	160
NDC vs Age	528	378	27	123	258
NDC vs Sex	4	1	0	3	91
Opioid MME Limit	8	3	4	1	182
Opioid Quantity	10	10	0	0	384
Other	216	76	86	54	116
Quantity vs Days Supply	262	175	36	51	256
STBS/STBSM	678	46	115	517	25
Step Therapy Exception	200	111	48	41	203
Third Brand Request	3	0	3	0	0
Overrides Total	**2,267**	**965**	**450**	**852**	
Total Regular PAs + Overrides	**4,911**	**2,062**	**1,099**	**1,750**	
Denial Reasons					
Alternatives Not Met					297
Medical Necessity					802

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

SoonerSelect Oklahoma Complete Health Prior Authorization Activity

7/1/2026 Through 7/31/2026

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Allergenic Extracts/Biologicals Misc.	1	0	1	0	0
Amebicides	1	1	0	0	365
Amphetamines	324	150	130	44	1,067
Analgesics - Anti-Inflammatory	94	50	24	20	915
Analgesics - Nonnarcotic	13	1	11	1	182
Analgesics - Opioid	282	99	125	58	312
Androgens - Anabolic	51	0	35	16	0
Anorectal and Related Products	7	1	1	5	365
Anorexiants Non-Amphetamine	2	0	0	2	0
Antacids	1	1	0	0	365
Anthelmintics	6	2	3	1	93
Antianxiety Agents	19	4	13	2	730
Antiasthmatic and Bronchodilator Agents	213	76	101	36	707
Antibiotics	16	8	2	6	305
Anticoagulants	3	2	1	0	1,173
Anticonvulsants	73	33	31	9	850
Antidepressants	173	45	106	22	936
Antidiabetics	739	373	249	117	930
Antiemetics	27	3	8	16	235
Antifungals	3	3	0	0	156
Antihistamines	11	3	6	2	791
Antihyperlipidemics	26	7	15	4	723
Antihypertensives	20	9	8	3	579
Anti-Infective Agents - Misc.	12	4	4	4	243
Antineoplastics and Adjunctive Therapies	122	40	12	70	388
Anti-Obesity Agents	315	69	103	143	576
Antiparkinson and Related Therapy Agents	6	1	4	1	176
Antipsychotics/Antimanic Agents	175	70	73	32	1,026
Antivirals	6	3	1	2	56
Attention-Deficit/Hyperactivity Disorder (ADHD) Agents	109	63	29	17	1,095
Beta Blockers	9	4	3	2	394
Calcium Channel Blockers	3	1	1	1	1,096
Cardiovascular Agents - Misc.	27	7	11	9	1,095
Chemicals	4	2	0	2	265
Contraceptives	16	6	8	2	375
Corticosteroids	12	1	0	11	365
Dermatologicals	341	114	157	70	521
Diagnostic Products	21	10	10	1	1,056
Dietary Products/Dietary Management Products	1	0	0	1	0
Digestive Aids	2	1	0	1	155
Diuretics	1	1	0	0	1,095
Dopamine and Norepinephrine Reuptake Inhibitors (DNRIs)	1	0	1	0	0
Endocrine and Metabolic Agents - Misc.	62	24	27	11	944
Estrogens	30	11	11	8	330

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

	Total	Approved	Denied	Incomplete	Average Length of Approvals in Days
Gastrointestinal Agents - Misc.	135	33	68	34	748
Genitourinary Agents - Misc.	2	0	1	1	0
Gout Agents	5	1	3	1	1,095
Hematological Agents - Misc.	16	10	5	1	433
Hematopoietic Agents	35	5	15	15	233
Histamine H3-Receptor Antagonist/Inverse Agonists	1	0	1	0	0
Hypnotics/Sedatives/Sleep Disorder Agents	32	6	18	8	270
Laxatives	13	8	1	4	357
Medical Devices and Supplies	145	76	40	29	1,044
Migraine Products	251	95	129	27	729
Minerals and Electrolytes	6	0	4	2	0
Miscellaneous Therapeutic Classes	28	17	5	6	719
Mouth/Throat/Dental Agents	1	0	1	0	0
Multivitamins	4	2	1	1	1,095
Musculoskeletal Therapy Agents	46	14	25	7	466
Nasal Agents - Systemic and Topical	16	8	6	2	382
Neuromuscular Agents	33	18	5	10	351
Ophthalmic Agents	52	16	28	8	374
Other	41	5	6	30	210
Otic Agents	68	22	35	11	269
Passive Immunizing and Treatment Agents	1	1	0	0	365
Progestins	1	0	0	1	0
Psychotherapeutic and Neurological Agents - Misc.	56	21	28	7	870
Respiratory Agents - Misc.	6	3	3	0	1,095
Stimulants - Misc.	102	55	31	16	928
Thyroid Agents	5	4	0	1	164
Ulcer Drugs/Antispasmodics/Anticholinergics	30	6	19	5	784
Urinary Antispasmodics	26	15	10	1	501
Vaccines	5	2	0	3	132
Vaginal and Related Products	1	0	0	1	0
Vasopressors	1	0	1	0	0
Vitamins	28	3	18	7	496
****Total**	**4,572**	**1,749**	**1,832**	**991**	

**PA overrides are also reported within the drug categories included in the PA Activity report.

Denial Reasons	
Medical Necessity	1,831
Benefit	1

*SoonerSelect totals are based on data provide to the College of Pharmacy from the SoonerSelect plans. Other includes missing and unmatched NDCs.

Appendix C

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 2026

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

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 data included in this report combines fee-for-service (FFS) and managed care (SoonerSelect) utilization for fiscal year (FY) 2025 (07/01/2024 to 06/30/2025). The College of Pharmacy will make recommendations as well as take recommendations from the DUR Board.

Date	Drug	Issue
08/27/2025	**Clozapine**	**Risk Evaluation and Mitigation Strategy (REMS) Removal**
Issue Details: The FDA removed the REMS program from clozapine. **FDA Recommendation(s):** The FDA deemed the *Prescribing Information* for clozapine to be sufficient in mitigating the risk of severe neutropenia and removed the REMS program requirements on June 13, 2025. The *Boxed Warning* regarding the risk of severe neutropenia and the associated recommendation to monitor the absolute neutrophil count (ANC) prior to initiating and during treatment with clozapine remains per package labeling. The FDA also announced the availability of an updated *Medication Guide*. Patients, pharmacies, and providers no longer need to enroll in the REMS program or submit ANC results for verification prior to dispensing. Removing the REMS is expected to improve clozapine access and reduce health care burden. **Pharmacy Claims Evaluation:** During FY 2025, a total of 161 SoonerCare members had paid claims for clozapine accounting for 998 paid claims and an average of 6.2 claims per member. **SoonerCare Action:** Currently, generic clozapine does not require a prior authorization (PA) for members 5 years of age and older while branded formulations, Fazaclo® (clozapine orally disintegrating tablet) and Versacloz® (clozapine oral suspension), require a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation. SoonerCare updated the atypical antipsychotic approval criteria to count clozapine as a Tier-1 trial after the REMS removal. The College of Pharmacy will continue to monitor the FDA recommendations.		

Date	Drug	Issue
08/28/2025	**Leqembi® (Lecanemab)**	**Additional Magnetic Resonance Imaging (MRI) for Patients with Alzheimer's Disease**

Issue Details: The FDA recommends an additional MRI scan before the 3rd infusion of Leqembi® for patients with Alzheimer's disease to monitor for the presence of amyloid-related imaging abnormalities with edema (ARIA-E). Previously, the *Prescribing Information* recommended an MRI scan before the 5th, 7th, and 14th infusions.
FDA Recommendation(s): The FDA determined that an additional MRI before the 3rd infusion of Leqembi® could aid in early detection of ARIA-E related events such as brain swelling or fluid buildup. There were 24 out of 101 cases (24%) of serious ARIA-E events reported in the FDA Adverse Event Reporting System (FAERS) that occurred before the 4th infusion.
Medical and Pharmacy Claims Evaluation: During FY 2025, one SoonerCare member had 16 paid claims for Leqembi®.
SoonerCare Action: Currently, Leqembi® requires a PA for coverage consideration. At the July 2026 DUR Board meeting, the College of Pharmacy recommended an update to the approval criteria for Leqembi® to include an MRI scan prior to the 3rd infusion. This change is pending a vote by the DUR Board in September 2026. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
01/13/2026	**Saxenda® (Liraglutide), Wegovy® (Semaglutide), and Zepbound® (Tirzepatide)**	**Removal of Suicidal Behavior and Ideation Warning**

Issue Details: Inconsistency was found within the *Warnings and Precautions* section of the *Prescribing Information* for glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications regarding the potential risk of suicidal ideation and behavior (SI/B).
FDA Recommendation(s): The FDA is requesting removal of SI/B from the *Prescribing Information* for Saxenda®, Wegovy®, and Zepbound®, to match labeling for the GLP-1 RA medications approved for use in patients with type 2 diabetes. Postmarketing reports of SI/B in patients taking GLP-1 RA spurred on a comprehensive evaluation by the FDA. A meta-analysis was done to estimate the risk of SI/B occurrence with GLP-1 RA use which included 91 placebo-controlled trials and nearly 110,000 patients treated with GLP-1 RA medications. Additionally, the FDA used data from the FDA Sentinel System to pilot a retrospective cohort study to compare the risk of intentional self-harm with GLP-1 RAs and sodium-glucose cotransporter 2 inhibitors (SGLT2i). Collectively, these studies do not support a causal association between GLP-1 RA use and SI/B.

Pharmacy Claims Evaluation: During FY 2025, a total of 150 SoonerCare members had paid claims for Wegovy® and Zepbound®, accounting for 390 paid claims and an average of 2.6 claims per member. There was no utilization for Saxenda® as it is not currently covered by SoonerCare.
SoonerCare Action: Current criteria requires a PA for coverage consideration of Wegovy® for cardiovascular risk reduction and metabolic dysfunction-associated steatohepatitis (MASH) and of Zepbound® for obstructive sleep apnea. Medications with a sole FDA indication for chronic weight management, like Saxenda®, are considered a coverage exclusion and are not covered by SoonerCare. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
03/20/2026	**Carbidopa/Levodopa**	**Vitamin B6 Deficiency and Increased Seizure Risk**

Issue Details: Carbidopa/levodopa is an FDA-approved combination therapy indicated for the treatment of Parkinson's disease and Parkinsonian syndrome. Although highly effective, its use has been associated with vitamin B6 deficiency and, in severe cases, vitamin B6 deficiency-associated seizures. Levodopa requires the active form of vitamin B6, pyridoxal-5'-phosphate (PLP), as a cofactor for its decarboxylation to dopamine. To increase central nervous system (CNS) delivery of levodopa, carbidopa inhibits peripheral conversion of levodopa to dopamine by binding to PLP. Once levodopa reaches the CNS, it is decarboxylated to dopamine, restoring dopaminergic neurotransmission and improving motor coordination and muscle control in patients with Parkinson's disease. Because both levodopa metabolism and carbidopa's mechanism of action rely on PLP, chronic therapy can reduce the bioavailability of vitamin B6. This depletion increases the risk of vitamin B6 deficiency-associated seizures. Many instances of seizures associated with vitamin B6 deficiency did not respond to traditional anti-seizure medications but only resolved after vitamin B6 administration.
FDA Recommendation(s): The FDA is requiring updated labeling within the *Prescribing Information* regarding the vitamin B6 deficiency and increased seizure risk along with wording to monitor vitamin B6 levels prior to initiating and periodically during treatment with carbidopa/levodopa. Post-marketing data was submitted to the FAERS, and all cases were in patients with daily doses of levodopa ≥1,000mg. The greater the levodopa dose, the quicker vitamin B6 deficiency occurred. Typical daily dosing with immediate-release carbidopa/levodopa is 200mg/800mg divided 3-4 times daily. Cases occurred with oral and enteral administration and presented as focal onset seizure with some progressing to status epilepticus. Two fatalities occurred in patients with documented low vitamin B6 levels and poorly controlled seizures. Other symptoms of B6 deficiency occurred such as elevated homocysteine levels, anemia, and neuropsychiatric symptoms.

Pharmacy Claims Evaluation: During FY 2025, a total of 410 SoonerCare members had paid claims for carbidopa/levodopa products, accounting for 1,904 paid claims and an average of 4.6 claims per member.
SoonerCare Action: Currently, generic carbidopa/levodopa tablets do not require a PA but branded formulations like Crexont® [carbidopa/levodopa extended-release (ER) capsules], Rytary® (carbidopa/levodopa ER capsules), and Duopa® (carbidopa/levodopa enteral suspension) require a PA for coverage consideration. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
03/31/2026	**Tavneos® (Avacopan)**	**Serious Liver Injury**

Issue Details: The FDA has issued a warning regarding the risk of severe and potentially fatal drug-induced liver injury (DILI), including vanishing bile duct syndrome (VBDS), associated with Tavneos® use. Postmarketing surveillance data from the FAERS and the FDA Adverse Event Monitoring System (AEMS) identified 76 reports of DILI associated with Tavneos®, including 54 cases requiring hospitalization and 8 fatalities.
FDA Recommendation(s): Liver panel testing should be performed every 2 weeks during the first month of treatment, followed by monthly monitoring for the next 5 months, and thereafter as clinically indicated. The FDA recommends discontinuing treatment with Tavneos® in patients who develop clinical evidence of cholestasis, like jaundice or pruritus, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) elevations >3 times the upper limit of normal (ULN), or alkaline phosphatase elevations >2 the ULN. Referral to a hepatologist should be considered if liver test abnormalities or symptoms of liver injury persist.
Pharmacy Claims Evaluation: During FY 2025, a total of 7 SoonerCare members had paid claims for Tavneos®, accounting for 40 paid claims and an average of 5.7 claims per member.
SoonerCare Action: Tavneos® requires a PA for coverage consideration and resides in the Special PA tier of the Targeted Immunomodulator Agents Tier Chart. Unique criteria exist which currently matches the published *Prescribing Information* for Tavneos®. The College of Pharmacy will continue to monitor the FDA recommendations.

Date	Drug	Issue
06/10/2026	**Alli® (Orlistat 60mg), Xenical® (Orlistat 120mg)**	**Risk of Kidney Stones and Kidney Injury**

Issue Details: The FDA is warning patients and prescribers about the risk of acute kidney injury (AKI), hyperoxaluria, and nephrolithiasis associated with orlistat use. A review of the AEMS and the medical literature identified 12 severe cases, of which 8 resulted in hospitalization and 5 required dialysis. Cases occurred in adults 36–76 years of age, with symptom onset occurring

after a median of 2.5 months of treatment with either 60mg or 120mg of orlistat administered 3 times daily.
FDA Recommendation(s): The FDA required the addition of a new warning to the labeling of all orlistat products regarding the risk of AKI and nephrolithiasis. The revised labeling advises patients to consult a health care provider before using the over-the-counter product Alli® if they have a history of renal disease or if they develop symptoms of AKI during treatment. A corresponding warning has also been added to the *Prescribing Information* for the prescription product Xenical®.
Pharmacy Claims Evaluation: During FY 2025, there was no utilization of orlistat as it is not a covered product.
SoonerCare Action: Currently, medications primarily used for the treatment of obesity are considered a coverage exclusion and are not covered by SoonerCare. 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 06/10/2026. Last accessed 07/29/2026.
[2] U.S. FDA. FDA Removes Risk Evaluation and Mitigation Strategy (REMS) Program for the Antipsychotic Drug Clozapine. Available online at: https://www.fda.gov/drugs/drug-safety-communications/fda-removes-risk-evaluation-and-mitigation-strategy-rems-program-antipsychotic-drug-clozapine. Issued 08/27/2025. Last accessed 07/29/2026.
[3] U.S. FDA. FDA to Recommend Additional, Earlier MRI Monitoring for Patients with Alzheimer's Disease Taking Leqembi® (Lecanemab). Available online at: https://www.fda.gov/drugs/drug-safety-communications/fda-recommend-additional-earlier-mri-monitoring-patients-alzheimers-disease-taking-leqembi-lecanemab. Issued 08/28/2025. Last accessed 07/29/2026.
[4] U.S. FDA. FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications. Available online at: https://www.fda.gov/drugs/drug-safety-communications/fda-requests-removal-suicidal-behavior-and-ideation-warning-glucagon-peptide-1-receptor-agonist-glp. Issued 01/13/2026. Last accessed 07/29/2026.
[5] U.S. FDA. FDA Is Requiring Warning about Vitamin B6 Deficiency and Associated Seizures for Drug Products Containing Carbidopa/Levodopa. Available online at: https://www.fda.gov/drugs/drug-safety-communications/fda-requiring-warning-about-vitamin-b6-deficiency-and-associated-seizures-drug-products-containing. Issued 03/20/2026. Last accessed 07/29/2026.
[6] U.S. FDA. FDA Identifies Cases of Serious Liver Injury in Patients Taking Tavneos® (Avacopan) for Severe Active Anti-neutrophil Cytoplasmic Autoantibody (ANCA)-associated Vasculitis. Available online at: https://www.fda.gov/drugs/drug-safety-communications/fda-identifies-cases-serious-liver-injury-patients-taking-tavneos-avacopan-severe-active-anti. Issued 03/31/2026. Last accessed 07/29/2026.
[7] U.S. FDA. FDA Approves Labeling Changes for Over-the-Counter (OTC) Weight Loss Drug Alli® (Orlistat) to Warn of Risk of Kidney Stones and Kidney Injury. Available online at: https://www.fda.gov/drugs/drug-safety-communications/fda-approves-labeling-changes-over-counter-otc-weight-loss-drug-alli-orlistat-warn-risk-kidney. Issued 06/10/2026. Last accessed 07/29/2026.

Appendix D

Fiscal Year 2025 Annual Review of Copper Metabolism Disorder Medications and 30-Day Notice to Prior Authorize Zycubo® (Copper Histidinate)

Oklahoma Health Care Authority
August 2026

Current Prior Authorization 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 a 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 generic penicillamine 250mg capsule, generic trientine hydrocholoride 250mg capsule, 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.

Penicillamine 250mg Tablet Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use penicillamine 250mg capsule must be provided.

Trientine Hydrochloride (HCl) 500mg Capsule Approval Criteria:

1. An FDA approved diagnosis of Wilson's disease; and
2. A patient-specific, clinically significant reason why the member cannot use trientine HCl 250mg capsule must be provided.

Utilization of Copper Metabolism Disorder Medications: Fiscal Year 2025

Fiscal Year 2025 Utilization: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	1	1	$73.65	$73.65	$2.46	30	30
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	1	1	$124.89	$124.89	$4.16	30	30
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**2**	**2**	**$198.54**	**$99.27**	**$3.31**	**60**	**60**
Fiscal Year 2025							
FFS	1	4	$3,374.52	$843.63	$28.12	360	120
Aetna	0	0	$0.00	$0.00	$0.00	0	0
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	0	0	$0.00	$0.00	$0.00	0	0
2025 Total	**1**	**4**	**$3,374.52**	**$843.63**	**$28.12**	**360**	**120**
% Change	**-50.00%**	**100.00%**	**1,599.70%**	**749.80%**	**749.50%**	**500.00%**	**100.00%**
Change	**-1**	**2**	**$3,175.98**	**$744.36**	**$24.81**	**300**	**60**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = OK Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Copper Metabolism Disorder Medications: Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing copper metabolism disorder medications during fiscal year 2025, detailed demographic information could not be provided.

Top Prescriber Specialties of Copper Metabolism Disorder Medications by Number of Claims: Pharmacy Claims (All Plans)

- There were 4 pharmacy claims for copper metabolism disorder medications during fiscal year 2025, all of which were prescribed by a family practitioner.

Prior Authorization of Copper Metabolism Disorder Medications

There were no prior authorization requests submitted for copper metabolism disorder medications during fiscal year 2025.

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

Anticipated Patent Expiration(s):

- Cuvrior® (trientine tetrahydrochloride): May 2039

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

- **January 2026:** The FDA approved Zycubo® (copper histidinate) for the treatment of Menkes disease in pediatric patients, making it the first FDA-approved therapy for this rare, inherited copper transport disorder.

Pipeline:

- **ALXN1840:** ALXN1840 (bis-choline tetrathiomolybdate, also known as tiomolibdate choline or TMC) is an investigational once-daily oral copper-protein binding agent being developed for the treatment of Wilson's disease. In the Phase 3 FoCus trial, ALXN1840 met the primary endpoint by demonstrating rapid and sustained copper mobilization that was significantly greater than standard of care over 48 weeks. Among patients with neurologic symptoms at baseline, ALXN1840 demonstrated greater neurologic improvement and less clinically meaningful worsening than standard of care, with a favorable safety and tolerability profile. In June 2026, the FDA granted ALXN1840 Rare Pediatric Disease designation, making the therapy eligible for a Priority Review Voucher upon approval.

Zycubo® (Copper Histidinate) Product Summary[6]

Therapeutic Class: Copper replacement product

Indication(s): Treatment of Menkes disease in pediatric patients

- **Limitation(s) of Use:** Zycubo® is not indicated for the treatment of occipital horn syndrome.

How Supplied: 2.9mg of copper histidinate (equivalent to 0.5mg elemental copper) as a lyophilized powder or cake in a single-dose vial (SDV) for reconstitution

Dosing and Administration:

- Before initiating Zycubo®, baseline serum copper and ceruloplasmin levels, serum electrolytes, kidney and liver function, and complete blood count (CBC) should be obtained.
- After initiating Zycubo®, laboratory values should be monitored every 6 weeks for the first 6 months, then every 3 months for 18 months, and then every 6 months thereafter during Zycubo® treatment.
- Zycubo® should be administered subcutaneously (sub-Q) with the dosing frequency based on age:
  - <1 year of age: 1.45mg twice daily (8-12 hours between injections)
  - 1 year to <17 years of age: 1.45mg once daily

Efficacy: The efficacy of Zycubo® for the treatment of Menkes disease was evaluated by assessing overall survival in 2 open-label, single-arm clinical trials (Trial 1 and Trial 2). Data from both trials were pooled and compared

with an untreated contemporaneous external control cohort. Patients in the pooled efficacy population were stratified based on whether treatment was initiated within 4 weeks of birth (early treatment) or after 4 weeks of birth (late treatment).

- Pooled Efficacy Population:
  - Patients with confirmed Menkes disease carrying severe *ATP7A* pathogenic variants
  - Born after 1999
  - Patients pooled from 2 open-label trials
  - Stratified into early (≤4 weeks of age) and late (>4 weeks of age) treatment cohorts
  - Compared with untreated external controls
- Intervention: Patients received sub-Q Zycubo® for up to 3 years dosed as 1.45mg twice daily if younger than 1 year of age or 1.45mg once daily if 1 year of age older.
- Outcome(s):
  - Primary Outcome: The primary efficacy analysis compared the overall survival in patients in the Zycubo®-ET (Early Treatment) and EC-ET (External Control Early Treatment) cohorts.
  - Secondary Outcome: The secondary efficacy analysis compared overall survival between the Zycubo®-LT (Late Treatment) cohort and the EC-LT (External Control Late Treatment) cohort.
- Pooled Efficacy Results:
  - Early Treatment Cohort: The percentage of patients alive was 52% (16/31) in the Zycubo®-ET cohort compared with 12% (2/17) in the EC-ET cohort. Median overall survival was 177.1 months [95% confidence interval (CI): 33, not estimable)] with Zycubo® versus 17.6 months (95% CI: 11.5, 28.6) in the EC-ET cohort, corresponding to a 78% reduction in the risk of death [hazard ratio (HR): 0.22; 95% CI: 0.10, 0.49].
  - Late Treatment Cohort: The percentage of patients alive was 34% (12/35) in the Zycubo®-LT cohort compared with 12% (2/16) in the EC-LT cohort. Median overall survival was 62.4 months (95% CI: 29.6, 80.7) with Zycubo® versus 20.7 months (95% CI: 12.6, 28.6) in the EC-LT cohort, corresponding to a 73% reduction in the risk of death (HR: 0.27; 95% CI: 0.12, 0.57).

Cost: The Wholesale Acquisition Cost (WAC) of Zycubo® is $1,867 per SDV. This would result in an estimated monthly cost of $56,010 or $672,120 annually for children 1 year of age or older. For infants younger than 1 year of age, the estimated monthly cost is $112,020 or $1,344,240 per year.

Recommendations

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

Zycubo® (Copper Histidinate) Approval Criteria:

1. An FDA approved diagnosis of Menkes disease; and
2. Diagnosis must be confirmed by 1 of the following (results of the selected test must be submitted):
    a. Plasma catecholamine analysis indicating elevated ratios of dihydroxyphenylacetic acid to dihydroxyphenylglycol and dopamine to norepinephrine; or
    b. Genetic testing identifying pathogenic or likely pathogenic variants in the *ATP7A* gene; or
    c. If plasma catecholamine analysis or genetic testing is pending:
        i. Documentation of clinical signs and symptoms consistent with Menkes disease; and
3. Member must be younger than 18 years of age; and
4. Member must not have occipital horn syndrome; and
5. Zycubo® must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of Menkes disease (or an advanced care practitioner with a supervising physician who is a geneticist, neurologist, or other specialist with expertise in the treatment of Menkes disease); and
6. Prescriber must confirm that all baseline assessments and follow-up monitoring will be performed as recommended in the package labeling for Zycubo®; and
7. For member or caregiver administration, the prescriber must verify the member or caregiver will be trained by a health care provider on proper preparation, administration, and storage of Zycubo®; and
8. Initial approval and subsequent approvals will be for the duration of 1 year. Subsequent approvals will be granted if the prescriber documents the member is responding well to therapy; or
    a. If the diagnosis of Menkes disease was based on clinical signs and symptoms, initial approvals will be for 3 months. Subsequent approvals for the duration of 1 year will require submitted documentation of a plasma catecholamine analysis or genetic testing confirming the diagnosis; and
9. A quantity limit of 1 vial (2.9mg) per day will apply; or
    a. For members younger than 1 year of age, a quantity limit override will be granted based on FDA approved dosing.

Utilization Details of Copper Metabolism Disorder Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
PENICILLAMINE CAP 250MG	4	1	$3,374.52	$843.63	4	100%
TOTAL	**4**	**1***	**$3,374.52**	**$843.63**	**4**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 07/2026. Last accessed 07/17/2026.
[2] U.S. Food and Drug Administration (FDA). FDA Approves First Treatment for Children With Menkes Disease. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-children-menkes-disease. Last revised 01/2026. Last accessed 07/17/2026.
[3] Monopar Therapeutics. Monopar Therapeutics Receives FDA Rare Pediatric Disease Designation for ALXN1840 for the Treatment of Wilson Disease. Available online at: https://ir.monopartx.com/press-releases/detail/134/monopar-therapeutics-receives-fda-rare-pediatric-disease. Issued 06/30/2026. Last accessed 07/17/2026.
[4] Monopar Therapeutics. Monopar Presents Phase 3 Data Showing Greater Neurologic Benefit with ALXN1840 vs SoC in Wilson Disease Patients with Neurologic Symptoms at AAN 2026. Available online at: https://ir.monopartx.com/press-releases/detail/129/monopar-presents-phase-3-data-showing-greater-neurologic. Issued 04/19/2026. Last accessed 07/17/2026.
[5] Monopar Therapeutics. Monopar Therapeutics Reports Second Quarter 2025 Financial Results and Recent Developments. Available online at: https://ir.monopartx.com/press-releases/detail/119/monopar-therapeutics-reports-secondquarter. Issued 08/12/2026. Last accessed 07/17/2026.
[6] Zycubo® (Copper Histidinate). Prescribing Information. Sentynl Therapeutics, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/211241s000lbl.pdf. Last revised 01/2026. Last accessed 07/17/2026.

Appendix E

Fiscal Year 2025 Annual Review of Iron Chelating Agents

Oklahoma Health Care Authority
August 2026

Current Prior Authorization Criteria

Jadenu® (Deferasirox), Jadenu® Sprinkle (Deferasirox), and Ferriprox® (Deferiprone) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox) must be provided; and
3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of 6 years of age and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why Jadenu® oral tablets cannot be used even when the tablets are crushed; 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.

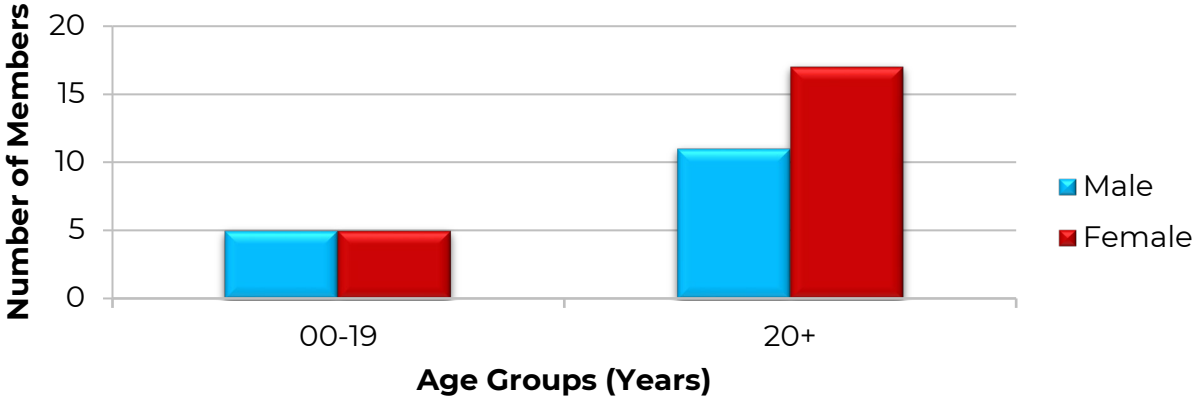
Utilization of Iron Chelating Agents: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

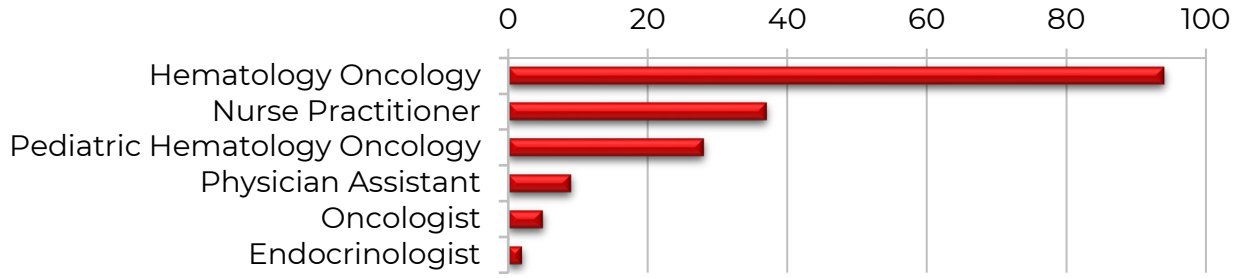
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	29	129	$509,312.02	$3,948.16	$129.56	10,292	3,931
Aetna	1	2	$6,483.74	$3,241.87	$108.06	180	60
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	1	1	$175.49	$175.49	$5.85	90	30
2024 Total	**29**	**132**	**$515,971.25**	**$3,908.87**	**$128.32**	**10,562**	**4,021**
Fiscal Year 2025							
FFS	27	127	$516,917.12	$4,070.21	$136.75	10,350	3,780
Aetna	6	28	$61,276.24	$2,188.44	$74.55	2,550	822
Humana	1	2	$514.82	$257.41	$8.58	180	60
OCH	6	18	$31,168.27	$1,731.57	$57.72	2,070	540
2025 Total	**38**	**175**	**$609,876.45**	**$3,485.01**	**$117.24**	**15,150**	**5,202**
% Change	**31.00%**	**32.60%**	**18.20%**	**-10.80%**	**-8.60%**	**43.40%**	**29.40%**
Change	**9**	**43**	**$93,905.20**	**-$423.86**	**-$11.08**	**4,588**	**1,181**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Iron Chelating Agents (All Plans)



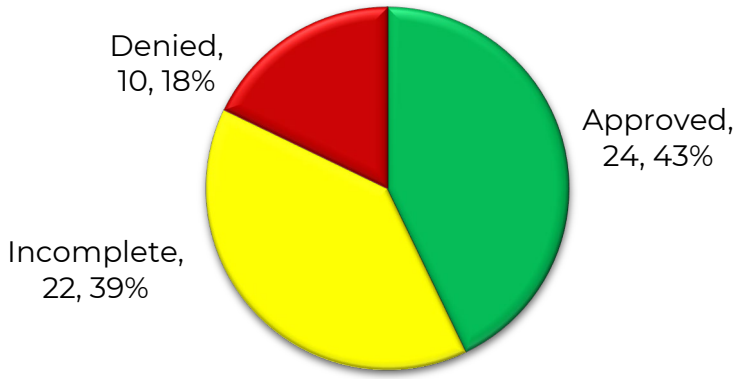
Top Prescriber Specialties of Iron Chelating Agents by Number of Claims (All Plans)



Prior Authorization of Iron Chelating Agents

There were 56 prior authorization requests submitted for iron chelating agents during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	21	40%	21	40%	10	19%	**52**
Aetna	2	67%	1	33%	0	0%	**3**
Humana	0	N/A	0	N/A	0	N/A	**0**
OCH	1	100%	0	0%	0	0%	**1**
Total	**24**	**43%**	**22**	**39%**	**10**	**18%**	**56**

FFS = fee-for-service; N/A = not applicable; OCH = OK Complete Health

Market News and Updates[1]

Anticipated Patent Expiration(s):

- Ferriprox® (deferiprone oral solution): October 2029
- Jadenu® (deferasirox tablet): November 2034
- Ferriprox® (deferiprone tablet): October 2038

Recommendations

The College of Pharmacy recommends updating the approval criteria for Exjade® (deferasirox) for clarity and recommends additional criteria for Ferriprox® 1,000mg tablet (deferiprone twice daily formulation) based on net cost (changes shown in red):

Jadenu® (Deferasirox), Jadenu® Sprinkle (Deferasirox), and Ferriprox® (Deferiprone) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox), which is available without prior authorization, must be provided; and
3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of 6 years of age and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why Jadenu® oral tablets cannot be used even when the tablets are crushed; and
4. For Ferriprox® 1,000mg tablet (deferiprone twice daily formulation), a patient-specific, clinically significant reason other than convenience why the member cannot use Ferriprox® 1,000mg tablet (deferiprone three times daily formulation) must be provided; and
5. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Utilization Details of Iron Chelating Agents: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEFERASIROX PRODUCTS						
DEFERASIROX TAB 360MG	56	14	$8,273.15	$147.73	4	1.36%
DEFERASIROX TAB 180MG	28	5	$6,832.32	$244.01	5.6	1.12%
DEFERASIROX TAB 250MG	27	8	$11,111.17	$411.52	3.38	1.82%
DEFERASIROX TAB 500MG	23	10	$75,610.27	$3,287.40	2.3	12.40%
DEFERASIROX GRA 90MG	18	2	$47,585.46	$2,643.64	9	7.80%
JADENU TAB 360MG	11	1	$207,775.02	$18,888.64	11	34.07%
DEFERASIROX TAB 125MG	1	1	$201.44	$201.44	1	0.03%
SUBTOTAL	**164**	**41**	**$357,388.83**	**$2,179.20**	**4**	**58.60%**
DEFERIPRONE PRODUCTS						
FERRIPROX TAB 1,000MG	11	1	$252,487.62	$22,953.42	11	41.40%
SUBTOTAL	**11**	**1**	**$252,487.62**	**$22,953.42**	**11**	**41.40%**
TOTAL	**175**	**38***	**$609,876.45**	**$3,485.01**	**4.17**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
GRA = granule; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[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 07/2026. Last Accessed 07/29/2026.

Appendix F

Fiscal Year 2025 Annual Review of Iron Products

Oklahoma Health Care Authority
August 2026

Current Prior Authorization Criteria

Accrufer® (Ferric Maltol) Approval Criteria:

1. Diagnosis of iron deficiency anemia (IDA); and
2. Lab results verifying IDA must be submitted; and
3. Member must be 18 years of age or older; and
4. Member must have a documented diagnosis of chronic kidney disease (CKD) or inflammatory bowel disease (IBD) (e.g., Crohn's disease, ulcerative colitis); and
5. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
6. A recent, failed trial of Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
7. A patient-specific clinically significant reason why the member cannot utilize all other forms of intravenous (IV) iron must be provided; and
8. Initial approvals will be for the duration of 3 months of treatment. Subsequent approvals (for 3 months of treatment) will require updated recent laboratory results documenting continued IDA.

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 Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided.

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 Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, 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.

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 Feraheme® (ferumoxytol), Infed® (iron dextran), or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed®, and Venofer® must be provided; and
5. A patient-specific, clinically significant reason why the member cannot utilize all other forms of intravenous (IV) iron must be provided.

Utilization of Iron Products: Fiscal Year 2025

Reimbursement of intravenous (IV) iron products for members with end stage renal disease (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 this report.

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	4	4	$1,933.77	$483.44	$16.11	210	120
Humana	7	8	$3,659.19	$457.40	$17.34	317	211
OCH	0	0	$0.00	$0.00	$0.00	0	0
2024 Total	**11**	**12**	**$5,592.96**	**$466.08**	**$16.90**	**527**	**331**
Fiscal Year 2025							
FFS	0	0	$0.00	$0.00	$0.00	0	0
Aetna	3	7	$2,509.11	$358.44	$15.21	270	165
Humana	9	19	$10,732.90	$564.89	$18.83	1,140	570
OCH	8	23	$10,166.70	$442.03	$18.38	1,070	553
2025 Total	**20**	**49**	**$23,408.71**	**$477.73**	**$18.17**	**2,480**	**1,288**
% Change	**81.80%**	**308.30%**	**318.50%**	**2.50%**	**7.50%**	**370.60%**	**289.10%**
Change	**9**	**37**	**$17,815.75**	**$11.65**	**$1.27**	**1,953**	**957**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	1,694	5,367	$463,202.93	$86.31	3.17
Aetna	18	34	$6,319.20	$185.86	1.89
Humana	40	63	$7,331.60	$116.37	1.58
OCH	64	137	$10,775.86	$78.66	2.14
2024 Total	**1,787**	**5,601**	**$487,629.59**	**$87.06**	**3.13**
Fiscal Year 2025					
FFS	793	2,033	$239,961.54	$118.03	2.56
Aetna	398	894	$108,547.80	$121.42	2.25
Humana	308	652	$85,113.47	$130.54	2.12
OCH	529	1,760	$118,899.00	$67.56	3.33
2025 Total	**1,993**	**5,339**	**$552,521.81**	**$103.49**	**2.68**
% Change	**11.53%**	**-4.68%**	**13.31%**	**18.87%**	**-14.38%**
Change	**206**	**-262**	**$64,892.22**	**$16.43**	**-0.45**

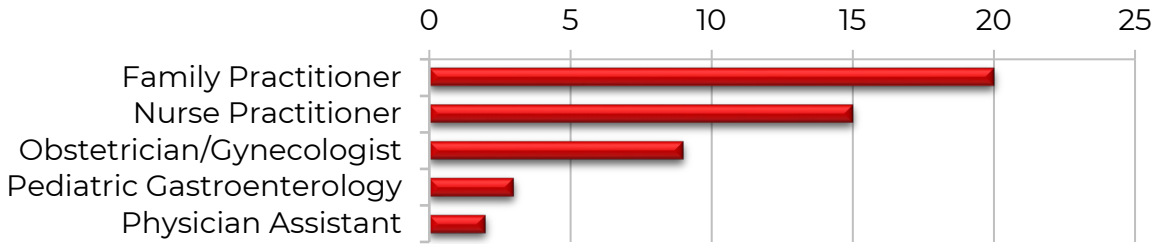
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for iron products totaled $283,272.80.[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 Iron Products: Pharmacy Claims (All Plans)

- Due to the limited number of members utilizing iron products during fiscal year 2025, detailed demographic information could not be provided.

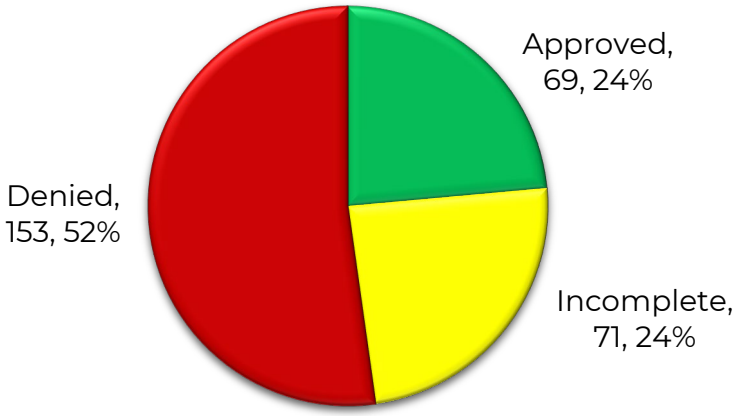
Top Prescriber Specialties of Iron Products by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Iron Products

There were 293 prior authorization requests submitted for iron products during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



[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.

Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	35	20%	54	31%	87	49%	**176**
Aetna	18	58%	4	13%	9	29%	**31**
Humana	8	21%	0	0%	31	79%	**39**
OCH	8	17%	13	28%	26	55%	**47**
Total	**69**	**24%**	**71**	**24%**	**153**	**52%**	**293**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Injectafer® (ferric carboxymaltose injection): February 2028
- Accrufer® (ferric maltol capsule): October 2035
- Monoferric® (ferric derisomaltose injection): June 2036

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

- **December 2025:** The FDA approved Accrufer® (ferric maltol) for an age expansion for the treatment of iron deficiency in adult and pediatric patients 10 years of age and older. Previously, Accrufer® was only approved for the treatment of iron deficiency in adults.

Recommendations

The College of Pharmacy recommends updating the Accrufer® (ferric maltol) approval criteria based on the recent FDA approved age expansion with the following changes (shown in red):

Accrufer® (Ferric Maltol) Approval Criteria:

1. Diagnosis of iron deficiency anemia (IDA); and
2. Lab results verifying IDA must be submitted; and
3. Member must be ~~18~~ 10 years of age or older; and
4. For members 18 years of age or older, all of the following must be met:
    a. Member must have a documented diagnosis of chronic kidney disease (CKD) or inflammatory bowel disease (IBD) (e.g., Crohn's disease, ulcerative colitis); and
    b. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
    c. A recent, failed trial of Feraheme® (ferumoxytol), Infed® (iron dextran) or Venofer® (iron sucrose) or a patient-specific, clinically significant reason why the member cannot utilize Feraheme®, Infed® and Venofer® must be provided; and

d. A patient-specific clinically significant reason why the member cannot utilize all other forms of intravenous (IV) iron must be provided; and

5. For members younger than 18 years of age, all of the following must be met:
   a. Documentation of intolerance or inadequate response to over-the-counter (OTC) oral iron therapy after at least 3 months at recommended dosing; and
   b. A patient-specific clinically significant reason why the member cannot utilize IV iron must be provided; and
6. Initial approvals will be for the duration of 3 months of treatment. Subsequent approvals (for 3 months of treatment) will require updated recent laboratory results documenting continued IDA.

Utilization Details of Iron Products: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ACCRUFER CAP 30MG	46	19	$23,160.69	$503.49	2.42	98.94%
VENOFER INJ 20MG/ML⁺	3	1	$248.02	$82.67	3	1.06%
TOTAL	**49**	**20***	**$23,408.71**	**$477.73**	**2.45**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺This product is typically not covered as a pharmacy claim by SoonerCare; however, there were paid claims in fiscal year 2025 through 1 of the SoonerSelect plans.
CAP = capsule; INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS⁺	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
J1756 IRON SUC INJ (VENOFER)	3,677	984	$96,704.49	$26.30	3.74	17.50%
J1750 IRON DEX INJ (INFED)	1,084	698	$258,913.22	$238.85	1.55	46.86%
Q0138 FERUMOXYTOL INJ (FERAHEME)	447	289	$96,000.20	$214.77	1.55	17.37%
J1439 FER CARB INJ (INJECTAFER)	120	65	$92,361.94	$769.68	1.85	16.72%
J1437 FER DERIS INJ (MONOFERRIC)	11	9	$8,541.96	$776.54	1.22	1.55%
TOTAL	**5,339**	**1,993**	**$552,521.81**	**$103.49**	**2.68**	**100%**

Costs do not reflect rebated prices or net costs.
⁺Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
CARB = carboxymaltose; DERIS = derisomaltose; DEX = dextran; FER = ferric; INJ = injection; SUC = sucrose
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[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 07/2026. Last accessed 07/22/2026.

[2] U.S. FDA. FDA Approves First Prescription Oral Medicine for Iron Deficiency in Pediatric Patients Ages 10 and Older. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-prescription-oral-medicine-iron-deficiency-pediatric-patients-ages-10-and-older. Issued 12/22/2025. Last accessed 07/22/2026.

Appendix G

Fiscal Year 2025 Annual Review of Miscellaneous Cancer Medications and 30-Day Notice to Prior Authorize Modeyso™ (Dordaviprone) and Vistogard® (Uridine Triacetate)

Oklahoma Health Care Authority
August 2026

Current Prior Authorization Criteria

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

1. Diagnosis of relapsed or refractory high-risk neuroblastoma in adult and pediatric members 1 year of age and older; and
2. Disease in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy (i.e., no progressive disease following most recent therapy); and
3. Must be given in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) according to package labeling (GM-CSF dosed at 250mcg/m^2/day daily starting 5 days prior to Danyelza® therapy and 500mcg/m^2/day daily on days 1 to 5 of Danyelza® therapy); and
4. Prescriber must agree to provide the member appropriate premedication for pain management and neuropathic pain (e.g., oral opioids, gabapentin); and
5. Prescriber must agree to provide the member appropriate premedication for infusion-related reactions and nausea/vomiting including an intravenous (IV) corticosteroid, a histamine 1 (H_1) antagonist, an H_2 antagonist, acetaminophen, and an antiemetic.

Fyarro® (Sirolimus Protein-Bound Particles for Injectable Suspension) Approval Criteria [Perivascular Epithelioid Cell Tumor (PEComa) Diagnosis]:

1. Diagnosis of locally advanced unresectable or metastatic PEComa; and
2. Member must be 18 years of age or older.

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

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

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

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

Loqtorzi® (Toripalimab-tpzi) Approval Criteria [Anal Carcinoma, Colorectal Cancer (CRC), and Small Bowel Adenocarcinoma Diagnosis]:

1. Diagnosis of anal carcinoma, CRC, or small bowel adenocarcinoma; and
2. Disease is locally unresectable, medically inoperable, advanced, or metastatic; and
3. Must meet 1 of the following:
    a. Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H); or
    b. Polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50mut/Mb]; and
4. No prior treatment with a checkpoint inhibitor; and
5. Used as a single agent; and
6. Dose as follows:
    a. 3mg/kg every 2 weeks.

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

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

Lutathera® (Lutetium Lu-177 Dotatate) Approval Criteria [Gastroenteropancreatic Neuroendocrine Tumor (GEP-NET) Diagnosis]:

1. Diagnosis of progressive locoregional advanced disease or metastatic disease; and
2. Positive imaging of somatostatin receptor; and
3. Member must be 12 years of age or older; and
4. Used in 1 of the following settings:
    a. As second-line or subsequent therapy following progression on octreotide or lanreotide; or
    b. As first-line for treatment of pheochromocytoma/paraganglioma; or
    c. As alternative front-line therapy if surgical cytoreduction of metastases is not possible and there is clinically significant tumor burden following progression on octreotide or lanreotide.

Niktimvo™ (Axatilimab-csfr) Approval Criteria [Chronic Graft Versus Host Disease (GVHD) Diagnosis]:

1. Diagnosis of chronic GVHD; and
2. Has failed at least 2 prior lines of systemic therapy for chronic GVHD; and
3. Member's recent weight must be provided and must be ≥40kg.

Ojemda™ (Tovorafenib) Approval Criteria [Low Grade Glioma (LGG) Diagnosis]:

1. Diagnosis of relapsed or refractory pediatric LGG; and
2. Member must be 6 months to 25 years of age; and
3. Presence of BRAF fusion, BRAF rearrangement, or BRAF V600 mutation; and
4. Member's recent body surface area (BSA) must be provided; and
    a. For members with a BSA ≥0.90m^2, requests for the oral suspension formulation will require a patient-specific, clinically significant reason why the member cannot use the tablet formulation.

Omisirge® (Omidubicel-onlv) Approval Criteria:

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

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

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

Rezurock® (Belumosudil) Approval Criteria [Graft-Versus-Host Disease (GVHD) Diagnosis]:

1. Diagnosis of chronic GVHD; and
2. Failure of at least 2 prior lines of systemic therapy; and
3. Member must be 12 years of age or older.

Ryoncil® (Remestemcel-L-rknd) Approval Criteria [Acute Graft Versus Host Disease (aGVHD) Diagnosis]:

1. Diagnosis of aGVHD; and
2. Disease is steroid refractory; and
3. Member is 2 months of age to younger than 18 years of age; and
4. Member is an allogeneic hematopoietic stem cell transplant (HSCT) recipient; and
5. Initial approvals will be for a maximum of 8 infusions; and
6. Subsequent approvals for additional infusions will require repeat authorization and clinical documentation must be submitted to support the need for additional infusions; and
    a. All requests for subsequent approvals will require review by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician.

Sylvant® (Siltuximab) Approval Criteria:

1. An FDA approved diagnosis of multicentric Castleman's disease (MCD; also known as giant lymph node hyperplasia); and
2. Member must be human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8) negative; and
3. Member must be 18 years of age or older; and
4. The following FDA approved dosing restrictions will apply:

a. 11mg/kg via intravenous (IV) infusion every 3 weeks until treatment failure (defined as disease progression based on increase in symptoms, radiologic progression, or deterioration in performance status); and
5. Sylvant® must be administered in a clinical setting able to provide resuscitation equipment, medications, and trained personnel; and
6. The prescriber must verify that a complete blood count (CBC) will be done prior to each dose for the first 12 months and for an additional 3 doses thereafter; and
7. Approvals will be for the duration of 6 months.

Tecelra® (Afamitresgene Autoleucel) Approval Criteria [Synovial Sarcoma Diagnosis]:

1. Diagnosis of unresectable or metastatic synovial sarcoma; and
2. Member must be 18 years of age or older; and
3. Has received previous anthracycline or ifosfamide-containing chemotherapy; and
4. HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive; and
5. Tumor expresses melanoma-associated antigen A4 (MAGE-A4) as detected by an FDA-approved test; and
6. Health care facilities must be able to administer cellular therapies and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and
7. Approvals will be for 1 dose per member per lifetime.

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

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

Vitrakvi® (Larotrectinib) Approval Criteria [Solid Tumors with Neurotrophic Receptor Tyrosine Kinase (*NTRK*) Gene Fusion Diagnosis]:

1. Diagnosis of a solid tumor with a *NTRK* gene fusion without a known acquired resistance mutation; and
2. Disease is metastatic or surgical resection (or radioactive iodine refractory if thyroid carcinoma) is contraindicated; and
3. Documentation of no satisfactory alternative treatments or progression following acceptable alternative treatments.

Voranigo® (Vorasidenib) Approval Criteria [Astrocytoma or Oligodendroglioma Diagnosis]:

1. Diagnosis of grade 2 astrocytoma or oligodendroglioma; and

2. Presence of susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection.

Oncology Medications Additional Criteria:

1. Approvals for oncology medications will be for the duration of 6 months unless otherwise specified in a particular medication's approval criteria; and
   a. Unless otherwise specified in a medication's approval criteria, continuation requests will be approved for the duration of 6 months if there is no evidence of disease progression or adverse drug reactions; and
2. The following situations require the request to be reviewed by a board-certified oncology pharmacist (BCOP) or plan-contracted oncologist or other oncology physician:
   a. Any request for an oncology medication which does not meet approval criteria; or
   b. Any continuation request if the member has evidence of disease progression or adverse drug reactions while on the requested medication; or
   c. Any level-1 appeal request for an oncology medication; or
   d. Any peer-to-peer request for an oncology medication.

Utilization of Miscellaneous Cancer Medications: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	10	73	$2,279,471.34	$31,225.63	$1,035.65	5,582	2,201
Aetna	2	3	$52,561.06	$17,520.35	$536.34	230	98
Humana	0	0	$0.00	$0.00	$0.00	0	0
OCH	2	3	$104,033.55	$34,677.85	$1,182.20	148	88
2024 Total	**11**	**79**	**$2,436,065.95**	**$30,836.28**	**$1,020.56**	**5,960**	**2,387**
Fiscal Year 2025							
FFS	8	38	$1,374,349.39	$36,167.09	$1,294.11	3,932	1,062
Aetna	4	32	$693,806.97	$21,681.47	$854.44	1,890	812
Humana	5	20	$731,157.60	$36,557.88	$1,235.06	910	592
OCH	5	29	$970,996.19	$33,482.63	$1,184.14	846	820
2025 Total	**19**	**119**	**$3,770,310.15**	**$31,683.28**	**$1,147.39**	**7,578**	**3,286**
% Change	**72.70%**	**50.60%**	**54.80%**	**2.70%**	**12.40%**	**27.10%**	**37.70%**
Change	**8**	**40**	**$1,334,244.20**	**$847.00**	**$126.83**	**1,618**	**899**

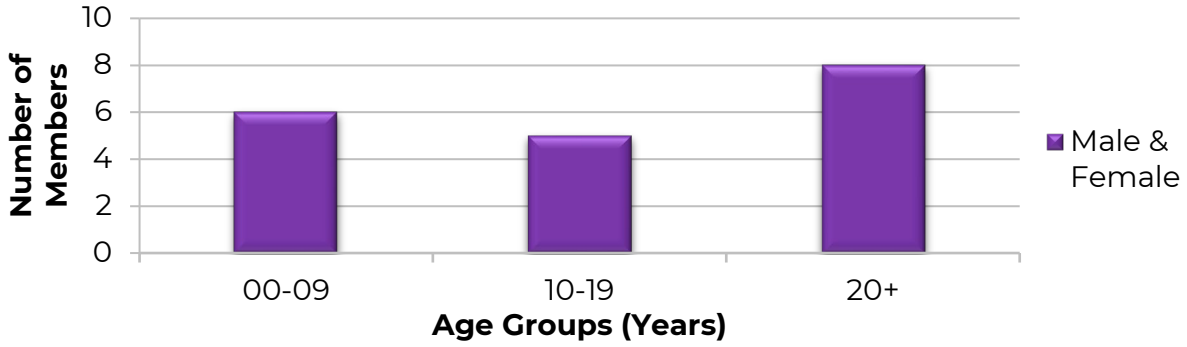
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Comparison of Fiscal Years: Medical Claims (All Plans)

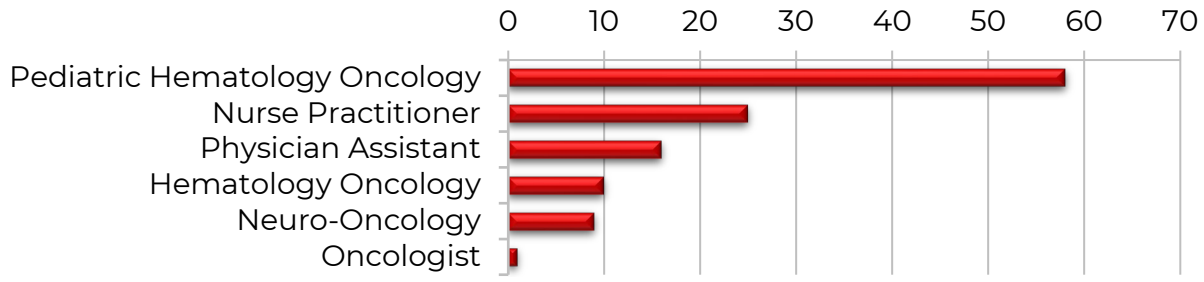
Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	1	14	$160,206.20	$11,443.30	14
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**1**	**14**	**$160,206.20**	**$11,443.30**	**14**
Fiscal Year 2025					
FFS	1	5	$47,131.20	$9,426.24	5
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2025 Total	**1**	**5**	**$47,131.20**	**$9,426.24**	**5**
% Change	**0.00%**	**-64.29%**	**-70.58%**	**-17.63%**	**-64.29%**
Change	**0**	**-9**	**-$113,075.00**	**-$2,017.06**	**-9**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

Demographics of Members Utilizing Miscellaneous Cancer Medications: Pharmacy Claims (All Plans)



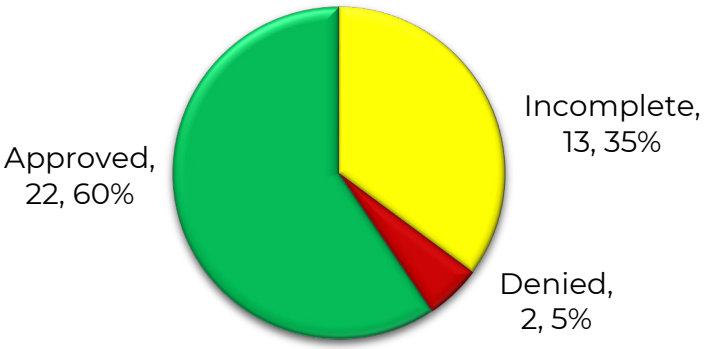
Top Prescriber Specialties of Miscellaneous Cancer Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Miscellaneous Cancer Medications

There were 37 prior authorization requests submitted for miscellaneous cancer medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	13	50%	12	46%	1	4%	**26**
Aetna	1	100%	0	0%	0	0%	**1**
Humana	3	100%	0	0%	0	0%	**3**
OCH	5	71%	1	14%	1	14%	**7**
Total	**22**	**60%**	**13**	**35%**	**2**	**5%**	**37**

FFS = fee-for-service; OCH = OK Complete Health

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

Anticipated Patent or Exclusivity Expiration(s):

- Vistogard® (uridine triacetate): August 2027
- Ojemda™ (tovorafenib): June 2035
- Iwilfin® (eflornithine): February 2036
- Modeyso™ (dordaviprone): January 2037
- Vijoice® (alpelisib): February 2037
- Vitrakvi® (larotrectinib): May 2037
- Lutathera® (lutetium Lu-177 dotatate): January 2039
- Voranigo® (vorasidenib): January 2039
- Pedmark® (sodium thiosulfate): July 2039
- Fyarro® (sirolimus): October 2040
- Rezurock® (belumosudil): July 2042

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

- **December 2015:** The FDA approved Vistogard® (uridine triacetate) for the emergency treatment of adult and pediatric patients following a

fluorouracil or capecitabine overdose regardless of the presence of symptoms, or who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions within 96 hours following the end of fluorouracil or capecitabine administration. Vistogard® was not covered by SoonerCare until July 2026 when the current manufacturer began participating in the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS).

- **August 2025:** The FDA granted accelerated approval to Modeyso™ (dordaviprone) for the treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy.
- **December 2025:** The FDA approved Omisirge® (omidubicel-onlv) for a new indication for the treatment of adults and pediatric patients 6 years of age and older with severe aplastic anemia (SAA) following reduced intensity conditioning.
- **June 2026:** The FDA approved Tecelra® (afamitresgene autoleucel) for an age expansion down to 12 years of age for the treatment of unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the melanoma-associated antigen A4 (MAGE-A4) antigen as determined by FDA-approved or cleared companion diagnostic devices. Previously, Tecelra® was only FDA approved for adults with this indication.

Modeyso™ (Dordaviprone) Product Summary[6]

Therapeutic Class: Protease activator

Indication(s): Treatment of adult and pediatric patients 1 year of age and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy

- This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

How Supplied: 125mg oral capsules

Dosing and Administration:

- The recommended dosage for adults is 625mg once weekly.
- The recommended dosage in pediatric patients 1 year to younger than 17 years of age who weigh at least 10kg is based on body weight, as follows:

Body Weight (kg)	Recommended Dosage
10kg to <12.5kg	125mg once weekly
12.5kg to <27.5kg	250mg once weekly
27.5kg to <42.5kg	375mg once weekly
42.5kg to <52.5kg	500mg once weekly
≥52.5kg	625mg once weekly

- Dosing should be continued until disease progression or unacceptable toxicity.
- Capsules may be swallowed whole or may be opened and the contents mixed with 15-30mL of liquid (e.g., sports drink, apple juice, lemonade, water) before administration orally as a liquid.

Cost: The Wholesale Acquisition Cost (WAC) of Modeyso™ is $3,200 per capsule. At the maximum recommended dose of 625mg once weekly, this would result in an estimated cost of $64,000 per 28 days or $832,000 per year.

Vistogard® (Uridine Triacetate) Product Summary[7]

Therapeutic Class: Pyrimidine analog

Indication(s): Treatment of adult and pediatric patients:
- Following a fluorouracil or capecitabine overdose regardless of the presence of symptoms, or
- Who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration
- **Limitation(s) of Use:**
  - Vistogard® is not recommended for the non-emergent treatment of adverse reactions associated with fluorouracil or capecitabine because it may diminish the efficacy of these drugs.
  - The safety and efficacy of Vistogard® initiated more than 96 hours following the end of fluorouracil or capecitabine administration has not been established.

How Supplied: Available as orange-flavored oral granules in 10 gram single-dose packets in the following configurations:
- Course of therapy package: 1 carton containing 20 single-dose packets
- 24-hour pack: 1 carton containing 4 single-dose packets

Dosing and Administration:
- Adults: The recommended dose 10 grams (1 packet) orally every 6 hours for 20 doses, without regard to meals.
- Pediatric: The recommended dose is 6.2 grams/m^2 of body surface area (BSA) (not to exceed 10 grams per dose) orally every 6 hours for 20

doses, without regard to meals. See the full *Prescribing Information* for BSA-based dosing.

Cost: The WAC of Vistogard® is $4,646 per single-dose packet. This would result in an estimated cost of $18,584 per day or $92,920 for the recommended 20-dose treatment regimen.

Recommendations

The College of Pharmacy recommends the prior authorization of Modeyso™ (dordaviprone) and Vistogard® (uridine triacetate) with the following criteria (shown in red):

Modeyso™ (Dordaviprone) Approval Criteria [Glioma Diagnosis]:

1. Diagnosis of diffuse midline glioma; and
2. Member must be 1 year of age or older; and
3. Presence of H3 K27M mutation; and
4. Member has progressed on at least 1 prior therapy.

Vistogard® (Uridine Triacetate) Approval Criteria:

1. Member received fluorouracil or capecitabine within the previous 96 hours; and
2. Member meets 1 of the following:
    a. Following fluorouracil or capecitabine overdose regardless of the presence of symptoms; or
    b. Exhibits early-onset, severe or life-threatening toxicity affecting cardiac or central nervous system; or
    c. Exhibits early-onset, unusually severe adverse reactions; and
3. A quantity limit of 20 packets for 5 days will apply; and
    a. Doses administered in an emergency room (ER) or inpatient (IP) setting do not require prior authorization. The number of remaining doses (following any ER or IP doses) must be specified on the request. Only the number of remaining doses for outpatient use will be approved.

Next, the College of Pharmacy recommends updating the Omisirge® (omidubicel-onlv) and Tecelra® (afamitresgene autoleucel) approval criteria based on recent FDA approvals with the following updates (shown in red):

Omisirge® (Omidubicel-onlv) Approval Criteria [Severe Aplastic Anemia Diagnosis]:

1. Diagnosis of severe aplastic anemia; and
2. Member is 6 years of age or older; and
3. Allogeneic stem cell transplant using umbilical cord blood donor source is planned; and
    a. No compatible donor is available; and

   b. Documentation of the donor source must be provided; and
4. Reduced intensity conditioning regimen will be used; and
   a. Documentation of the member's conditioning regimen must be provided; and
5. Will be used to reduce time to neutrophil recovery and incidence of infection.

Tecelra® (Afamitresgene Autoleucel) Approval Criteria [Synovial Sarcoma Diagnosis]:

1. Diagnosis of unresectable or metastatic synovial sarcoma; and
2. Member must be ~~18~~ 12 years of age or older; and
3. Has received previous anthracycline or ifosfamide-containing chemotherapy; and
4. HLA-A*02:01P, -A*02:02P, A*02:03P, or -A*02:06P positive; and
5. Tumor expresses melanoma-associated antigen A4 (MAGE-A4) as detected by an FDA-approved test; and
6. Health care facilities must be able to administer cellular therapies and must be trained in the management of cytokine release syndrome (CRS) and neurologic toxicities; and
7. Approvals will be for 1 dose per member per lifetime.

Lastly, the College of Pharmacy recommends updating Voranigo® (vorasidenib) approval criteria to be consistent with the FDA approved age range with the following updates (shown in red):

Voranigo® (Vorasidenib) Approval Criteria [Astrocytoma or Oligodendroglioma Diagnosis]:

1. Diagnosis of grade 2 astrocytoma or oligodendroglioma; and
2. Member must be 12 years of age or older; and
3. Presence of susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation following surgery including biopsy, sub-total resection, or gross total resection.

Utilization Details of Miscellaneous Cancer Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALPELISIB PRODUCTS						
VIJOICE TAB 50MG	35	3	$1,137,899.35	$32,511.41	11.67	30.18%
VIJOICE GRA 50MG	6	2	$195,068.46	$32,511.41	3	5.17%
SUBTOTAL	**41**	**5**	**$1,332,967.81**	**$32,511.41**	**8.2**	**35.35%**
BELUMOSUDIL PRODUCTS						
REZUROCK TAB 200MG	33	4	$921,817.11	$27,933.85	8.25	24.45%
SUBTOTAL	**33**	**4**	**$921,817.11**	**$27,933.85**	**8.25**	**24.45%**
LAROTRECTINIB PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VITRAKVI SOL 20MG/ML	26	3	$766,798.16	$29,492.24	8.67	20.34%
SUBTOTAL	**26**	**3**	**$766,798.16**	**$29,492.24**	**8.67**	**20.34%**
VORASIDENIB PRODUCTS						
VORANIGO TAB 40MG	17	5	$678,158.97	$39,891.70	3.4	17.99%
SUBTOTAL	**17**	**5**	**$678,158.97**	**$39,891.70**	**3.4**	**17.99%**
TOVORAFENIB PRODUCTS						
OJEMDA TAB 100MG	2	2	$70,568.10	$35,284.05	1	1.87%
SUBTOTAL	**2**	**2**	**$70,568.10**	**$35,284.05**	**1**	**1.87%**
TOTAL	**119**	**19***	**$3,770,310.15**	**$31,683.28**	**6.26**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
GRA = granules; SOL = solution; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J3263 TORIPALIMAB-TPZI INJ	5	1	$47,131.20	$9,426.24	5
TOTAL	**5**	**1**	**$47,131.20**	**$9,426.24**	**5**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

---

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 07/2026. Last accessed 07/10/2026.
[2] U.S. FDA. Vistogard® NDA Approval Letter. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/208159Orig1s000ltr.pdf. Issued 12/11/2015. Last accessed 07/10/2026.
[3] U.S. FDA. FDA Grants Accelerated Approval to Dordaviprone for Diffuse Midline Glioma. Available online at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dordaviprone-diffuse-midline-glioma. Issued 08/06/2025. Last accessed 07/10/2026.
[4] U.S. FDA. FDA Approves First Cellular Therapy to Treat Patients with Severe Aplastic Anemia. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-cellular-therapy-treat-patients-severe-aplastic-anemia. Issued 12/08/2025. Last accessed 07/10/2026.
[5] US WorldMeds. US WorldMeds Receives Full U.S. FDA Approval of Tecelra® (Afamitresgene Autoleucel) with an Expanded Indication, Extending the First Approved Engineered T-Cell Therapy for a Solid Tumor to Children as Young as 12. Available online at: https://www.prnewswire.com/news-releases/us-worldmeds-receives-full-us-fda-approval-of-tecelra-afamitresgene-autoleucel-with-an-expanded-indication-extending-the-first-approved-engineered-t-cell-therapy-for-a-solid-tumor-to-children-as-young-as-12-302806599.html. Issued 06/22/2026. Last accessed 07/10/2026.
[6] Modeyso™ (Dordaviprone) Prescribing Information. Jazz Pharmaceuticals, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219876s000lbl.pdf. Last revised 08/2025. Last accessed 07/10/2026.
[7] Vistogard® (Uridine Triacetate) Prescribing Information. BTG International, Inc. Available online at: https://vistogard.com/Vistogard/media/Main-Media/Professional/PDFs/Vistogard-Prescribing-Information_October-2023.pdf. Last revised 10/2023. Last accessed 07/10/2026.

Appendix H

Fiscal Year 2025 Annual Review of Opioid Analgesics and Opioid Medication Assisted Treatment (MAT) Medications and 30-Day Notice to Prior Authorize Morphine Oral Solution Syringes, Tapentadol Tablet, Tapentadol Extended-Release (ER) Tablet, and Tapentadol Oral Solution

Oklahoma Health Care Authority
August 2026

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®)	methadone soln (Dolophine®)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tramadol ER tab (Ultram® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER) – **Brand Preferred**	tramadol ER cap (ConZip®)
	tramadol ER tab (Ryzolt®)	hydromorphone ER tab (Exalgo®)	
		methadone tab (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
Short-Acting			
APAP/butalbital/ caff/codeine cap 50/325/40/30mg (Fioricet® with Codeine)	hydrocodone/IBU tab 10/200mg (Ibudone®, Reprexain™)		APAP/butalbital/ caff/codeine cap 50/300/40/30mg (Fioricet® with Codeine)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)		APAP/codeine elixir & soln
codeine tab			hydrocodone/ APAP soln
codeine/APAP tab (Tylenol® with Codeine)			hydrocodone/ APAP tab (Xodol®)
hydrocodone/ APAP tab (Norco®)			levorphanol tab
hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®, Ibudone®, Reprexain™)			oxycodone tab (RoxyBond™)
hydromorphone tab & soln (Dilaudid®)			oxycodone/APAP tab (Nalocet®)
meperidine tab & soln (Demerol®)			oxycodone/APAP tab & soln (Prolate®)
morphine IR tab & soln (MSIR®)			tramadol 25mg, 75mg, & 100mg tab
oxycodone/APAP tab & soln (Percocet®)			tramadol soln (Qdolo™)
oxycodone IR cap (Oxy IR®)			
oxycodone IR tab & soln (Roxicodone®)			
tramadol 50mg tab (Ultram®)			***Oncology Only:***
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

- Tier-1 products are covered with no prior authorization necessary.
- Members with an oncology-related diagnosis are exempt from the prior authorization process and do not require a pain contract.
- 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 exception applies to members with a current oncology-related diagnosis, sickle cell disease diagnosis, or hemophilia diagnosis.
- An age restriction applies on oral liquid narcotic analgesic products for all members 12 years of age or older 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. Actiq® is 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. Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:
    a. 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; or
    b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.
4. Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/ caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.
5. Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:
    a. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; or
    b. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior authorization is required, unless the prescription is written by an otolaryngologist or a dentist; and
    c. For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.
6. 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.
7. Methadone Oral Solution Approval Criteria:
    a. For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or

    b. For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.
8. Oxycodone (RoxyBond™) Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other available short-acting opioid analgesic must be provided.
9. Oxycodone/APAP Unique Formulations and Strengths Approval Criteria:
    a. For Nalocet® (oxycodone/APAP 2.5mg/300mg) tablet and Prolate® (oxycodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg) tablets, a patient specific, clinically significant reason why the member cannot use generic Percocet® (oxycodone/APAP 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, or 10mg/325mg) tablets must be provided; and
    b. For Prolate® (10mg-300mg/5mL) oral solution, a patient specific, clinically significant reason why the member cannot use generic oxycodone/APAP tablets and generic oxycodone/APAP (5mg-325mg/5mL) oral solution must be provided.
10. Oxymorphone ER Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other available ER opioid analgesic must be provided.
11. 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.
12. Tramadol 25mg, 75mg, and 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 or split a tramadol 50mg tablet to achieve a 25mg or 75mg 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.

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.
3. Members in long-term care facilities 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) Film] and Zubsolv® (Buprenorphine/Naloxone SL Tablet) Approval Criteria:

1. Generic buprenorphine/naloxone SL tablet and buprenorphine SL tablet are the preferred products. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why the preferred SL tablets are not appropriate; and
2. Member must have an FDA approved diagnosis of opioid abuse/ dependence [i.e., opioid use disorder (OUD)]; and
3. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
4. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
5. 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 90 SL units per 30 days will apply.
   c. Suboxone® 12mg/3mg SL films: A quantity limit of 60 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 90 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 90 SL tablets per 30 days will apply.
   h. Zubsolv® 8.6mg/2.1mg: A quantity limit of 60 SL tablets per 30 days will apply.

i. Zubsolv® 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 >24mg 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; and
7. For Opioid Treatment Programs (OTPs), high-dose authorization will be approved for 1 year if urine drug screen and other documentation are submitted indicating high-dose therapy is necessary.

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

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder (OUD); and
2. Member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
3. Concomitant treatment with opioids (including tramadol) will be denied; and
4. Medication should only be prepared and administered by a health care provider; and

5. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual (SL) tablets or buprenorphine SL tablets) must be provided; and
6. For new starts, a patient-specific, clinically reason why the member cannot use Brixadi® (buprenorphine ER injection), which is available without a prior authorization, must be provided. Members currently stable on Sublocade® may be approved for continuation of therapy; and
7. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
8. Approvals will be for the duration of 90 days to allow for concurrent medication monitoring; and
9. The following quantity limits will apply:
    a. Sublocade® 100mg/0.5mL and 300mg/1.5mL: 1 monthly dose per 28 days
        i. A quantity limit override will be approved for initial dosing for members who need the second injection 1 week after the first injection when requested.

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.

Utilization of Opioid Analgesics and MAT Medications: Fiscal Year 2025

Comparison of Fiscal Years: Opioid Analgesics: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	89,446	256,775	$9,225,492.65	$35.93	$1.96	16,391,832	4,698,095
Aetna	6,383	10,723	$338,573.56	$31.57	$1.88	623,310	180,135
Humana	7,572	14,132	$454,014.16	$32.13	$2.18	759,208	208,103
OCH	6,376	10,217	$279,457.13	$27.35	$1.70	567,606	164,624
2024 Total	**99,975**	**291,847**	**$10,297,537.50**	**$35.28**	**$1.96**	**18,341,956**	**5,250,957**
Fiscal Year 2025							
FFS	39,001	130,444	$5,556,849.80	$42.60	$2.06	9,180,578	2,700,769
Aetna	18,168	44,563	$1,495,953.03	$33.57	$1.97	2,620,907	757,979
Humana	20,455	56,549	$2,133,486.08	$37.73	$2.23	3,307,505	956,522
OCH	18,704	43,423	$1,386,773.78	$31.94	$2.11	2,304,153	656,213
2025 Total	**90,541**	**274,979**	**$10,573,062.69**	**$38.45**	**$2.08**	**17,413,143**	**5,071,483**
% Change	**-9.40%**	**-5.80%**	**2.70%**	**9.00%**	**6.10%**	**-5.10%**	**-3.40%**
Change	**-9,434**	**-16,868**	**$275,525.19**	**$3.17**	**$0.12**	**-928,813**	**-179,474**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.
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 fiscal year 2025 for opioid analgesics totaled $5,599,687.84.[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.

Comparison of Fiscal Years: MAT Medications: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	9,905	53,378	$7,615,955.13	$142.68	$5.60	2,308,387	1,360,172
Aetna	1,155	2,888	$401,572.66	$139.05	$5.78	125,053	69,434
Humana	1,303	3,302	$428,660.37	$129.82	$5.34	147,115	80,209
OCH	1,148	2,685	$276,741.69	$103.07	$4.27	118,112	64,829
2024 Total	**10,618**	**62,253**	**$8,722,929.85**	**$140.12**	**$5.54**	**2,698,667**	**1,574,644**
Fiscal Year 2025							
FFS	5,763	24,843	$4,162,540.25	$167.55	$6.33	1,126,348	657,788
Aetna	2,191	12,049	$1,807,238.11	$149.99	$6.00	545,572	301,035
Humana	2,526	13,314	$2,072,925.43	$155.70	$5.95	640,215	348,630
OCH	2,237	12,137	$1,547,747.87	$127.52	$5.07	553,268	305,274
2025 Total	**10,561**	**62,343**	**$9,590,451.66**	**$153.83**	**$5.95**	**2,865,403**	**1,612,727**
% Change	**-0.50%**	**0.10%**	**9.90%**	**9.80%**	**7.40%**	**6.20%**	**2.40%**
Change	**-57**	**90**	**$867,521.81**	**$13.71**	**$0.41**	**166,736**	**38,083**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.
Please note: The above MAT medications data does not include Butrans® or Belbuca® claims.

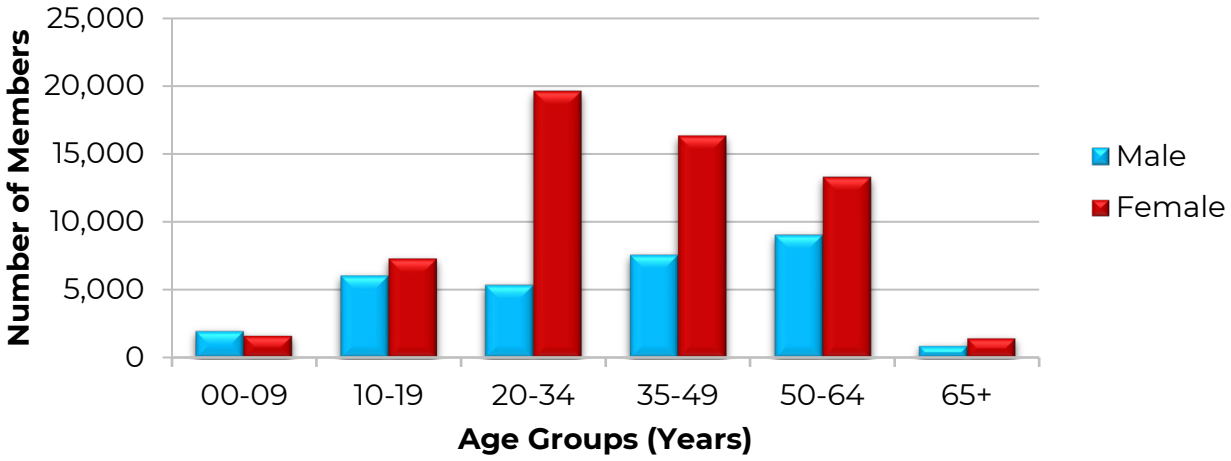
Comparison of Fiscal Years: MAT Medications: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	9	19	$9,058.09	$476.74	2.11
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**9**	**19**	**$9,058.09**	**$476.74**	**2.11**
Fiscal Year 2025					
FFS	3	4	$4,689.20	$1,172.30	1.33
Aetna	3	3	$1,569.70	$523.23	1
Humana	1	3	$0.00	$0.00	3
OCH	4	6	$6,262.40	$1,043.73	1.5
2025 Total	**11**	**16**	**$12,521.30**	**$782.58**	**1.45**
% Change	**22.22%**	**-15.79%**	**38.23%**	**64.15%**	**-31.28%**
Change	**2**	**-3**	**$3,463.21**	**$305.84**	**-0.66**

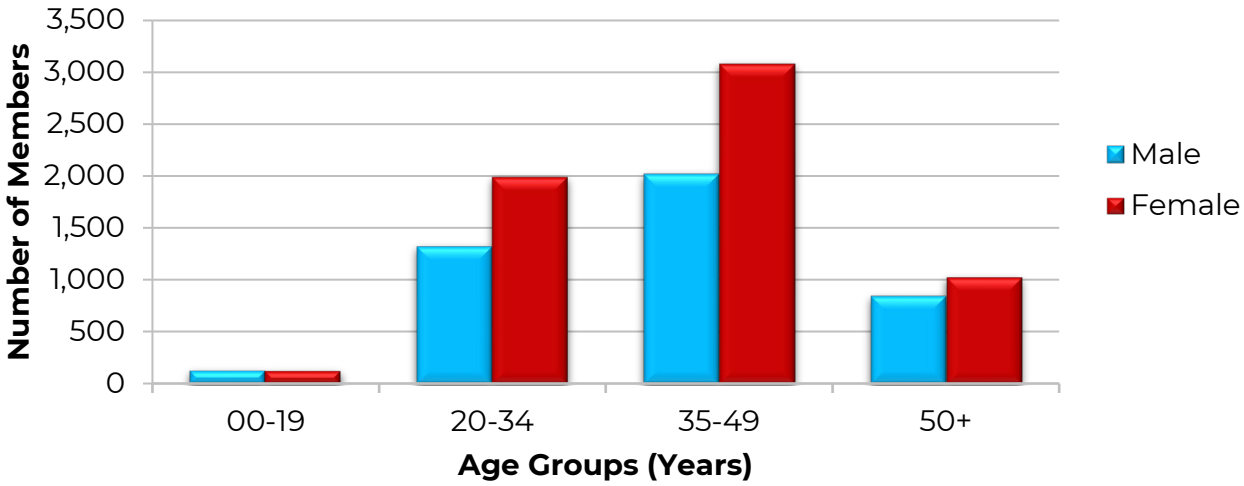
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members. †Total number of unduplicated claims.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for MAT medications totaled $2,401,727.44.[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 Opioid Analgesics: Pharmacy Claims (All Plans)

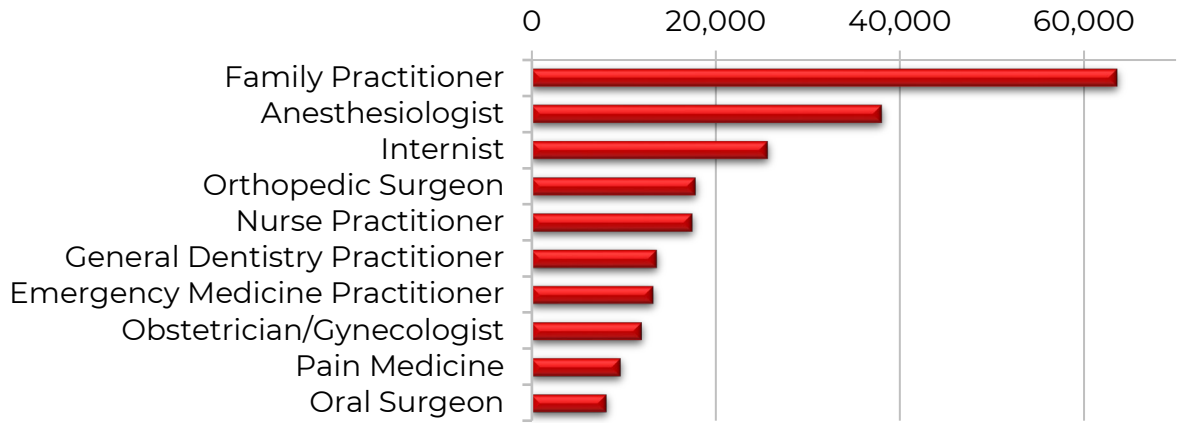


Demographics of Members Utilizing MAT Medications: Pharmacy Claims (All Plans)

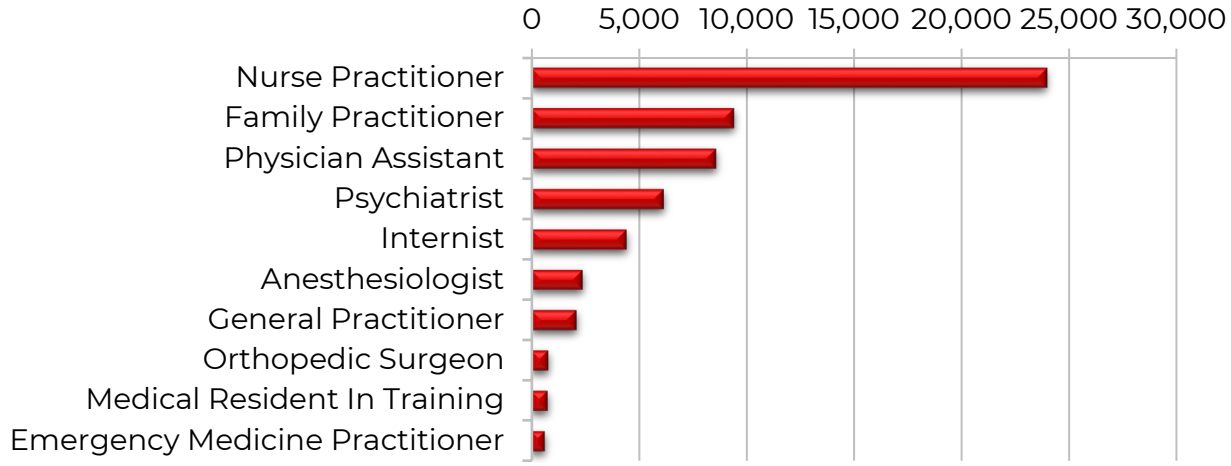


[Δ] Important considerations: Aggregate drug rebates are based on the date the claim is paid rather than the date dispensed. Claims data are based on the date dispensed.

Top Prescriber Specialties of Opioid Analgesics by Number of Claims: Pharmacy Claims (All Plans)



Top Prescriber Specialties of MAT Medications by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Opioid Analgesics and MAT Medications

There were 6,689 prior authorization requests submitted for opioid analgesics during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions: Opioid Analgesics (All Plans)

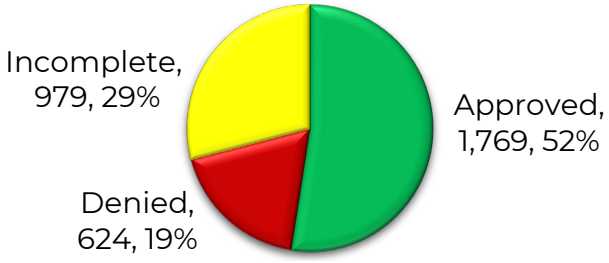
Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	1,392	35%	2,296	57%	341	8%	**4,029**
Aetna	293	45%	173	27%	181	28%	**647**
Humana	105	43%	0	0%	138	57%	**243**
OCH	570	32%	300	17%	900	51%	**1,770**
Total	**2,360**	**35%**	**2,769**	**42%**	**1,560**	**23%**	**6,689**

FFS = fee-for-service; OCH = OK Complete Health

There were 3,372 prior authorizations submitted for MAT medications during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions: MAT Medications (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	1,017	51%	768	39%	191	10%	**1,976**
Aetna	295	59%	116	23%	88	18%	**499**
Humana	168	58%	0	0%	121	42%	**289**
OCH	289	47%	95	16%	224	37%	**608**
Total	**1,769**	**52%**	**979**	**29%**	**624**	**19%**	**3,372**

FFS = fee-for-service; OCH = OK Complete Health

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

Anticipated Patent Expiration(s):

- Brixadi® [buprenorphine extended-release (ER) injection]: July 2032
- Zubsolv® [buprenorphine/naloxone sublingual (SL) tablet]: September 2032
- Belbuca® (buprenorphine ER buccal film): December 2032
- Sublocade® (buprenorphine ER injection): November 2035
- Qdolo™ (tramadol oral solution): September 2040

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

- **September 2025:** The FDA approved a new 0.25mL syringe of morphine sulfate oral solution 100mg per 5mL (20mg/mL). It was previously available in a 0.5mL and 1mL oral syringe in the same concentration.
- **January 2026:** The FDA approved a new generic formulation of Nucynta® (tapentadol) immediate-release (IR) tablets to Epic Pharma through an Abbreviated New Drug Application (ANDA) in 50mg, 75mg, and 100mg IR tablets. Currently, brand name Nucynta® and Nucynta® ER are not covered by SoonerCare due to the manufacturer no longer participating in the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS).
- **July 2026:** The FDA approved a new generic tapentadol 20mg/mL oral solution in January 2026 through an ANDA. The National Drug Code Directory indicates a start marketing date of July 13, 2026.

News:

- **February 2026:** Hikma Pharmaceuticals launched an authorized generic of IR Nucynta® for patients in the United States.
- **March 2026:** Hikma Pharmaceuticals launched an authorized generic of Nucynta® ER for patients in the United States.

Cost Comparison: Morphine Oral Solution

Product	Cost Per Unit	Cost Per 30 Days
morphine sulfate 20mg/mL syringe (generic)	**$3.94**	**$472.80***
morphine sulfate 5mg/0.25mL syringe (generic)	**$3.10**	**$372.00***
morphine sulfate 10mg/0.5mL syringe (generic)	**$2.96**	**$355.20***
morphine sulfate 100mg/5mL solution (generic)	$0.32	$38.40¥
morphine sulfate 20mg/5mL solution (generic)	$0.07	$42.00¥
morphine sulfate 10mg/5mL solution (generic)	$0.04	$24.00α

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 = mL or syringe
*Cost per 30 days is based on the use of 1 syringe four times daily.
¥Cost per 30 days is based on the use of 80mg of morphine sulfate daily.
αCost per 30 day is based on the use of 40mg of morphine sulfate daily.

Cost Comparison: Tapentadol[8,9]

Product	Cost Per Unit	Cost Per 30 Days
tapentadol 250mg ER tablet (generic)	**$48.39**	**$2,903.40***
tapentadol 20mg/mL oral solution (generic)	**$3.75**	**$2,250.00¥**
tapentadol 100mg tablet (generic)	**$13.41**	**$1,609.20¥**

Costs do not reflect rebated prices or net costs. Costs based on National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
ER = extended-release, Unit = mL or tablet
*Cost per 30 days based on the FDA approved dose of 250mg twice daily.
¥Cost per 30 days based on the FDA approved dose of 100mg every 6 hours.

Recommendations

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

1. Prior authorization of tapentadol tablet, tapentadol oral solution, and tapentadol ER tablet with placement into the Special PA Tier with the following additional criteria; and
2. Prior authorization of morphine oral solution syringes with placement into the Special PA Tier with the following additional criteria; and
3. Making buprenorphine ER buccal film (Belbuca®) brand preferred; and
4. Moving hydrocodone/ibuprofen (IBU) 5/200mg and 7.5/200mg tablets (Vicoprofen®, Ibudone®, Reprexain™) from Tier-1 to Tier-2.

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®) – **Brand Preferred**	methadone soln (Dolophine®)
oxycodone ER tab 10mg, 15mg, 20mg only (OxyContin®) – **Brand Preferred**	morphine ER tab (MS Contin®)	hydrocodone ER cap (Zohydro® ER)	oxymorphone ER tab
tramadol ER tab (Ultram® ER)	oxycodone ER tab 30mg, 40mg, 60mg, 80mg (OxyContin®) – **Brand Preferred**	hydrocodone ER tab (Hysingla® ER) – **Brand Preferred**	**tapentadol ER tab**
	tramadol ER tab (Ryzolt®)	hydromorphone ER tab (Exalgo®)	tramadol ER cap (ConZip®)
		methadone tab (Dolophine®)	
		morphine ER cap (Avinza®, Kadian®)	
Short-Acting			
APAP/butalbital/ caff/codeine cap 50/325/40/30mg (Fioricet® with Codeine)	hydrocodone/IBU tab ~~**10/200mg**~~ (Ibudone®, Reprexain™**,** **Vicoprofen®**)		APAP/butalbital/ caff/codeine cap 50/300/40/30mg (Fioricet® with Codeine)

Opioid Analgesics*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
ASA/butalbital/caff/ codeine cap (Fiorinal® with Codeine)	oxymorphone IR tab (Opana®)		APAP/codeine elixir & soln
codeine tab			hydrocodone/ APAP soln
codeine/APAP tab (Tylenol® with Codeine)			hydrocodone/ APAP tab (Xodol®)
hydrocodone/ APAP tab (Norco®)			levorphanol tab
~~**hydrocodone/IBU tab 5/200mg, 7.5/200mg only (Vicoprofen®; Ibudone®; Reprexain™)**~~			**morphine oral soln syringes**
hydromorphone tab & soln (Dilaudid®)			oxycodone tab (RoxyBond™)
meperidine tab & soln (Demerol®)			oxycodone/APAP tab (Nalocet®)
morphine IR tab & soln (MSIR®)			oxycodone/APAP tab & soln (Prolate®)
oxycodone/APAP tab & soln (Percocet®)			**tapentadol tab & soln**
oxycodone IR cap (Oxy IR®)			tramadol 25mg, 75mg, & 100mg tab
oxycodone IR tab & soln (Roxicodone®)			tramadol soln (Qdolo™)
tramadol 50mg tab (Ultram®)			***Oncology Only:***
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. Actiq® is 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. Acetaminophen (APAP)/Codeine Elixir and Solution Approval Criteria:
    a. 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; or
    b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation, which is available without a prior authorization, must be provided.
4. Fioricet® with Codeine (Butalbital/APAP/Caffeine/Codeine 50mg/300mg/40mg/30mg) Approval Criteria:
    a. A patient-specific, clinically significant reason why the member cannot take the 325mg APAP formulation butalbital/APAP/ caffeine/codeine 50mg/325mg/40mg/30mg), which is available generically, must be provided.
5. Hydrocodone/APAP Unique Formulations and Strengths Approval Criteria:
    a. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®) or Xodol® (hydrocodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg), a patient-specific, clinically significant reason why the member cannot use generic Norco® (hydrocodone/APAP 5/325mg, 7.5/325mg, or 10/325mg) tablets must be provided; or
    b. For hydrocodone/APAP 7.5mg-325mg/15mL oral solution (generic Hycet®), a prior authorization is not required for members 14 years of age or younger. For members older than 14 years of age, a prior authorization is required, unless the prescription is written by an otolaryngologist or a dentist; and
    c. For hydrocodone/APAP oral solution unit dose cups, a prior authorization is required for all members and a patient-specific, clinically significant reason why the member cannot use hydrocodone/APAP in bulk solution must be provided.
6. 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.
7. Methadone Oral Solution Approval Criteria:

a. For the lower strengths of methadone (5mg/5mL or 10mg/5mL), a prior authorization is not required for members 1 year of age and younger; or
b. For members older than 1 year of age, a patient specific clinically significant reason why the member cannot use methadone tablets and other lower-tiered opioid analgesics must be provided.

8. Morphine Oral Solution Syringes (5mg/0.25mL Syringe, 10mg/0.5mL Syringe, and 20mg/mL Syringe) Approval Criteria:
   a. For morphine oral solution syringes, a patient-specific, clinically significant reason why the member cannot use morphine oral solution in bulk solution must be provided.
9. Oxycodone (RoxyBond™) Approval Criteria:
   a. A patient specific, clinically significant reason why the member cannot use any other available short-acting opioid analgesic must be provided.
10. Oxycodone/APAP Unique Formulations and Strengths Approval Criteria:
    a. For Nalocet® (oxycodone/APAP 2.5mg/300mg) tablet and Prolate® (oxycodone/APAP 5mg/300mg, 7.5mg/300mg, and 10mg/300mg) tablets, a patient specific, clinically significant reason why the member cannot use generic Percocet® (oxycodone/APAP 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, or 10mg/325mg) tablets must be provided; and
    b. For Prolate® (10mg-300mg/5mL) oral solution, a patient specific, clinically significant reason why the member cannot use generic oxycodone/APAP tablets and generic oxycodone/APAP (5mg-325mg/5mL) oral solution must be provided.
11. Oxymorphone ER Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other available ER opioid analgesic must be provided.
12. 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.
13. Tapentadol ER Tablet Approval Criteria:

    a. A patient specific, clinically significant reason why the member cannot use any other lower-tiered ER opioid analgesic must be provided.
14. Tapentadol Tablet Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use any other lower-tiered short-acting opioid analgesic must be provided.
15. Tapentadol Oral Solution Approval Criteria:
    a. A patient specific, clinically significant reason why the member cannot use lower-tiered opioid analgesic oral solutions must be provided; and
    b. For members 12 years of age or older, a patient-specific, clinically significant reason why the member cannot use the tablet formulation must be provided.
16. Tramadol 25mg, 75mg, and 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 or split a tramadol 50mg tablet to achieve a 25mg or 75mg 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.

The College of Pharmacy also recommends the following changes to the MAT medications based on clinical practice (changes shown in red):

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

1. Generic buprenorphine/naloxone SL tablet and buprenorphine SL tablet are the preferred products. Authorization consideration of Zubsolv® and Suboxone® films (brand and generic) requires a patient-specific, clinically significant reason why the preferred SL tablets are not appropriate; and
2. Member must have an FDA approved diagnosis of opioid abuse/ dependence [i.e., opioid use disorder (OUD)]; and
3. Concomitant treatment with opioid analgesics (including tramadol) will be denied; and
4. Approvals will be for the duration of ~~90 days~~ 6 months to allow for concurrent medication monitoring; and
5. 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 90 SL units per 30 days will apply.
c. Suboxone® 12mg/3mg SL films: A quantity limit of 60 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 90 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 90 SL tablets per 30 days will apply.
h. Zubsolv® 8.6mg/2.1mg: A quantity limit of 60 SL tablets per 30 days will apply.

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

1. An FDA approved diagnosis of moderate-to-severe opioid use disorder (OUD); and
2. Member must have initiated treatment with a single dose of a transmucosal buprenorphine product or is currently treated with buprenorphine; and
3. Concomitant treatment with opioids (including tramadol) will be denied; and
4. Medication should only be prepared and administered by a health care provider; and
5. A patient-specific, clinically significant reason why the member cannot use the preferred buprenorphine product(s) (buprenorphine/naloxone sublingual (SL) tablets or buprenorphine SL tablets) must be provided; and
6. For new starts, a patient-specific, clinically reason why the member cannot use Brixadi® (buprenorphine ER injection), which is available without a prior authorization, must be provided. Members currently stable on Sublocade® may be approved for continuation of therapy; and
7. In general, concomitant treatment with transmucosal buprenorphine will not be approved long term; and
8. Approvals will be for the duration of ~~90 days~~ 6 months to allow for concurrent medication monitoring; and
9. The following quantity limits will apply:
    a. Sublocade® 100mg/0.5mL and 300mg/1.5mL: 1 monthly dose per 28 days
        i. A quantity limit override will be approved for initial dosing for members who need the second injection 1 week after the first injection when requested.

Utilization Details of Opioid Analgesics: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SHORT-ACTING OPIOID ANALGESICS						
IMMEDIATE-RELEASE HYDROCODONE PRODUCTS						
HYDROCO/APAP TAB 5/325MG	48,201	32,762	$685,604.82	$14.22	1.47	6.48%
HYDROCO/APAP TAB 10/325MG	42,185	7,512	$892,107.66	$21.15	5.62	8.44%
HYDROCO/APAP TAB 7.5/325MG	36,752	15,353	$698,123.45	$19.00	2.39	6.60%
HYDROCO/APAP SOL 7.5/325MG	3,308	3,028	$146,083.98	$44.16	1.09	1.38%
HYDROCO/IBU TAB 7.5/200MG	55	16	$2,186.09	$39.75	3.44	0.02%
HYDROCO/IBU TAB 10/200MG	17	4	$7,588.84	$446.40	4.25	0.07%
HYDROCO/APAP TAB 7.5/300MG	15	7	$241.00	$16.07	2.14	0.00%
HYDROCO/IBU TAB 5/200MG	5	3	$287.67	$57.53	1.67	0.00%
HYDROCO/APAP TAB 10/300MG	1	1	$34.67	$34.67	1	0.00%
HYDROCO/APAP TAB 5/300MG	1	1	$10.55	$10.55	1	0.00%
SUBTOTAL	**130,540**	**58,687**	**$2,432,268.73**	**$18.63**	**2.22**	**23.00%**
IMMEDIATE-RELEASE OXYCODONE PRODUCTS						
OXYCOD/APAP TAB 10-325MG	20,489	3,952	$581,705.57	$28.39	5.18	5.50%
OXYCOD/APAP TAB 5-325MG	15,898	10,545	$230,008.06	$14.47	1.51	2.18%
OXYCODONE TAB 5MG	12,811	9,377	$166,110.64	$12.97	1.37	1.57%
OXYCOD/APAP TAB 7.5-325	12,608	4,444	$276,374.85	$21.92	2.84	2.61%
OXYCODONE TAB 10MG	7,917	1,915	$175,001.90	$22.10	4.13	1.66%
OXYCODONE TAB 15MG	4,887	808	$128,030.26	$26.20	6.05	1.21%
OXYCODONE SOL 5MG/5ML	2,007	1,834	$36,592.39	$18.23	1.09	0.35%
OXYCODONE TAB 20MG	1,189	237	$34,570.99	$29.08	5.02	0.33%
OXYCODONE TAB 30MG	439	88	$15,060.26	$34.31	4.99	0.14%
OXYCODONE CAP 5MG	202	165	$4,126.83	$20.43	1.22	0.04%
ROXYBOND TAB 5MG	123	35	$153,091.99	$1,244.65	3.51	1.45%
ENDOCET TAB 5-325MG	59	52	$874.30	$14.82	1.13	0.01%
ENDOCET TAB 10-325MG	57	16	$1,692.39	$29.69	3.56	0.02%
ENDOCET TAB 7.5-325	33	21	$759.60	$23.02	1.57	0.01%
ROXYBOND TAB 10MG	16	6	$29,017.05	$1,813.57	2.67	0.27%
PROLATE TAB 10-300MG	15	1	$40,012.80	$2,667.52	15	0.38%
ROXYBOND TAB 15MG	8	3	$11,228.94	$1,403.62	2.67	0.11%
PERCOCET TAB 10-325MG	7	2	$32,554.96	$4,650.71	3.5	0.31%
OXYCODONE CON 100/5ML	6	1	$688.80	$114.80	6	0.01%
NALOCET TAB 2.5-300	1	1	$3,475.91	$3,475.91	1	0.03%
PERCOCET TAB 5-325MG	1	1	$796.47	$796.47	1	0.01%
SUBTOTAL	**78,773**	**33,504**	**$1,921,774.96**	**$24.40**	**2.35**	**18.18%**
IMMEDIATE-RELEASE TRAMADOL PRODUCTS						
TRAMADOL HCL TAB 50MG	29,845	11,677	$374,625.19	$12.55	2.56	3.54%
TRAMADOL/APAP TAB 37.5/325MG	186	132	$2,685.60	$14.44	1.41	0.03%
TRAMADOL HCL TAB 100MG	73	39	$6,757.10	$92.56	1.87	0.06%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRAMADOL HCL TAB 25MG	12	12	$1,083.14	$90.26	1	0.01%
SUBTOTAL	**30,116**	**11,860**	**$385,151.03**	**$12.79**	**2.54**	**3.64%**
CODEINE PRODUCTS						
APAP/CODEINE TAB 300/30MG	9,019	5,368	$172,214.45	$19.09	1.68	1.63%
APAP/CODEINE TAB 300/60MG	6,956	1,743	$255,849.62	$36.78	3.99	2.42%
BUT/APAP/CAF/COD CAP 50/325/40/30MG	257	70	$14,190.67	$55.22	3.67	0.13%
APAP/CODEINE TAB 300/15MG	219	156	$3,823.99	$17.46	1.4	0.04%
BUT/ASA/CAF/COD CAP 50/325/40/30MG	57	13	$5,379.03	$94.37	4.38	0.05%
APAP/CODEINE SOL 120-12MG/5ML	34	20	$4,612.62	$135.67	1.7	0.04%
CODEINE SULF TAB 30MG	25	8	$1,066.99	$42.68	3.13	0.01%
CODEINE SULF TAB 15MG	8	5	$212.50	$26.56	1.6	0.00%
ASCOMP/COD CAP 30MG	5	2	$638.13	$127.63	2.5	0.01%
BUT/APAP/CAF/COD CAP 50/300/40/30MG	1	1	$61.77	$61.77	1	0.00%
SUBTOTAL	**16,581**	**7,386**	**$458,049.77**	**$27.62**	**2.24**	**4.33%**
IMMEDIATE-RELEASE MORPHINE PRODUCTS						
MORPHINE SULF TAB 15MG	1,275	357	$34,457.63	$27.03	3.57	0.33%
MORPHINE SULF TAB 30MG	112	34	$4,187.07	$37.38	3.29	0.04%
MORPHINE SULF SOL 20MG/5ML	20	4	$283.18	$14.16	5	0.00%
MORPHINE SULF SOL 100MG/5ML	16	11	$380.04	$23.75	1.45	0.00%
MORPHINE SULF SOL 10MG/5ML	13	12	$210.55	$16.20	1.08	0.00%
MORPHINE SULF SOL 10MG/0.5ML	3	3	$291.75	$97.25	1	0.00%
SUBTOTAL	**1,439**	**421**	**$39,810.22**	**$27.67**	**3.42**	**0.38%**
IMMEDIATE-RELEASE HYDROMORPHONE PRODUCTS						
HYDROMORPHONE TAB 4MG	616	162	$13,179.63	$21.40	3.8	0.12%
HYDROMORPHONE TAB 2MG	562	278	$8,852.29	$15.75	2.02	0.08%
HYDROMORPHONE TAB 8MG	93	26	$3,154.46	$33.92	3.58	0.03%
HYDROMORPHONE POW HCL	9	2	$2,266.45	$251.83	4.5	0.02%
HYDROMORPHONE POW LIQ 1MG/ML	1	1	$68.34	$68.34	1	0.00%
SUBTOTAL	**1,281**	**469**	**$27,521.17**	**$21.48**	**2.73**	**0.26%**
MEPERIDINE PRODUCTS						
MEPERIDINE SOL 50MG/5ML	125	104	$1,409.59	$11.28	1.2	0.01%
MEPERIDINE TAB 50MG	5	3	$953.55	$190.71	1.67	0.01%
SUBTOTAL	**130**	**107**	**$2,363.14**	**$18.18**	**1.21**	**0.02%**
PENTAZOCINE PRODUCTS						
PENTAZ/NALOX TAB 50/0.5MG	55	14	$8,748.57	$159.06	3.93	0.08%
SUBTOTAL	**55**	**14**	**$8,748.57**	**$159.06**	**3.93**	**0.08%**
IMMEDIATE-RELEASE TAPENTADOL PRODUCTS						
NUCYNTA TAB 50MG	40	12	$37,391.30	$934.78	3.33	0.35%
NUCYNTA TAB 100MG	4	1	$5,733.76	$1,433.44	4	0.05%
SUBTOTAL	**44**	**13**	**$43,125.06**	**$980.12**	**3.38**	**0.41%**
IMMEDIATE-RELEASE OXYMORPHONE PRODUCTS						
OXYMORPHONE TAB 10MG	1	1	$59.56	$59.56	1	0.00%
SUBTOTAL	**1**	**1**	**59.56**	**$59.56**	**1**	**0.00%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SHORT-ACTING SUBTOTAL	**258,960**	**112,462**	**$5,318,872.21**	**$20.54**	**2.3**	**50.31%**
LONG-ACTING OPIOID ANALGESICS						
BUPRENORPHINE PAIN PRODUCTS						
BUTRANS DIS 10MCG/HR	1,931	775	$589,015.05	$305.03	2.49	5.57%
BUTRANS DIS 20MCG/HR	1,769	325	$947,523.37	$535.63	5.44	8.96%
BUTRANS DIS 15MCG/HR	1,526	434	$777,526.15	$509.52	3.52	7.35%
BUTRANS DIS 5MCG/HR	809	442	$167,449.70	$206.98	1.83	1.58%
BUTRANS DIS 7.5/HR	661	278	$188,965.30	$285.88	2.38	1.79%
BELBUCA MIS 900MCG	140	21	$145,197.04	$1,037.12	6.67	1.37%
BELBUCA MIS 300MCG	135	52	$89,996.23	$666.64	2.6	0.85%
BELBUCA MIS 600MCG	128	28	$122,983.90	$960.81	4.57	1.16%
BELBUCA MIS 150MCG	117	56	$49,148.69	$420.07	2.09	0.46%
BELBUCA MIS 450MCG	114	32	$102,036.15	$895.05	3.56	0.97%
BELBUCA MIS 750MCG	103	22	$102,944.06	$999.46	4.68	0.97%
BELBUCA MIS 75MCG	46	32	$19,003.21	$413.11	1.44	0.18%
BUPRENORPHINE DIS 10MCG/HR	26	13	$3,507.03	$134.89	2	0.03%
BUPRENORPHINE DIS 15MCG/HR	20	8	$3,795.83	$189.79	2.5	0.04%
BUPRENORPHINE DIS 20MCG/HR	8	4	$1,956.60	$244.58	2	0.02%
BUPRENORPHINE DIS 5MCG/HR	8	5	$763.45	$95.43	1.6	0.01%
BUPRENORPHINE DIS 7.5/HR	6	1	$816.82	$136.14	6	0.01%
SUBTOTAL	**7,547**	**2,528**	**$3,312,628.58**	**$438.93**	**2.99**	**31.33%**
EXTENDED-RELEASE OXYCODONE PRODUCTS						
OXYCONTIN TAB 10MG ER	1,681	357	$446,551.08	$265.65	4.71	4.22%
OXYCONTIN TAB 20MG ER	705	152	$373,899.44	$530.35	4.64	3.54%
OXYCONTIN TAB 15MG ER	602	118	$255,428.02	$424.30	5.1	2.42%
OXYCONTIN TAB 30MG ER	235	38	$179,695.69	$764.66	6.18	1.70%
OXYCONTIN TAB 40MG ER	131	25	$129,048.76	$985.11	5.24	1.22%
XTAMPZA ER CAP 9MG	42	14	$14,282.35	$340.06	3	0.14%
OXYCONTIN TAB 60MG ER	40	12	$53,792.38	$1,344.81	3.33	0.51%
OXYCONTIN TAB 80MG ER	38	7	$70,618.74	$1,858.39	5.43	0.67%
XTAMPZA ER CAP 13.5MG	35	11	$15,808.95	$451.68	3.18	0.15%
XTAMPZA ER CAP 18MG	20	6	$13,840.57	$692.03	3.33	0.13%
XTAMPZA ER CAP 36MG	17	3	$19,313.23	$1,136.07	5.67	0.18%
XTAMPZA ER CAP 27MG	11	3	$10,123.52	$920.32	3.67	0.10%
SUBTOTAL	**3,557**	**746**	**$1,582,402.73**	**$444.87**	**4.77**	**14.97%**
EXTENDED-RELEASE MORPHINE PRODUCTS						
MORPHINE SUL TAB 15MG ER	1,574	359	$32,811.88	$20.85	4.38	0.31%
MORPHINE SUL TAB 30MG ER	893	195	$26,396.77	$29.56	4.58	0.25%
MORPHINE SUL TAB 60MG ER	115	31	$4,904.85	$42.65	3.71	0.05%
MORPHINE SUL TAB 100MG ER	53	11	$4,002.18	$75.51	4.82	0.04%
MORPHINE SUL CAP 10MG ER	18	4	$2,806.59	$155.92	4.5	0.03%
MORPHINE SUL CAP 20MG ER	3	1	$292.17	$97.39	3	0.00%
MORPHINE SUL CAP 75MG ER	2	1	$2,061.72	$1,030.86	2	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MORPHINE SUL CAP 60MG ER	1	1	$265.55	$265.55	1	0.00%
SUBTOTAL	**2,659**	**603**	**$73,541.71**	**$27.66**	**4.41**	**0.70%**
EXTENDED-RELEASE FENTANYL PRODUCTS						
FENTANYL DIS 25MCG/HR	362	100	$19,867.67	$54.88	3.62	0.19%
FENTANYL DIS 12MCG/HR	166	45	$15,825.36	$95.33	3.69	0.15%
FENTANYL DIS 50MCG/HR	154	61	$13,638.55	$88.56	2.52	0.13%
FENTANYL DIS 75MCG/HR	113	35	$13,875.35	$122.79	3.23	0.13%
FENTANYL DIS 100MCG/HR	104	24	$18,209.34	$175.09	4.33	0.17%
FENTANYL DIS 37.5MCG	42	7	$17,289.46	$411.65	6	0.16%
FENTANYL DIS 62.5MCG	7	2	$4,374.03	$624.86	3.5	0.04%
SUBTOTAL	**948**	**274**	**$103,079.76**	**$108.73**	**3.46**	**0.97%**
EXTENDED-RELEASE TRAMADOL PRODUCTS						
TRAMADOL HCL TAB 100MG ER	418	98	$16,582.22	$39.67	4.27	0.16%
TRAMADOL HCL TAB 200MG ER	369	76	$20,738.67	$56.20	4.86	0.20%
TRAMADOL HCL TAB 300MG ER	86	19	$6,269.91	$72.91	4.53	0.06%
TRAMADOL HCL CAP ER 100MG	1	1	$233.06	$233.06	1	0.00%
TRAMADOL HCL CAP ER 200MG	1	1	$28.86	$28.86	1	0.00%
SUBTOTAL	**875**	**195**	**$43,852.72**	**$50.12**	**4.49**	**0.41%**
METHADONE PRODUCTS						
METHADONE TAB 10MG	89	18	$2,216.44	$24.90	4.94	0.02%
METHADONE TAB 5MG	79	21	$1,715.39	$21.71	3.76	0.02%
METHADONE SOL 5MG/5ML	50	26	$523.47	$10.47	1.92	0.00%
SUBTOTAL	**218**	**65**	**$4,455.30**	**$20.44**	**3.35**	**0.04%**
EXTENDED-RELEASE HYDROCODONE PRODUCTS						
HYSINGLA ER TAB 40 MG	73	7	$51,570.13	$706.44	10.43	0.49%
HYSINGLA ER TAB 20 MG	42	5	$14,750.96	$351.21	8.4	0.14%
HYSINGLA ER TAB 30 MG	21	4	$10,267.97	$488.95	5.25	0.10%
HYSINGLA ER TAB 60 MG	14	2	$13,822.41	$987.32	7	0.13%
HYSINGLA ER TAB 80 MG	13	1	$17,144.10	$1,318.78	13	0.16%
HYDROCODONE TAB 60MG ER	6	1	$3,896.52	$649.42	6	0.04%
HYDROCODONE TAB 30MG ER	1	1	$326.62	$326.62	1	0.00%
HYDROCODONE CAP 30MG ER	1	1	$227.75	$227.75	1	0.00%
SUBTOTAL	**171**	**22**	**$112,006.46**	**$655.01**	**7.77**	**1.06%**
EXTENDED-RELEASE TAPENTADOL PRODUCTS						
NUCYNTA ER TAB 50MG	30	10	$18,279.19	$609.31	3	0.17%
NUCYNTA ER TAB 100MG	2	1	$846.93	$423.47	2	0.01%
SUBTOTAL	**32**	**11**	**$19,126.12**	**$597.69**	**2.91**	**0.18%**
EXTENDED-RELEASE HYDROMORPHONE PRODUCTS						
HYDROMORPHONE TAB 12MG ER	10	1	$2,285.20	$228.52	10	0.02%
SUBTOTAL	**10**	**1**	**$2,285.20**	**$228.52**	**10**	**0.02%**
EXTENDED-RELEASE OXYMORPHONE PRODUCTS						
OXYMORPHONE TAB 10MG ER	1	1	$522.70	$522.70	1	0.00%
OXYMORPHONE TAB 5MG ER	1	1	$289.20	$289.20	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**2**	**2**	**$811.90**	**$405.95**	**1**	**0.01%**
LONG-ACTING SUBTOTAL	**16,019**	**4,447**	**$5,254,190.48**	**$328.00**	**3.60**	**49.69%**
OPIOID TOTAL	**274,979**	**90,541***	**$10,573,062.69**	**$38.45**	**3.04**	**100%**

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; CON = concentrate; DIS = patch; ER = extended-release; HCL = hydrochloride; HR = hour; HYDROCO = hydrocodone; IBU = ibuprofen; LIQ = liquid; MIS = film; NALOX = naloxone; OXYCOD = oxycodone; PENTAZ = pentazocine; POW = powder; SOL = solution; SULF = sulfate; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: As of 1/1/2025, brand name Nucynta®, brand name Nucynta® ER, and Xtampza® ER are no longer covered by SoonerCare due to the manufacturer no longer participating in the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS).

Utilization Details of MAT Medications: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BUPRENORPHINE MAT PRODUCTS						
BUPREN/NALOX SUB 8-2MG	36,213	5,118	$1,819,285.95	$50.24	7.08	18.97%
BUPRENORPHINE SUB 8MG	5,661	839	$309,638.66	$54.70	6.75	3.23%
BUPREN/NALOX SUB 2-0.5MG	3,141	745	$102,670.15	$32.69	4.22	1.07%
BUPREN/NALOX MIS 8-2MG	1,736	305	$239,562.99	$138.00	5.69	2.50%
SUBLOCADE INJ 300MG/1.5ML	1,179	390	$2,444,364.07	$2,073.25	3.02	25.49%
BUPRENORPHINE SUB 2MG	1,116	280	$33,769.18	$30.26	3.99	0.35%
SUBLOCADE INJ 100MG/0.5ML	675	175	$1,380,618.79	$2,045.36	3.86	14.40%
BRIXADI SOL 128MG/0.36ML	168	48	$288,860.88	$1,719.41	3.5	3.01%
BRIXADI SOL 96MG/0.27ML	140	45	$240,717.40	$1,719.41	3.11	2.51%
BRIXADI SOL 64MG/0.18ML	132	31	$226,962.12	$1,719.41	4.26	2.37%
ZUBSOLV SUB 5.7-1.4MG	110	13	$55,472.23	$504.29	8.46	0.58%
SUBOXONE MIS 8-2MG	109	15	$84,456.56	$774.83	7.27	0.88%
BUPREN/NALOX MIS 2-0.5MG	80	33	$5,991.95	$74.90	2.42	0.06%
BUPREN/NALOX MIS 4-1MG	57	30	$9,439.86	$165.61	1.9	0.10%
ZUBSOLV SUB 8.6-2.1MG	36	4	$27,430.59	$761.96	9	0.29%
BUPREN/NALOX MIS 12-3MG	15	3	$4,149.55	$276.64	5	0.04%
BRIXADI SOL 24MG/0.48ML	2	2	$2,157.82	$1,078.91	1	0.02%
BRIXADI SOL 32MG/0.64ML	2	1	$876.82	$438.41	2	0.01%
BRIXADI SOL 16MG/0.32ML	2	1	$876.82	$438.41	2	0.01%
ZUBSOLV SUB 1.4-0.36MG	1	1	$304.55	$304.55	1	0.00%
ZUBSOLV SUB 0.7-0.18MG	1	1	$163.75	$163.75	1	0.00%
SUBTOTAL	**50,576**	**8,080**	**$7,277,770.69**	**$143.90**	**6.26**	**75.89%**
NALTREXONE PRODUCTS						
NALTREXONE TAB 50MG	10,600	3,547	$427,785.51	$40.36	2.99	4.46%
VIVITROL INJ 380MG	1,165	374	$1,882,903.00	$1,616.23	3.11	19.63%
SUBTOTAL	**11,765**	**3,921**	**$2,310,688.51**	**$196.40**	**3**	**24.09%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LOFEXIDINE PRODUCTS						
LOFEXIDINE TAB 0.18MG	2	1	$1,992.46	$996.23	2	0.02%
SUBTOTAL	**2**	**1**	**$1,992.46**	**$996.23**	**2**	**0.02%**
MAT TOTAL	**62,343**	**10,561***	**$9,590,451.66**	**$153.83**	**5.9**	**100%**

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; SOL = solution; SUB = sublingual tablet; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J2315 NALTREXONE INJ 1MG (VIVITROL)	16	11	$12,521.30	$782.58	1.45
MAT TOTAL	**16**	**11**	**$12,521.30**	**$782.58**	**1.45**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated utilizing members.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

---

[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 07/2026. Last accessed 07/28/2026.
[2] U.S. FDA. National Drug Code (NDC) Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm. Last accessed 07/28/2026.
[3] Morphine Sulfate Solution Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=67f0ee8d-696e-4c08-9007-3df0e3988bad. Last revised 06/09/2026. Last accessed 07/28/2026.
[4] U.S. FDA. Drugs@FDA: FDA-Approved Drugs Abbreviated New Drug Application (ANDA): 214378. Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=214378. Last revised 01/2026. Last accessed 07/28/2026.
[5] U.S. FDA. Drugs@FDA: FDA-Approved Drugs Abbreviated New Drug Application (ANDA): 219119. Available online at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=219119. Last revised 01/2026. Last accessed 07/29/2026.
[6] Hikma Pharmaceuticals. Hikma Launches Authorized Generic of Nucynta (Tapentadol) in the U.S. Available online at: https://www.hikma.com/news/hikma-launches-authorised-generic-of-nucynta-tapentadol-in-the-us/. Issued 02/25/2026. Last accessed 0728/2026.
[7] Hikma Pharmaceuticals. Hikma Launches Authorized Generic of Nucynta ER (Tapentadol) Extended-Release in the U.S. Available online at: https://www.hikma.com/news/hikma-launches-authorised-generic-of-nucynta-er-tapentadol-extended-release-in-the-us/. Issued 03/11/2026. Last accessed 07/28/2026.
[8] Tapentadol Extended-Release Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=38de863e-56ff-4c43-9ab8-9b3e1ba82858. Last revised 02/26/2026. Last accessed 07/28/2026.
[9] Tapentadol Tablet Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fecd2104-5bf3-47ed-a6f0-5c6ebb0a17b4. Last revised 01/28/2026. Last accessed 07/28/2026.

Appendix I

Fiscal Year 2025 Annual Review of Topical Corticosteroids and 30-Day Notice to Prior Authorize Amcinonide 0.1% Ointment

Oklahoma Health Care Authority
August 2026

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,L,O	augmented betamethasone dipropionate 0.05% (Diprolene®)	G	amcinonide 0.1%	C
betamethasone dipropionate 0.05% (Diprosone®)	C,O	clobetasol propionate 0.05% (Clobex®, Clodan®)	L,Sh,Spr	clobetasol propionate 0.025% (Impoyz®)	C
clobetasol propionate 0.05% (Olux®)	F	clobetasol propionate/skin cleanser 0.05% kit (Clodan®)	Sh	clobetasol propionate emollient 0.05% (Olux-E®, Tovet®)	F
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	desoximetasone 0.25% (Topicort®)	Spr
clobetasol propionate emollient 0.05% (Temovate® Emollient	C	desoximetasone 0.05% (Topicort®)	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
desoximetasone 0.25% (Topicort®)	C,O	fluocinonide 0.05%	G	halcinonide 0.1% (Halog®)	C,So
fluocinonide 0.05%	C,O,So	halobetasol propionate 0.05% (Ultravate®)	L	halobetasol propionate 0.05%	F
fluocinonide 0.1% (Vanos®)	C				
halobetasol propionate 0.05% (Ultravate®)	C,O				

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
Medium-High to Medium Potency					
betamethasone dipropionate 0.05%	L	betamethasone valerate 0.12% (Luxiq®)	F	betamethasone dipropionate/ calcipotriene 0.064%/0.005% (Taclonex®)	O,Sus
betamethasone valerate 0.1% (Beta-Val®)	C,O	betamethasone valerate 0.1% (Beta-Val®)	L	clocortolone pivalate 0.1% (Cloderm®)	C
fluticasone propionate 0.005% (Cutivate®)	O	calcipotriene/ betamethasone dipropionate 0.064%/0.005% (Enstilar®)	F	desoximetasone 0.05% (Topicort LP®)	C,O
fluticasone propionate 0.05% (Cutivate®)	C	fluocinolone acetonide 0.025% (Synalar®)	C,O	flurandrenolide 0.05%	L
hydrocortisone valerate 0.2% (Westcort®)	C	fluocinolone acetonide/emollient 0.025% kit (Synalar®)	C,O	fluticasone propionate 0.05% (Cutivate®)	L
mometasone furoate 0.1% (Elocon®)	C,L,O, So	fluocinonide emollient 0.05% (Lidex E®)	C	hydrocortisone butyrate 0.1%	C,L
triamcinolone acetonide 0.025%	O	hydrocortisone butyrate 0.1%	O, So	triamcinolone acetonide 0.147mg/g (Kenalog®)	Spr
triamcinolone acetonide 0.1%	C,L,O	hydrocortisone probutate 0.1% (Pandel®)	C		
triamcinolone acetonide 0.5%	C,O	hydrocortisone valerate 0.2% (Westcort®)	O		
		triamcinolone acetonide 0.05% (Trianex®)	O		
Low Potency					
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C,O	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	hydrocortisone 2.5% (Texacort®)	So

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
hydrocortisone acetate 1%	C,O	fluocinolone acetonide 0.01% (Synalar®)	C		
hydrocortisone acetate 2.5%	C,L,O	fluocinolone acetonide/skin cleanser 0.01% kit (Synalar® TS)	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.

Proctofoam® HC (Hydrocortisone/Pramoxine 1%/1% Rectal Foam) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Epifoam® (hydrocortisone/pramoxine 1%/1% rectal foam) or other rectal formulations of hydrocortisone available without a prior authorization must be provided.

Utilization of Topical Corticosteroids: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

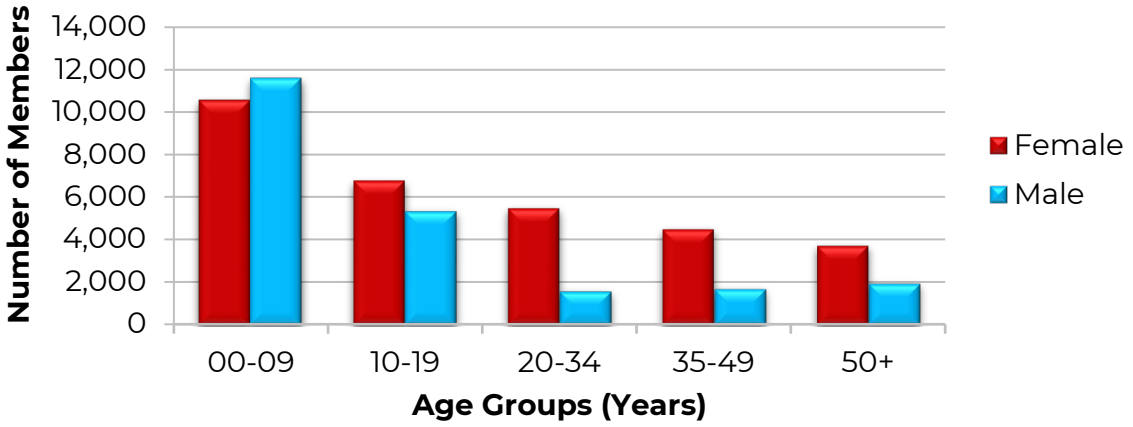
Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	44,806	65,853	$1,174,058.65	$17.83	$0.93	4,905,347	1,265,456
Aetna	4,096	4,847	$87,291.50	$18.01	$1.04	367,191	84,284
Humana	4,521	5,473	$105,145.93	$19.21	$1.04	399,404	100,979
OCH	4,208	5,014	$95,189.99	$18.98	$0.98	383,242	96,822
2024 Total	**53,625**	**81,187**	**$1,461,686.07**	**$18.00**	**$0.94**	**6,055,184**	**1,547,541**
Fiscal Year 2025							
FFS	15,500	22,970	$416,583.93	$18.14	$0.94	1,790,534	444,557
Aetna	12,380	18,538	$330,481.44	$17.83	$0.94	1,502,327	350,708
Humana	12,875	19,484	$352,042.44	$18.07	$0.93	1,468,803	379,433
OCH	13,823	20,272	$360,279.50	$17.77	$0.93	1,580,530	387,669
2025 Total	**53,131**	**81,264**	**$1,459,387.31**	**$17.96**	**$0.93**	**6,342,194**	**1,562,367**
% Change	**-0.90%**	**0.10%**	**-0.20%**	**-0.20%**	**-1.10%**	**4.70%**	**1.00%**
Change	**-494**	**77**	**-$2,298.76**	**-$0.04**	**-$0.01**	**287,010**	**14,826**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

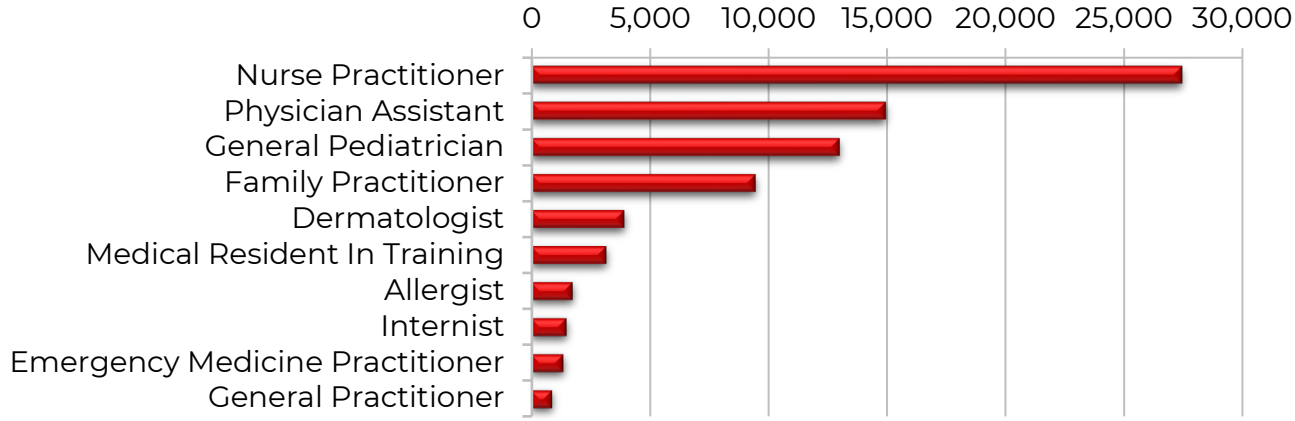
- Aggregate drug rebates collected during fiscal year 2025 for the topical corticosteroids totaled $123,921.02.[Δ] Rebates are collected after reimbursement for the medication and are not reflected in this report. The costs included in this report do not reflect net costs.

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

Demographics of Members Utilizing Topical Corticosteroids: Pharmacy Claims (All Plans)



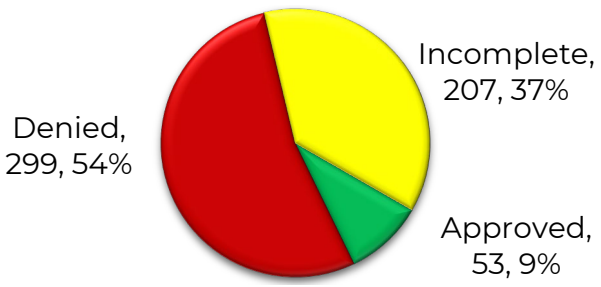
Top Prescriber Specialties of Topical Corticosteroids by Number of Claims: Pharmacy Claims (All Plans)



Prior Authorization of Topical Corticosteroids

There were 559 prior authorization requests submitted for topical corticosteroids during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	11	5%	121	55%	90	41%	**222**
Aetna	9	6%	72	47%	71	47%	**152**
Humana	7	8%	0	0%	79	92%	**86**
OCH	26	26%	14	14%	59	60%	**99**
Total	**53**	**9%**	**207**	**37%**	**299**	**54%**	**559**

FFS = fee-for-service; OCH = OK Complete Health

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Topicort® (desoximetasone 0.25% spray): September 2028
- Enstilar® (calcipotriene/betamethasone dipropionate 0.064%/0.005% foam): December 2031
- Ultravate® (halobetasol 0.05% lotion): June 2033

News:

- **July 2026:** Ayurax began marketing amcinonide 0.1% ointment in May 2023; however, it was not covered by SoonerCare until July 2026 when the manufacturer began participating in the Medicaid Drug Rebate Program (MDRP) with the Centers for Medicare and Medicaid Services (CMS). The Wholesale Acquisition Cost (WAC) is $29.77 per gram or $1,786.20 per 60-gram tube.

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. Prior authorization of amcinonide 0.1% ointment and placement into Tier-3; and
    b. Move augmented betamethasone dipropionate 0.05% (Diprolene®) gel, clobetasol propionate/skin cleanser 0.05% (Clodan®) kit, desoximetasone 0.05% (Topicort®) gel, and halobetasol propionate 0.05% (Ultravate®) lotion from Tier-2 to Tier-3; and
    c. Move desoximetasone 0.25% (Topicort®) spray from Tier-3 to Tier-2; and
    d. Move clobetasol propionate 0.05% (Temovate® Emollient) emollient cream from Tier-1 to Tier-2; and
2. Medium-High to Medium Potency:
    a. Move hydrocortisone butyrate 0.1% solution from Tier-2 to Tier-3; and

b. Move triamcinolone acetonide 0.1% lotion from Tier-1 to Tier-2; and

3. Low Potency:
   a. Move fluocinolone acetonide/skin cleanser 0.01% (Synalar® TS) kit 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,L,O	~~**augmented betamethasone dipropionate 0.05% (Diprolene®)**~~	~~**C**~~	amcinonide 0.1%	C**,O**
betamethasone dipropionate 0.05% (Diprosone®)	C,O	clobetasol propionate 0.05% (Clobex®, Clodan®)	L,Sh,Spr	**augmented betamethasone dipropionate 0.05% (Diprolene®)**	**G**
clobetasol propionate 0.05% (Olux®)	F	~~**clobetasol propionate/skin cleanser 0.05% kit (Clodan®)**~~	~~**Sh**~~	clobetasol propionate 0.025% (Impoyz®)	C
clobetasol propionate 0.05% (Temovate®)	C,O,So	clobetasol propionate 0.05% (Temovate®)	G	clobetasol propionate emollient 0.05% (Olux-E®, Tovet®)	F
~~**clobetasol propionate emollient 0.05% (Temovate® Emollient**~~	~~**C**~~	**clobetasol propionate emollient 0.05% (Temovate® Emollient**	**C**	**clobetasol propionate/skin cleanser 0.05% kit (Clodan®)**	**Sh**
desoximetasone 0.25% (Topicort®)	C,O	~~**desoximetasone 0.05% (Topicort®)**~~	~~**G**~~	~~**desoximetasone 0.25% (Topicort®)**~~	~~**Spr**~~
fluocinonide 0.05%	C,O,So	**desoximetasone 0.25% (Topicort®)**	**Spr**	**desoximetasone 0.05% (Topicort®)**	**G**
fluocinonide 0.1% (Vanos®)	C	fluocinonide 0.05%	G	diflorasone diacetate 0.05% (Apexicon®)	C,O
halobetasol propionate 0.05% (Ultravate®)	C,O	~~**halobetasol propionate 0.05% (Ultravate®)**~~	~~**L**~~	halcinonide 0.1% (Halog®)	C,So
				halobetasol propionate 0.05%	F

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

Topical Corticosteroids					
Tier-1		**Tier-2**		**Tier-3**	
desonide emollient 0.05%	C,O	alclometasone dipropionate 0.05% (Aclovate®)	C,O	desonide 0.05%	L
fluocinolone acetonide 0.01% (Synalar®)	So	fluocinolone acetonide 0.01% (Derma-Smoothe®; Derma-Smoothe FS®) – **Brand Preferred**	Oil	**fluocinolone acetonide/skin cleanser 0.01% kit (Synalar® TS)**	**C**
hydrocortisone acetate 1%	C,O	fluocinolone acetonide 0.01% (Synalar®)	C	hydrocortisone 2.5% (Texacort®)	So
hydrocortisone acetate 2.5%	C,L,O	~~**fluocinolone acetonide/skin cleanser 0.01% kit (Synalar® TS)**~~	~~**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: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
LOW POTENCY PRODUCTS						
HYDROCORT CRE 2.5%	6,551	5,191	$85,283.01	$13.02	1.26	5.84%
HYDROCORT OIN 2.5%	4,115	2,984	$73,615.47	$17.89	1.38	5.04%
TRIAMCINOLONE CRE 0.025%	3,847	3,093	$51,564.65	$13.40	1.24	3.53%
HYDROCORT CRE 1%	1,100	952	$11,579.75	$10.53	1.16	0.79%
HYDROCORT OIN 1%	653	552	$8,073.05	$12.36	1.18	0.55%
DESONIDE CRE 0.05%	536	408	$12,559.24	$23.43	1.31	0.86%
HYDROCORT LOT 2.5%	347	271	$9,343.62	$26.93	1.28	0.64%
DESONIDE OIN 0.05%	175	127	$4,367.71	$24.96	1.38	0.30%
FLUOCINOLONE SOL 0.01%	146	106	$3,097.49	$21.22	1.38	0.21%
TRIAMCINOLONE LOT 0.025%	121	110	$4,047.38	$33.45	1.1	0.28%
TRIAMCINOLONE ACT POW	6	5	$115.63	$19.27	1.2	0.01%
HYDROCORT CRE 0.5%	2	2	$22.98	$11.49	1	0.00%
FT ITCH RELF CRE 1%	1	1	$12.68	$12.68	1	0.00%
SM HYDROCORT CRE 1% PLUS	1	1	$12.54	$12.54	1	0.00%
FT ITCH RELF CRE /ALOE 1%	1	1	$8.38	$8.38	1	0.00%
SUBTOTAL	**17,602**	**13,804**	**$263,703.58**	**$14.98**	**1.28**	**18.07%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TRIAMCINOLONE CRE 0.1%	25,046	19,189	$352,440.86	$14.07	1.31	24.15%
TRIAMCINOLONE OIN 0.1%	15,111	11,382	$235,776.00	$15.60	1.33	16.16%
TRIAMCINOLONE OIN 0.025%	2,678	2,186	$40,446.32	$15.10	1.23	2.77%
TRIAMCINOLONE CRE 0.5%	2,598	1,975	$38,921.63	$14.98	1.32	2.67%
TRIAMCINOLONE OIN 0.5%	1,155	925	$21,545.74	$18.65	1.25	1.48%
MOMETASONE CRE 0.1%	684	478	$16,362.80	$23.92	1.43	1.12%
BETAMETH VAL CRE 0.1%	490	352	$13,163.06	$26.86	1.39	0.90%
TRIAMCINOLONE LOT 0.1%	413	359	$10,947.73	$26.51	1.15	0.75%
MOMETASONE OIN 0.1%	265	184	$5,508.49	$20.79	1.44	0.38%
BETAMETH VAL OIN 0.1%	222	170	$6,272.07	$28.25	1.31	0.43%
FLUTICASONE CRE 0.05%	197	150	$4,502.56	$22.86	1.31	0.31%
MOMETASONE SOL 0.1%	154	102	$4,333.34	$28.14	1.51	0.30%
BETAMETH DIP LOT 0.05%	120	66	$3,547.72	$29.56	1.82	0.24%
FLUTICASONE OIN 0.005%	96	68	$3,038.63	$31.65	1.41	0.21%
HYDROCORT VAL CRE 0.2%	16	16	$376.96	$23.56	1	0.03%
SUBTOTAL	**49,245**	**37,602**	**$757,183.91**	**$15.38**	**1.31**	**51.88%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL CRE 0.05%	2,922	1,988	$49,392.12	$16.90	1.47	3.38%
CLOBETASOL SOL 0.05%	2,551	1,512	$50,644.76	$19.85	1.69	3.47%
CLOBETASOL OIN 0.05%	2,248	1,481	$40,774.09	$18.14	1.52	2.79%
BETAMETH DIP CRE 0.05%	1,168	931	$34,361.06	$29.42	1.25	2.35%
FLUOCINONIDE SOL 0.05%	818	497	$17,716.10	$21.66	1.65	1.21%
AUG BETAMETH DIP CRE 0.05%	580	440	$9,611.54	$16.57	1.32	0.66%
BETAMETH DIP OIN 0.05%	426	312	$13,919.63	$32.68	1.37	0.95%
FLUOCINONIDE OIN 0.05%	228	150	$6,622.22	$29.04	1.52	0.45%
CLOBETASOL FOAM 0.05%	171	92	$5,449.25	$31.87	1.86	0.37%
FLUOCINONIDE CRE 0.05%	156	100	$4,166.50	$26.71	1.56	0.29%
AUG BETAMETH DIP OIN 0.05%	98	74	$3,441.95	$35.12	1.32	0.24%
CLOBETASOL EMOL CRE 0.05%	103	60	$3,549.61	$34.46	1.72	0.24%
HALOBETASOL CRE 0.05%	37	23	$1,201.85	$32.48	1.61	0.08%
DESOXIMETASONE CRE 0.25%	23	17	$620.72	$26.99	1.35	0.04%
HALOBETASOL OIN 0.05%	20	14	$602.17	$30.11	1.43	0.04%
FLUOCINONIDE CRE 0.1%	16	12	$337.43	$21.09	1.33	0.02%
AUG BETAMETH DIP LOT 0.05%	6	5	$191.46	$31.91	1.2	0.01%
DESOXIMETASONE OIN 0.25%	2	2	$53.94	$26.97	1	0.00%
SUBTOTAL	**11,573**	**7,710**	**$242,656.40**	**$20.97**	**1.5**	**16.63%**
TIER-1 TOTAL	**78,420**	**59,116**	**$1,263,543.89**	**$16.11**	**1.33**	**86.58%**
TIER-2 UTILIZATION						
LOW POTENCY PRODUCTS						
FLUOCINOLONE ACT BODY OIL 0.01%	22	13	$694.99	$31.59	1.69	0.05%
DERMA-SMOOTH FS BODY OIL 0.01%	14	9	$648.85	$46.35	1.56	0.04%
FLUOCINOLONE ACT SCALP OIL 0.01%	13	9	$418.13	$32.16	1.44	0.03%
DERMA-SMOOTH FS SCALP OIL 0.01%	9	5	$396.35	$44.04	1.8	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ALCLOMETASONE CRE 0.05%	1	1	$42.28	$42.28	1	0.00%
ALCLOMETASONE OIN 0.05%	1	1	$37.67	$37.67	1	0.00%
FLUOCINOLONE CRE 0.01%	1	1	$31.81	$31.81	1	0.00%
SUBTOTAL	**61**	**39**	**$2,270.08**	**$37.21**	**1.56**	**0.16%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
TRIAMCINOLONE OIN 0.05%	29	28	$3,010.02	$103.79	1.04	0.21%
BETAMETH VAL LOT 0.1%	7	3	$267.03	$38.15	2.33	0.02%
FLUOCINONIDE EMOL CRE 0.05%	6	2	$315.05	$52.51	3	0.02%
BETAMETH VAL AER 0.12%	6	5	$389.92	$64.99	1.2	0.03%
HYDROCORT VAL OIN 0.2%	3	3	$137.31	$45.77	1	0.01%
FLUOCINOLONE OIN 0.025%	2	2	$118.66	$59.33	1	0.01%
ENSTILAR FOAM 0.005-0.064%	1	1	$1,318.57	$1,318.57	1	0.09%
SUBTOTAL	**54**	**44**	**$5,556.56**	**$102.90**	**1.23**	**0.38%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL SHA 0.05%	60	38	$2,508.06	$41.80	1.58	0.17%
CLOBETASOL SPR 0.05%	12	3	$447.79	$37.32	4	0.03%
CLOBETASOL GEL 0.05%	10	10	$283.93	$28.39	1	0.02%
CLOBETASOL LOT 0.05%	7	6	$204.46	$29.21	1.17	0.01%
FLUOCINONIDE GEL 0.05%	4	2	$121.98	$30.50	2	0.01%
DESOXIMETASONE GEL 0.05%	2	1	$370.99	$185.50	2	0.03%
SUBTOTAL	**95**	**60**	**$3,937.21**	**$41.44**	**1.58**	**0.27%**
TIER-2 TOTAL	**210**	**143**	**$11,763.85**	**$56.02**	**1.47**	**0.81%**
TIER-3 UTILIZATION						
LOW POTENCY PRODUCTS						
TEXACORT SOL 2.5%	1	1	$198.13	$198.13	1	0.01%
DESONIDE LOT 0.05%	1	1	$45.30	$45.30	1	0.00%
SUBTOTAL	**2**	**2**	**$243.43**	**$121.72**	**1**	**0.02%**
MEDIUM-HIGH TO MEDIUM POTENCY PRODUCTS						
CALCIP/BETAMETH OIN 0.005-0.064%	4	4	$753.46	$188.37	1	0.05%
HYDROCORT BUTYRATE LOT 0.1%	1	1	$211.41	$211.41	1	0.01%
HYDROCORT BUTYRATE CRE 0.1%	1	1	$106.12	$106.12	1	0.01%
FLUTICASONE LOT 0.05%	1	1	$197.52	$197.52	1	0.01%
DESOXIMETASONE CRE 0.05%	1	1	$87.20	$87.20	1	0.01%
SUBTOTAL	**8**	**8**	**$1,355.71**	**$169.46**	**1**	**0.09%**
ULTRA-HIGH TO HIGH POTENCY PRODUCTS						
CLOBETASOL EMOL FOAM 0.05%	1	1	$190.41	$190.41	1	0.01%
SUBTOTAL	**1**	**1**	**$190.41**	**$190.41**	**1**	**0.01%**
TIER-3 TOTAL	**11**	**11**	**$1,789.55**	**$162.69**	**1**	**0.12%**
TOPICAL RECTAL PRODUCTS						
PROCTO-MED HC CRE 2.5%	713	614	$12,877.86	$18.06	1.16	0.88%
PROCTOFOAM HC 1%	684	531	$136,388.94	$199.40	1.29	9.35%
HYDROCORT PERIANAL CRE 2.5%	755	639	$14,031.58	$18.58	1.18	0.96%
HYDROCORT PERIANAL CRE 1%	290	255	$8,619.40	$29.72	1.14	0.59%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LIDOCAINE/HYDROCORT CRE 3%-0.5%	88	73	$5,001.98	$56.84	1.21	0.34%
PROCTOZONE HC CRE 2.5%	29	28	$526.36	$18.15	1.04	0.04%
PROCTOSOL HC CRE 2.5%	18	17	$324.84	$18.05	1.06	0.02%
HYDROCORT ENEMA 100MG	17	11	$2,893.37	$170.20	1.55	0.20%
HYDROCORT ACETATE SUP 25MG	15	15	$408.09	$27.21	1	0.03%
EPIFOAM 1%	5	3	$529.44	$105.89	1.67	0.04%
ANUSOL-HC CRE 2.5%	5	4	$98.35	$19.67	1.25	0.01%
HYDROCORT/PRAMOXINE CRE 1-1%	1	1	$113.25	$113.25	1	0.01%
CORTIFOAM 10%	1	1	$449.78	$449.78	1	0.03%
HYDROCORT OIN 1%	2	2	$26.78	$13.39	1	0.00%
TOPICAL RECTAL TOTAL	**2,623**	**2,194**	**$182,290.02**	**$69.50**	**1.2**	**12.49%**
TOTAL	**81,264**	**53,131***	**$1,459,387.31**	**$17.96**	**1.53**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = acetonide; AUG = augmented; BETAMETH = betamethasone; CALCIP = calcipotriene; CRE = cream; DIP = dipropionate; EMOL = emollient; HYDROCORT = hydrocortisone; LOT = lotion; OIN = ointment; POW = powder; SOL = solution; SHA = shampoo; SPR = spray; SUP = suppository; VAL = valerate
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 07/2026. Last accessed 07/28/2026.
[2] U.S. FDA. National Drug Code Directory. Available online at: https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm. Last revised 07/28/2026. Last accessed 07/28/2026.

Appendix J

Fiscal Year 2025 Annual Review of Various Systemic Antibiotics and 30-Day Notice to Prior Authorize Contepo™ (Fosfomycin for Injection), Doxycycline Hyclate 75mg Capsule, and Orlynvah™ (Sulopenem Etzadroxil/Probenecid)

Oklahoma Health Care Authority
August 2026

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/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®, Doryx® MPC)
   - Doxycycline monohydrate 75mg capsules
   - Doxycycline monohydrate 150mg capsules and tablets
   - Doxycycline monohydrate DR 40mg capsules (Oracea®)
   - Metronidazole 125mg tablets
   - Metronidazole 375mg capsules
   - Minocycline ER tablets (Minolira™)
   - Minocycline ER tablets (Solodyn®)
   - Nitrofurantoin 50mg/5mL suspension

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
   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 at least 31 weeks gestational 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 when indicated, 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.

Blujepa (Gepotidacin) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae, Citrobacter freundii* complex, *Staphylococcus saprophyticus,* and *Enterococcus faecalis* (culture/sensitivity results must be submitted); and
2. Member must be a female 12 years of age or older and weigh ≥40kg; and
3. Member must have an estimated glomerular filtration rate (eGFR) >30mL/min/1.73m^2) and must not be on dialysis; and
4. Member must not have severe hepatic impairment (Child Pugh C); and
5. Prior to and during treatment, the potential for drug interactions should be evaluated, including:
   a. Avoid concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole) or inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and
   b. Avoid concomitant administration with CYP3A4 substrates with a narrow therapeutic index (e.g., quinidine, cyclosporine); and
   c. Monitor digoxin serum concentrations as clinically indicated; and
   d. Monitor for adverse effects with concomitant administration with acetylcholinesterase inhibitors, anticholinergic medications, or non-depolarizing neuromuscular blocking agents; and
6. Prescriber must verify that members with medical conditions that may be exacerbated by acetylcholinesterase inhibition will be monitored for adverse effects; and
7. If administration of Blujepa cannot be avoided in members with a history of QTc interval prolongation, taking antiarrhythmic medications, or taking other medications that may prolong the QTc interval, prescriber must verify that serum electrolyte abnormalities will be corrected and monitored and an ECG should be collected prior to administration and duration treatment, as clinically indicated; and
8. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
9. A quantity limit of 20 tablets per 5 days will apply.

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 Approval Criteria:

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.

Emblaveo® (Aztreonam/Avibactam) Approval Criteria:

1. An FDA approved diagnosis of complicated intra-abdominal infections (cIAI) caused by susceptible gram-negative microorganisms (e.g., *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca*, *Enterobacter cloacae* complex*, Citrobacter freundii* complex, *Serratia marcescens*) in adults who have limited or no alternative treatment options (culture/sensitivity results must be submitted); and
2. Member must 18 years of age or older; and
3. 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, a fluoroquinolone (e.g., ciprofloxacin or levofloxacin) in combination with metronidazole, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
5. A quantity limit of 57 vials per 14 days will apply.

Fetroja® (Cefiderocol) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):

    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. 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
4. 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. 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
4. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Likmez® (Metronidazole 500mg/5mL Suspension) Approval Criteria:

1. A patient-specific clinically significant reason (beyond convenience) must be provided regarding why the member cannot use the 250mg and 500mg tablets, which are available without prior authorization, including but not limited to:
    a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
    b. Clinically indicated dose cannot be achieved with available tablet formulations; or
    c. Treatment course was initiated inpatient; and
2. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request; and
3. A quantity limit of 200mL per 10 days will apply.

Meropenem 2 Gram Vial Approval Criteria:

1. An FDA approved diagnosis of bacterial meningitis; and
2. Member must be 3 months of age or older; and

3. A patient-specific, clinically significant reason why the meropenem 1 gram or 500mg vials, which are available without a prior authorization, cannot be used must be provided.

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

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).

Pivya™ (Pivmecillinam) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection caused by designated susceptible isolates of *Escherichia coli, Proteus mirabilis*, and *Staphylococcus saprophyticus* (culture/sensitivity results must be submitted); and
2. Member must be a female 18 years of age or older; and
3. Member must not have any of the following contraindications:
    a. Serious hypersensitivity reactions (e.g., anaphylaxis, Stevens-Johnson syndrome) to Pivya™ or to other beta-lactam antibacterial drugs (e.g., penicillins, cephalosporins); and
    b. Primary or secondary carnitine deficiency resulting from inherited disorders of mitochondrial fatty acid oxidation and carnitine metabolism and other inborn errors of metabolism (e.g., methylmalonic aciduria, propionic acidemia); and
    c. Acute porphyria; and
4. Provider must verify that concurrent treatment with valproic acid, valproate, or other pivalate-generating drugs will be avoided due to increased risk of carnitine depletion; or
    a. If concomitant use is necessary, member must be counseled to monitor for and report adverse reactions associated with carnitine depletion (e.g., hypoglycemia, muscle aches, fatigue, confusion); and
5. Pivya™ must not be used when prolonged antibacterial treatment (i.e., longer than the FDA-approved treatment duration of up to 7 days) is necessary; and
6. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
7. A quantity limit of 21 tablets per 7 days will apply.

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

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
    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. 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 when indicated, or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. A quantity limit of 56 vials per 14 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 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.

Suprax® (Cefixime) Approval Criteria:

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

Tetracycline 250mg and 500mg Capsule and Tablet Approval Criteria:

1. For the capsule formulation, a quantity of 56 capsules for 14 days is available without a prior authorization for a diagnosis of *Helicobacter pylori* (*H. pylori*) infection; or
2. For the tablet formulation, approval requires a patient-specific, clinically significant reason why the member requires the tablet formulation and cannot use the capsule formulation, which is available without prior authorization; and
3. A quantity limit of 56 capsules or tablets per 14 days will apply; and

a. A quantity limit override for longer durations of therapy for indications other than for the eradication of *H. pylori* infection will require 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 (culture/sensitivity results must be submitted); 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).

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 (culture/sensitivity results must be submitted); 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) must be provided; or
    a. A clinical exception will apply for infections caused by carbapenem-resistant Acinetobacter baumannii (CRAB), in which case Xacduro will be approved; and
4. The prescriber must confirm that the member will be treated for other pathogens present, if applicable; and
5. Approval quantity will be based on Xacduro 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.

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
    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 when indicated, 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).

Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Diagnosis]:

1. An FDA approved diagnosis of ABSSSI caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); 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. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [Community-Acquired Bacterial Pneumonia (CABP) Diagnosis]:

1. An FDA approved diagnosis of CABP caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); and

2. Member must be 3 months 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. For members who require weight-based dosing, the member's recent weight, taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate dose according to package labeling; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Zevtera® (Ceftobiprole Medocaril Sodium) Approval Criteria [*Staphylococcus aureus* Bloodstream Infection (Bacteremia) (SAB) Diagnosis]:

1. An FDA approved diagnosis of SAB caused by designated susceptible microorganisms (culture/sensitivity results must be submitted); and
2. Member must be 18 years of age or older; and
3. For methicillin-resistant *Staphylococcus aureus* (MRSA), a patient-specific, clinically significant reason why the member cannot use vancomycin or other cost-effective therapeutic equivalent alternative(s) must be provided; and
4. For methicillin-susceptible *Staphylococcus aureus* (MSSA), a patient-specific, clinically significant reason why the member cannot use an appropriate beta-lactam (e.g., nafcillin, oxacillin) 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: Fiscal Year 2025

Comparison of Fiscal Years: Pharmacy Claims (All Plans)

Plan Type	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
Fiscal Year 2024							
FFS	303	434	$573,573.67	$1,321.60	$109.59	34,649	5,234
Aetna	83	86	$6,529.00	$75.92	$6.44	3,342	1,014
Humana	132	145	$121,264.25	$836.31	$69.85	5,404	1,736
OCH	121	132	$33,263.34	$251.99	$20.66	5,001	1,610
2024 Total	**632**	**797**	**$734,630.26**	**$921.74**	**$76.57**	**48,396**	**9,594**
Fiscal Year 2025							
FFS	291	371	$439,704.11	$1,185.19	$90.75	28,740	4,845
Aetna	229	254	$52,868.25	$208.14	$16.78	18,096	3,151
Humana	250	289	$213,377.44	$738.33	$51.54	15,825	4,140
OCH	263	313	$110,762.98	$353.88	$29.69	16,399	3,731
2025 Total	**1,026**	**1,227**	**$816,712.78**	**$665.62**	**$51.47**	**79,060**	**15,867**
% Change	**62.30%**	**54.00%**	**11.20%**	**-27.80%**	**-32.80%**	**63.40%**	**65.40%**
Change	**394**	**430**	**$82,082.52**	**-$256.12**	**-$25.10**	**30,664**	**6,273**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
FFS = fee-for-service; OCH = Oklahoma Complete Health
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

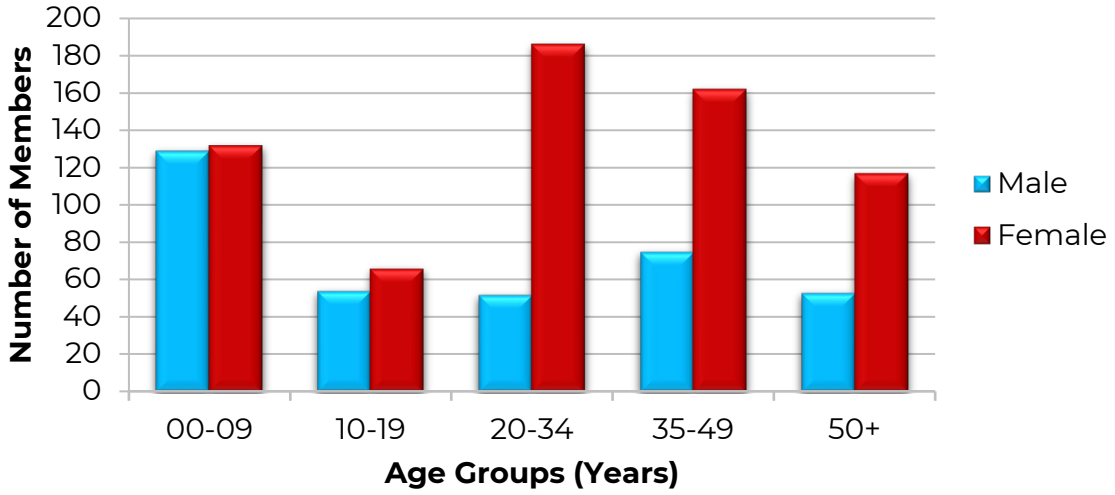
Comparison of Fiscal Years: Medical Claims (All Plans)

Plan Type	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
Fiscal Year 2024					
FFS	12	92	$106,677.00	$1,159.53	7.67
Aetna	0	0	$0.00	$0.00	0
Humana	0	0	$0.00	$0.00	0
OCH	0	0	$0.00	$0.00	0
2024 Total	**12**	**92**	**$106,677.00**	**$1,159.53**	**7.67**
Fiscal Year 2025					
FFS	12	51	$76,758.00	$1,505.06	4.25
Aetna	13	13	$55,935.00	$4,302.69	1
Humana	9	11	$37,530.01	$3,411.82	1.22
OCH	6	6	$23,265.00	$3,877.50	1
2025 Total	**40**	**81**	**$193,488.01**	**$2,388.74**	**2.03**
% Change	**233.33%**	**-11.96%**	**81.38%**	**106.01%**	**-73.60%**
Change	**28**	**-11**	**$86,811.01**	**$1,229.21**	**-5.65**

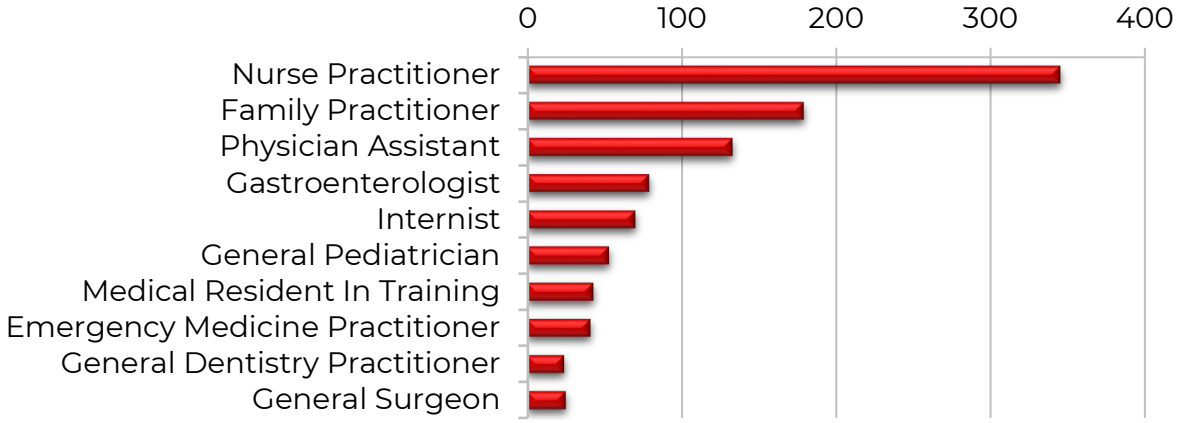
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2024 = 07/01/2023 to 06/30/2024; Fiscal Year 2025 = 07/01/2024 to 06/30/2025
Please note: SoonerSelect managed care plans became effective on 04/01/2024.

- Aggregate drug rebates collected during fiscal year 2025 for the various systemic antibiotics totaled $362,482.95.[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: Pharmacy Claims (All Plans)



Top Prescriber Specialties of Various Systemic Antibiotics by Number of Claims: Pharmacy Claims (All Plans)

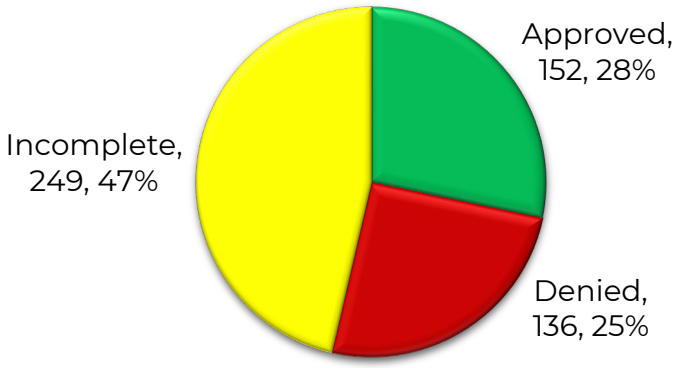


Prior Authorization of Various Systemic Antibiotics

There were 537 prior authorization requests submitted for various systemic antibiotics during fiscal year 2025. The following charts show the status of the submitted petitions for fiscal year 2025.

[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.

Status of Petitions (All Plans)



Status of Petitions by Plan Type

Plan Type	Approved		Incomplete		Denied		Total
	Number	Percent	Number	Percent	Number	Percent	
FFS	88	25%	213	61%	49	14%	**350**
Aetna	24	36%	24	36%	18	27%	**66**
Humana	7	16%	0	0%	36	84%	**43**
OCH	33	42%	12	15%	33	42%	**78**
Total	**152**	**28%**	**249**	**47%**	**136**	**25%**	**537**

FFS = fee-for-service; OCH = OK Complete Health

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

Anticipated Patent Expiration(s):

- 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
- Recarbrio™ (imipenem/cilastatin/relebactam vial for IV infusion): November 2029
- Sivextro® (tedizolid tablet and vial for IV infusion): December 2030
- 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
- Emblaveo™ (aztreonam/avibactam): June 2032
- Baxdela® (delafloxacin vial for IV infusion): February 2033
- Contepo™ (fosfomycin vial for IV infusion): October 2033
- Zevtera® (ceftobiprole medocaril sodium vial for IV infusion): April 2034
- Doryx® MPC (doxycycline hyclate DR tablet): October 2034
- Bluejpa (gepotidacin tablet): March 2035
- 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
- Likmez™ (metronidazole oral suspension): January 2039
- Vabomere® (meropenem/vaborbactam vial for IV infusion): April 2039
- Orlynvah™ (sulopenem etzadroxil/probenecid tablet): December 2039

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

- **October 2024:** The FDA approved Orlynvah™ (sulopenem etzadroxil/probenecid) for the treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae,* or *Proteus mirabilus* in adult women who have limited or no alternative oral antibacterial treatment options.
- **October 2025:** The FDA approved Contepo™ (fosfomycin for injection) for the treatment of adults with complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible strains of *Escherichia coli* or *Klebsiella pneumoniae*. Despite being available internationally, an IV formulation of fosfomycin has not been available in the United States until this approval.
- **December 2025:** The FDA approved an expanded indication for Blujepa (gepotidacin) as a new oral option for the treatment of uncomplicated urogenital gonorrhea in adult and pediatric patients 12 years of age and older, weighing at least 45kg, and who have limited or no alternative treatment options. The approval of this indication was based on limited clinical and safety data.

News:

- **June 2026:** A doxycycline hyclate 75mg capsule formulation began being marketed. Doxycycline hyclate 75mg is also available in a tablet formulation.

Pipeline:

- **Fetroja® (Cefiderocol):** The FDA has accepted a supplemental New Drug Application (sNDA) for Fetroja® (cefiderocol) which would expand the indication to include treatment of pediatric patients. Currently, Fetroja® is FDA approved only for the treatment of adults. The target Prescription Drug User Feed Act (PDUFA) date is currently February 23, 2027.

Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Product Summary[7]

Therapeutic Class: Penem antibacterial and renal tubular transport inhibitor combination

Indication(s): Treatment of uUTI caused by the designated microorganisms *Escherichia coli*, *Klebsiella pneumoniae,* or *Proteus mirabilus* in adult women who have limited or no alternative oral antibacterial treatment options

- Limitation(s) of Use: Orlynvah™ is not indicated for the treatment of cUTI or complicated intraabdominal infections (cIAI) or as step-down treatment after IV antibacterial treatment.

How Supplied: 500mg/500mg film-coated tablet

Dosing and Administration: 500mg/500mg (1 tablet) orally twice daily for 5 days

- Administration with food is recommended.
- Administration is not recommended in patients with creatinine clearance (CrCl) <15mL/min or patients on hemodialysis.
- Orlynvah™ is contraindicated in patients with known uric acid kidney stones or with concomitant use of ketorolac tromethamine.

Efficacy: The safety and efficacy of Orlynvah™ were evaluated in 2 Phase 3 randomized, double blind clinical trials, designated as Trial 1 and Trial 2 in the *Prescribing Information*.

- Key Inclusion Criteria:
  - Female ≥18 years of age
  - Diagnosis of uUTI
  - Trial 1: Microbiological modified intention-to-treat (micro-MITT) population
    - ≥1 uropathogen isolated at baseline
    - Received ≥1 dose of study drug
    - Micro-MITT susceptible (micro-MITTS) population: baseline pathogen(s) susceptible to amoxicillin/clavulanate
    - Micro-MITT resistant (micro-MITTR) population: baseline pathogen(s) resistant to amoxicillin/clavulanate
  - Trial 2: Micro-MITT population
    - ≥1 uropathogen isolated at baseline
    - Received ≥1 dose of study drug
    - Micro-MITTS population: baseline pathogen(s) susceptible to ciprofloxacin
    - Micro-MITTR population: baseline pathogen(s) resistant to ciprofloxacin
- Key Exclusion Criteria:
  - Signs and symptoms of pyelonephritis

    - Any anatomical abnormality of the urinary tract
    - Receiving hemodialysis
- Intervention(s):
    - Trial 1: Orlynvah™ 500mg/500mg orally twice daily for 5 days vs. amoxicillin/clavulanate 875mg/125mg orally twice daily for 5 days
    - Trial 2: Orlynvah™ 500mg/500mg orally twice daily for 5 days vs. ciprofloxacin 250mg orally twice daily for 3 days
- Primary Endpoint(s):
    - Trial 1 and Trial 2: Composite response (combined microbiological response and clinical cure rates) in the micro-MITTS population 12 days after randomization
- Results:
    - Trial 1:
        - At day 12, for the micro-MITTS population, 61.7% (296/480) of patients in the Orlynvah™ group vs. 55.0% (243/442) of patients in the amoxicillin/clavulanate group met the primary endpoint of composite response; therefore, Orlynvah™ was noninferior to amoxicillin/clavulanate, with a treatment difference of 6.7% [95% confidence interval (CI): 0.3, 13.0].
        - The micro-MITTR population had insufficient power to determine efficacy (N=67).
    - Trial 2:
        - At day 12, in the micro-MITTR population, Orlynvah™ demonstrated superiority to ciprofloxacin with 48.1% (78/162) of patients vs. 32.9% (49/149) meeting the composite response endpoint (treatment difference: 15.3%; 95% CI: 4.3, 25.8; P=0.006).
        - Orlynvah™ did not demonstrate noninferiority to ciprofloxacin in the micro-MITTS population with 60.4% (227/376) vs. 71.8% (300/418) meeting the composite response endpoint (treatment difference: -11.4%; 95% CI: -17.9, -4.8).

Cost: The Wholesale Acquisition Cost (WAC) of Orlynvah™ is $297.50 per tablet, which results in a cost of $2,975.00 per 5-day treatment course based on the FDA-approved dosing of 1 tablet twice daily.

Cost Comparison: IV Products for Treatment of cUTI

Product	Cost Per Unit	Cost Per Dose	Cost Per Day*
Contepo™ (fosfomycin for injection) 6-gram vial	**$182.74**	**$182.74**	**$548.22**
ceftriaxone 2-gram vial (generic)	$3.05	$3.05	$3.05
ciprofloxacin 400mg/40mL vial (generic)	$0.08	$3.20	$6.40

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).
*Costs per dose and per day is based on a typical adult dose of 6 grams every 8 hours for Contepo™, 2 grams once daily for ceftriaxone, and 400mg twice daily for ciprofloxacin.
Unit = mL or vial

Cost Comparison: Doxycycline Products

Product	Cost Per Unit	Cost Per Day*
doxycycline hyclate 75mg capsule (generic)	**$10.00**	**$20.00**
doxycycline hyclate 50mg tablet (generic)	$5.42	$10.84
doxycycline hyclate 75mg tablet (generic)	$0.27	$0.54
doxycycline hyclate 50mg capsule (generic)	$0.15	$0.30
doxycycline hyclate 100mg tablet (generic)	$0.12	$0.24
doxycycline hyclate 100mg capsule (generic)	$0.08	$0.16

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 is based on a typical adult dose of 1 tablet or capsule twice daily.
Unit = capsule or tablet

Recommendations

The College of Pharmacy recommends the prior authorization of Contepo™ (fosfomycin for injection) and Orlynvah™ (sulopenem etzadroxil/probenecid) with the following criteria (shown in red):

Contepo™ (Fosfomycin for Injection) Approval Criteria:

1. An FDA approved diagnosis of complicated urinary tract infection (cUTI), including acute pyelonephritis, caused by *Escherichia coli* or *Klebsiella pneumoniae* (culture/sensitivity results must be submitted with the request); and
2. A patient-specific, clinically significant reason why the member cannot use an appropriate cephalosporin (e.g., cefuroxime, ceftriaxone, cefepime), penicillin/beta lactamase inhibitor combination (e.g., piperacillin/ tazobactam), a fluoroquinolone (e.g., ciprofloxacin or levofloxacin), or other cost-effective therapeutic equivalent alternative(s); and
3. A quantity limit of 42 vials per 14 days will apply.

Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Approval Criteria:

1. An FDA approved diagnosis of uncomplicated urinary tract infection (uUTI) caused by designated susceptible microorganisms in members who have limited or no alternative oral treatment options (culture/sensitivity results must be submitted); and
    a. Must not be used for the treatment of complicated urinary tract infections (cUTI) or complicated intraabdominal infections (cIAI) or as step-down treatment after intravenous antibacterial treatment of cUTI or cIAI; and
2. Member must be a female 18 years of age or older; and
3. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and
4. A quantity limit of 10 tablets per 5 days will apply.

The College of Pharmacy recommends updating the approval criteria for Blujepa (gepotidacin) based on the new FDA approved indication and for clarity (changes shown in red):

Blujepa (Gepotidacin) Approval Criteria:

1. An FDA approved diagnosis of 1 of the following:
    a. Uncomplicated urinary tract infection (uUTI) caused by ~~the designated microorganisms~~ *Escherichia coli*, *Klebsiella pneumoniae, Citrobacter freundii* complex, *Staphylococcus saprophyticus,* ~~and~~ or *Enterococcus faecalis* (culture/sensitivity results must be submitted); and
        i. Member must be a female 12 years of age or older and weigh ≥40kg; ~~and~~ or
    b. Uncomplicated urogenital gonorrhea in members who have limited or no alternative treatment options; and
        i. Member must be 12 years of age or older and weigh ≥45kg; and
2. Member must have an estimated glomerular filtration rate (eGFR) >30mL/min/1.73m^2) and must not be on dialysis; and
3. Member must not have severe hepatic impairment (Child Pugh C); and
~~4. Prior to and during treatment, the potential for drug interactions should be evaluated, including:~~
    ~~a. Avoid concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole) or inducers (e.g., rifampin, carbamazepine, phenytoin, St. John's wort); and~~
    ~~b. Avoid concomitant administration with CYP3A4 substrates with a narrow therapeutic index (e.g., quinidine, cyclosporine); and~~
    ~~c. Monitor digoxin serum concentrations as clinically indicated; and~~

~~d. Monitor for adverse effects with concomitant administration with acetylcholinesterase inhibitors, anticholinergic medications, or non-depolarizing neuromuscular blocking agents; and~~

5. Prescriber must evaluate the potential for drug-drug interactions prior to and during treatment with Blujepa and agree to address interactions with concomitant medications according to package labeling; and
6. Prescriber must verify that members with medical conditions that may be exacerbated by acetylcholinesterase inhibition will be monitored for adverse effects; and
7. If administration of Blujepa cannot be avoided in members with a history of QTc interval prolongation, taking antiarrhythmic medications, or taking other medications that may prolong the QTc interval, prescriber must verify that serum electrolyte abnormalities will be corrected and monitored and an ECG should be collected prior to administration and during treatment, as clinically indicated; and

~~8. A patient-specific, clinically significant reason why the member cannot use an appropriate cost-effective, therapeutic alternative (e.g., nitrofurantoin, sulfamethoxazole/trimethoprim, fosfomycin) must be provided; and~~

9. A patient-specific, clinically significant reason why the member cannot use a cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis (e.g., ceftriaxone, nitrofurantoin, fosfomycin, sulfamethoxazole/trimethoprim) must be provided; and

~~10. A quantity limit of 20 tablets per 5 days will apply.~~

11. Approval quantity will be based on package labeling and FDA-approved dosing regimens.

The College of Pharmacy also recommends replacing the Oral Antibiotic Special Formulation approval criteria with individual criteria describing the preferred cost-effective therapeutic equivalent products for clarity and recommends the prior authorization of doxycycline hyclate 75mg capsule within the new approval criteria for the doxycycline special formulations (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/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®, Doryx® MPC)~~
- ~~Doxycycline monohydrate 75mg capsules~~
- ~~Doxycycline monohydrate 150mg capsules and tablets~~
- ~~Doxycycline monohydrate DR 40mg capsules (Oracea®)~~
- ~~Metronidazole 125mg tablets~~
- ~~Metronidazole 375mg capsules~~
- ~~Minocycline ER tablets (Minolira™)~~
- ~~Minocycline ER tablets (Solodyn®)~~
- ~~Nitrofurantoin 50mg/5mL suspension~~

Amoxicillin/Clavulanate Potassium Extended Release (ER) Tablets (Augmentin XR®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the generic immediate release (IR) tablet formulations, which are available without prior authorization, must be provided.

Cephalexin 750mg Capsule and Cephalexin 250mg and 500mg Tablets Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use the 250mg or 500mg capsule formulations, which are available without prior authorization, must be provided.

Doxycycline Hyclate 75mg and 150mg Tablets (Acticlate®), Doxycycline Hyclate 75mg Capsule, Doxycycline Hyclate 50mg Tablet (Targadox®), Doxycycline Hyclate Delayed Release (DR) Tablets (Doryx®, Doryx® MPC), Doxycycline Monohydrate 75mg Capsule, Doxycycline Monohydrate 150mg Capsules and Tablets, and Doxycycline Monohydrate DR 40mg Capsules (Oracea®) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use generic immediate release (IR) doxycycline hyclate 20mg tablet, 50mg capsule, or 100mg capsule or tablet or doxycycline monohydrate 50mg capsule or tablet, 75mg tablet, or 100mg capsule or tablet, which are available without prior authorization, must be provided; and
2. For doxycycline hyclate 75mg capsule, a patient specific, clinically significant reason why the member cannot use the doxycycline hyclate 75mg tablet formulation must be provided.

Metronidazole 125mg Tablet and 375 mg Capsule Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use a dosing regimen with the 250mg or 500mg generic metronidazole tablets, which are available without prior authorization, must be provided.

Minocycline (50mg, 75mg, and 100mg) Immediate-Release (IR) Tablet, Minocycline ER Tablet (Minolira™), and Minocycline ER Tablet (Solodyn®) Approval Criteria:

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).

Nitrofurantoin 50mg/5mL Suspension Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use the generic nitrofurantoin 25mg/5mL suspension, which is available without prior authorization, must be provided.

The College of Pharmacy also recommends updating the approval criteria for Avycaz® (ceftazidime/avibactam), Baxdela® (delafloxacin), ciprofloxacin 250mg/mL and 500mg/mL oral suspension and levofloxacin 25mg/mL oral solution, Likmez® (metronidazole 500mg/5mL suspension), and Zerbaxa® (ceftolozane/avibactam) based on clinical practice and for clarity (changes shown in red):

Avycaz® (Ceftazidime/Avibactam) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
    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~~ or
    d. Other diagnosis in which treatment with Avycaz® is supported by compendia or clinical literature (documentation must be submitted with the request); and
2. Member must be at least 31 weeks gestational 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 a ~~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 when indicated, or other cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis 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 1 of the following caused by designated susceptible bacteria (culture/sensitivities must be provided):
   a. Acute Bacterial Skin and Skin Structure Infection (ABSSSI) ~~caused by designated susceptible bacteria; and~~ or
   b. Community Acquired Bacteria Pneumonia (CABP); and
2. A patient-specific, clinically significant reason why the member cannot use a cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis (e.g., other fluroquinolone, beta-lactam, doxycycline, linezolid, trimethoprim/sulfamethoxazole, vancomycin) must be provided; 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. 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~~

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

1. ~~Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet formulations cannot be used.~~
2. Products will be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age require a patient-specific, clinically significant reason why the oral tablet

formulations, which are available without prior authorization, cannot be used, including but not limited to:
    a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
    b. Clinically indicated dose cannot be achieved with available tablet formulations; or
    c. Treatment course was initiated inpatient; and
3. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request.

Likmez® (Metronidazole 500mg/5mL Suspension) Approval Criteria:

1. Products will be available without prior authorization for members 6 years of age and younger. Members older than 6 years of age require a ~~A~~ patient-specific clinically significant reason (beyond convenience) must be provided regarding why the member cannot use the 250mg and 500mg tablets, which are available without prior authorization, including but not limited to:
    a. Member is unable to swallow the oral tablet (i.e., has diagnosis characterized by difficulty or inability to swallow); or
    b. Clinically indicated dose cannot be achieved with available tablet formulations; or
    c. Treatment course was initiated inpatient; and
2. For members who require weight-based dosing, the member's recent weight (within the last 3 months) must be provided on the prior authorization request; and
3. A quantity limit of 200mL per 10 days will apply

Zerbaxa® (Ceftolozane/Tazobactam) Approval Criteria:

1. ~~An FDA approved~~ A diagnosis of 1 of the following infections caused by designated susceptible microorganisms (culture/sensitivity results must be submitted):
    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~~ or
    d. Other diagnosis in which treatment with Zerbaxa® is supported by compendia or clinical literature (documentation must be submitted with the request); 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 a ~~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 when indicated, or other cost-effective therapeutic equivalent alternative(s) appropriate for the diagnosis must be provided; and
5. Approval quantity will be based on package labeling and FDA approved dosing regimen(s).

Utilization Details of Various Systemic Antibiotics: Fiscal Year 2025

Pharmacy Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TETRACYCLINE PRODUCTS						
TETRACYCLINE CAP 500MG	415	391	$18,572.26	$44.75	1.06	2.27%
TETRACYCLINE CAP 250MG	15	14	$591.08	$39.41	1.07	0.07%
SUBTOTAL	**430**	**405**	**$19,163.34**	**$44.57**	**1.06**	**2.35%**
LEVOFLOXACIN PRODUCTS						
LEVOFLOXACIN SOL 25MG/ML	185	133	$34,939.30	$188.86	1.39	4.28%
SUBTOTAL	**185**	**133**	**$34,939.30**	**$188.86**	**1.39**	**4.28%**
METRONIDAZOLE PRODUCTS						
METRONIDAZOLE CAP 375MG	113	97	$14,169.34	$125.39	1.16	1.73%
LIKMEZ SUS 500/5ML	44	41	$15,838.00	$359.95	1.07	1.94%
SUBTOTAL	**157**	**138**	**$30,007.34**	**$191.13**	**1.14**	**3.67%**
CEPHALEXIN PRODUCTS						
CEPHALEXIN TAB 500MG	104	103	$5,309.66	$51.05	1.01	0.65%
CEPHALEXIN TAB 250MG	9	9	$267.57	$29.73	1	0.03%
CEPHALEXIN CAP 750MG	6	6	$566.78	$94.46	1	0.07%
SUBTOTAL	**119**	**118**	**$6,144.01**	**$51.63**	**1.01**	**0.75%**
CIPROFLOXACIN PRODUCTS						
CIPRO 500MG/5ML SUS	53	42	$9,491.25	$179.08	1.26	1.16%
CIPRO 250MG/5ML SUS	53	48	$8,741.27	$164.93	1.1	1.07%
CIPROFLOXACIN 250MG/5ML SUS	1	1	$261.41	$261.41	1	0.03%
SUBTOTAL	**107**	**91**	**$18,493.93**	**$172.84**	**1.18**	**2.26%**
CEFIXIME PRODUCTS						
CEFIXIME CAP 400MG	40	35	$1,969.22	$49.23	1.14	0.24%
CEFIXIME SUS 200MG/5ML	8	6	$1,288.20	$161.03	1.33	0.16%
CEFIXIME SUS 100MG/5ML	4	4	$663.20	$165.80	1	0.08%
SUBTOTAL	**52**	**45**	**$3,920.62**	**$75.40**	**1.16**	**0.48%**
MINOCYCLINE PRODUCTS						
MINOCYCLINE TAB 100MG	28	20	$864.15	$30.86	1.4	0.11%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
MINOCYCLINE TAB 50MG	17	6	$492.01	$28.94	2.83	0.06%
MINOCYCLINE TAB 75MG	5	2	$113.25	$22.65	2.5	0.01%
MINOCYCLINE TAB 65MG ER	2	1	$277.68	$138.84	2	0.03%
MINOCYCLINE TAB 80MG ER	1	1	$101.86	$101.86	1	0.01%
MINOCYCLINE TAB 90MG ER	1	1	$117.66	$117.66	1	0.01%
SUBTOTAL	**54**	**31**	**$1,966.61**	**$36.42**	**1.74**	**0.24%**
DOXYCYCLINE PRODUCTS						
DOXYCYCLINE HYC TAB 50MG	21	16	$4,897.50	$233.21	1.31	0.60%
DOXYCYCLINE HYC TAB 100MG DR	9	9	$384.99	$42.78	1	0.05%
DOXYCYCLINE HYC TAB 150MG	6	2	$162.55	$27.09	3	0.02%
DOXYCYCLINE CAP 40MG	3	3	$1,573.82	$524.61	1	0.19%
DORYX MPC TAB 60MG	1	1	$1,142.03	$1,142.03	1	0.14%
DOXYCYCLINE HYC TAB 200MG DR	1	1	$359.40	$359.40	1	0.04%
DOXYCYCLINE HYC TAB 50MG DR	1	1	$82.76	$82.76	1	0.01%
SUBTOTAL	**42**	**33**	**$8,603.05**	**$204.83**	**1.27**	**1.05%**
TEDIZOLID PRODUCTS						
SIVEXTRO TAB 200MG	30	11	$359,986.06	$11,999.54	2.73	44.08%
SUBTOTAL	**30**	**11**	**$359,986.06**	**$11,999.54**	**2.73**	**44.08%**
OMADACYCLINE PRODUCTS						
NUZYRA TAB 150MG	18	11	$270,725.17	$15,040.29	1.64	33.1%
SUBTOTAL	**18**	**11**	**$270,725.17**	**$15,040.29**	**1.64**	**33.1%**
AMOXICILLIN/CLAVULANATE PRODUCTS						
AMOX/CLA TAB ER 1,000-62.5MG	14	13	$1,464.66	$104.62	1.08	0.18%
SUBTOTAL	**14**	**13**	**$1,464.66**	**$104.62**	**1.08**	**0.18%**
CEFTOLOZANE/TAZOBACTAM PRODUCTS						
ZERBAXA INJ 1.5GM	7	3	$24,590.55	$3,512.94	2.33	3.01%
SUBTOTAL	**7**	**3**	**$24,590.55**	**$3,512.94**	**2.33**	**3.01%**
SECNIDAZOLE PRODUCTS						
SOLOSEC GRA 2GM	5	5	$1,438.82	$287.76	1	0.18%
SUBTOTAL	**5**	**5**	**$1,438.82**	**$287.76**	**1**	**0.18%**
NITROFURANTOIN PRODUCTS						
NITROFURANTOIN SUS 50MG/5ML	3	3	$11,756.90	$3,918.97	1	1.44%
SUBTOTAL	**3**	**3**	**$11,756.90**	**$3,918.97**	**1**	**1.44%**
CEFTAZIDIME/AVIBACTAM PRODUCTS						
AVYCAZ INJ 2-0.5GM	2	2	$18,408.58	$9,204.29	1	2.25%
SUBTOTAL	**2**	**2**	**$18,408.58**	**$9,204.29**	**1**	**2.25%**
DALBAVANCIN PRODUCTS						
DALVANCE INJ 500MG	1	1	$4,748.11	$4,748.11	1	0.58%
SUBTOTAL	**1**	**1**	**$4,748.11**	**$4,748.11**	**1**	**0.58%**
OFLOXACIN PRODUCTS						
OFLOXACIN TAB 400MG	1	1	$355.73	$355.73	1	0.04%
SUBTOTAL	**1**	**1**	**$355.73**	**$355.73**	**1**	**0.04%**
TOTAL	**1,227**	**1,026***	**$816,712.78**	**$665.62**	**1.2**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AMOX CLA = amoxicillin/clavulanate; CAP = capsule; DR = delayed release; ER = extended-release; HYC = hyclate; INJ = injection; MONO = monohydrate; SOL = solution; SUS = suspension; TAB = tablet
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

Medical Claims (All Plans)

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DALBAVANCIN INJ (J0875)	44	38	$186,954.01	$4,405.16	1.16
ERAVACYCLINE INJ (J0122)	36	1	$6,534.00	$181.50	36
CEFTAZIDIME-AVIBACTAM INJ (J0714)	1	1	$0.00	$0.00	1
TOTAL	**81⁺**	**40***	**$193,488.01**	**$2,388.74**	**2.03**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
⁺Total number of unduplicated claims.
INJ = injection
Fiscal Year 2025 = 07/01/2024 to 06/30/2025

[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 07/2026. Last accessed 07/28/2026.
[2] U.S. FDA. FDA Approves New Treatment for Uncomplicated Urinary Tract Infections in Adult Women Who Have Limited or No Alternative Oral Antibiotic Treatment Options. Available online at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-new-treatment-uncomplicated-urinary-tract-infections-adult-women-who-have-limited-or-no. Issued 10/24/2024. Last accessed 07/28/2026.
[3] Contepo™ (Fosfomycin for Injection) Prescribing Information. Meitheal. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/212271s000lbl.pdf. Last revised 10/22/2025. Last accessed 07/28/2026.
[4] GSK. Blujepa (Gepotidacin) Approved by US FDA as Oral Option for Treatment of Uncomplicated Urogenital Gonorrhea (uGC). Available online at: https://us.gsk.com/en-us/media/press-releases/blujepa-gepotidacin-approved-by-us-fda-as-oral-option-for-treatment-of-uncomplicated-urogenital-gonorrhea-ugc/. Issued 12/11/2025. Last accessed 07/28/2026.
[5] Doxycycline Hyclate 75mg Capsule Prescribing Information. U.S. National Library of Medicine: DailyMed. Available online at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fad03768-f1d2-459f-965e-0ec29f189f1f. Last revised 06/30/2026. Last accessed 07/28/2026.
[6] Shiongi. FDA Accepts Shiongi's sNDA for Fetroja® (Cefiderocol) for Use in Pediatric Patients with Serious Infectious Caused by Susceptible Gram-negative Bacteria. Available online at: https://www.shionogi.com/us/en/news/2026/07/fda-accepts-shionogis-snda-for-fetroja-cefiderocol-for-use-in-pediatric-patients-with-serious-infections-caused-by-susceptible-gram-negative-bacteria.html. Issued 07/16/2026. Last accessed 07/28/2026.
[7] Orlynvah™ (Sulopenem Etzadroxil/Probenecid) Prescribing Information. Interim Therapeutics. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/213972s000lbl.pdf. Last revised 12/23/2025. Last accessed 07/28/2026.

Appendix K

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 17, 2026

FDA Approves First Oral PCSK9 Inhibitor to Lower LDL Cholesterol in Adults with High Cholesterol

The FDA approved Lipfendra® (enlicitide), the first oral inhibitor of proprotein convertase subtilisin/kexin type 9 (PCSK9), as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).

PCSK9 inhibitors have previously been available only as injectable therapies. Lipfendra® is administered as a once-daily oral tablet and provides an additional treatment option for adults who require further LDL-C reduction despite existing therapies. The approval also reflects continued advances in the development of therapies for chronic cardiovascular disease management.

Several classes of medications are available to lower LDL-C, including statins, ezetimibe, and injectable PCSK9 inhibitors. Lipfendra® is the first oral therapy to inhibit PCSK9.

The efficacy and safety of Lipfendra® were evaluated in 2 randomized, double-blind, placebo-controlled clinical trials involving 3,207 adults with hypercholesterolemia, including patients with and without HeFH, who were receiving maximally tolerated statin therapy. The primary endpoint in both studies was the percent change in LDL-C from baseline to week 24 compared with placebo.

In the first trial, which enrolled adults with established atherosclerotic cardiovascular disease (ASCVD) or those at high risk for ASCVD, participants had a mean baseline LDL-C of 96mg/dL. Treatment with Lipfendra® resulted in an average 56% reduction in LDL-C at week 24 compared with placebo.

In the second trial, which enrolled adults with HeFH, participants had a mean baseline LDL-C of 119mg/dL. Treatment with Lipfendra® resulted in an average 59% reduction in LDL-C at week 24 compared with placebo.

In the first trial, the frequency of adverse reactions was similar between patients treated with Lipfendra® and those receiving placebo. In the second trial, the most common adverse reactions occurring more frequently with Lipfendra® than placebo were diarrhea and dizziness. Across both trials, discontinuation rates due to adverse reactions were comparable between the Lipfendra®-treated and placebo-recipient groups.

Lipfendra® received Priority Review for this indication. The application was also reviewed under the Commissioner's National Priority Voucher (CNPV) pilot program, which is intended to help accelerate the review of therapies that address national public health priorities. The approval was granted to Merck Sharp & Dohme LLC.

FDA NEWS RELEASE

For Immediate Release: July 1, 2026

FDA Approves First Gene Therapy for Young Children with Sickle Cell Disease

The FDA issued a supplemental approval for Casgevy® (exagamglogene autotemcel) for patients 2 years of age and older with either sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) or transfusion-dependent β thalassemia (TDT). This is the first gene therapy approved for patients 2 years of age and older with SCD. Casgevy® has been previously approved for the treatment of patients 12 years of age and older with SCD with recurrent VOCs or TDT.

SCD affects red blood cells (RBCs), which contain hemoglobin, a protein that transports oxygen throughout the body. SCD can cause various symptoms and health issues, including episodes of severe pain called sickle cell crises or VOCs.

Thalassemia is a genetic blood disorder that causes the body to have an abnormally low level of hemoglobin, resulting in reduced oxygen delivery to the body's tissues. In some cases, individuals require regular blood transfusions to maintain adequate levels of functional hemoglobin.

Casgevy® is a gene therapy consisting of the patient's own hematopoietic stem cells, administered as a one-time dose for intravenous infusion. The cells are edited using CRISPR/Cas9, a type of genome editing technology, and then engrafted in the body's bone marrow. CRISPR/Cas9 can be directed to a specific spot in DNA, where it cuts the genetic material so that DNA can be accurately removed, added, or replaced. In patients with severe SCD, this treatment increases a type of hemoglobin which is called fetal hemoglobin (HbF). This helps prevent RBCs from forming into abnormal sickle shapes and addresses the underlying cause of disease, thereby eliminating VOCs. In patients with TDT, treatment increases HbF levels and total hemoglobin levels, hence eliminating dependence on regular RBC transfusions.

Full myeloablative conditioning, a high-intensity preparatory treatment given to patients before they receive a stem cell transplant or gene therapy, is administered prior to treatment with Casgevy®.

The safety and effectiveness of Casgevy® in patients 5 years to younger than 12 years of age with SCD were evaluated in a clinical trial which included 11 patients. All 8 patients who were evaluable for efficacy achieved the primary efficacy outcome of VF12 (no protocol-defined severe VOCs for at

least 12 consecutive months within the first 24 months after infusion with Casgevy®).

The efficacy and safety of Casgevy® in patients 5 years to younger than 12 years of age with TDT were evaluated in a trial of 15 patients. Eight of the 9 efficacy evaluable patients with TDT achieved transfusion independence for 12 consecutive months, with a median duration of transfusion independence of 20.1 months.

Based on product characteristics and clinical study data, extrapolation to the younger pediatric age population was granted to expand the indication to 2 years of age and above for both conditions.

The most common adverse reactions were mucositis and febrile neutropenia in patients with SCD and in patients with TDT, and decreased appetite in patients with SCD. Additionally, the *Prescribing Information* contains warnings for neutrophil engraftment failure, delayed platelet engraftment, hypersensitivity reactions, and off-target genome editing risk (refers to the possibility that the CRISPR/Cas9 editing process may make unintended edits to parts of the genome other than the intended target site).

The approval decision was granted just 53 days after filing and represented the eighth approval selected for the Commissioner's National Priority Voucher (CNPV) pilot program. The FDA granted Casgevy® Orphan Drug, Regenerative Medicine Advanced Therapy (RMAT), and Fast Track designations. The FDA granted the approval to Vertex Pharmaceuticals, Incorporated.

FDA NEWS RELEASE

For Immediate Release: June 30, 2026

FDA Approves New Treatment That Uses Donor Immune Cells to Prevent Serious Complications in Blood Cancer Patients

The FDA approved Tregzi™, the first regulatory T (Treg) cell-based immunotherapy for improving chronic graft-versus-host disease (GVHD)-free survival in adult patients with blood cancers undergoing allogeneic hematopoietic stem cell transplantation (allo-HSCT). It represents a novel approach to allo-HSCT in some adult patients with high-risk blood cancers. It addresses an important unmet need in transplantation, where curing the cancer is often only part of the challenge; avoiding chronic GVHD is equally important for long-term outcomes.

Tregzi™ uses stem cells and immune cells collected from blood of a closely matched donor to help the body fight cancer while reducing the risk of a serious complication called chronic GVHD - a condition that can occur when transplanted donor blood cells attack the patient's body. Patients receive this treatment after undergoing chemotherapy to prepare their bodies for a bone marrow or stem cell transplant.

Tregzi™ is a donor-derived cellular immunotherapy composed of 3 cell components: purified hematopoietic stem and progenitor cells (HSPCs), Treg

cells, and conventional T (Tcon) cells, each derived from the mobilized peripheral blood of an 8/8 HLA-matched related or unrelated donor. Treg cells are a type of immune cell that help regulate immune responses and maintain immune tolerance. Tregzi™ is designed to reduce the risk of chronic GVHD during reconstitution of the patient's blood-forming and immune systems.

The safety and effectiveness of Tregzi™ were established through PRECISION-T, a clinical trial in which 187 adult patients with blood cancers, including acute leukemia and myelodysplastic syndrome, were randomly assigned to receive either Tregzi™ or a standard stem cell transplant. The primary endpoint was chronic GVHD-free survival, defined as the time from HSCT to the earliest occurrence of either death from any cause or the first onset of moderate or severe chronic GVHD within 2 years after day 0. Patients who received Tregzi™ achieved significantly higher rates of chronic GVHD-free survival. At 1 year, 78% of patients who received Tregzi™ achieved this outcome, compared to 38.4% of patients who received a standard transplant. After accounting for death as a competing risk, 12.6% of patients who received Tregzi™ developed serious chronic GVHD within 1 year, compared with 44% of patients who received a standard transplant. The highly persuasive and internally consistent results from this randomized controlled trial denote clinical benefit in the indicated population. The FDA reviewed the results of this trial and determined that the benefits of Tregzi™ outweigh its risks.

The side effects observed with Tregzi™ were generally consistent with those expected in patients undergoing stem cell transplantation - most commonly, infections. No patient had a severe reaction during the infusion of Tregzi™, and no cases of graft failure were observed within the study period. Patients and health care professionals should review the full *Prescribing Information* for complete safety information.

The application was granted Orphan Drug and RMAT designations. The FDA granted approval of Tregzi™ to Orca Biosystems, Inc.

Current Drug Shortages Index (as of July 29, 2026):

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

Albuterol Sulfate Solution	***Currently in Shortage***
Amino Acid Injection	***Currently in Shortage***
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet	***Currently in Shortage***
Atropine Sulfate Injection	***Currently in Shortage***
Azacitidine Injection	***Currently in Shortage***

Bacitracin Ophthalmic Ointment	***Currently in Shortage***
Bumetanide Injection	***Currently in Shortage***
Bupivacaine Hydrochloride Injection	***Currently in Shortage***
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	***Currently in Shortage***
Carboplatin Injection	***Currently in Shortage***
Cefotaxime Sodium Powder, for Solution	***Currently in Shortage***
Clindamycin Phosphate Injection	***Currently in Shortage***
Clonazepam Tablet	***Currently in Shortage***
Conivaptan Hydrochloride Injection	***Currently in Shortage***
Cromolyn Sodium Concentrate	***Currently in Shortage***
Desmopressin Acetate Spray	***Currently in Shortage***
Dexamethasone Sodium Phosphate Injection	***Currently in Shortage***
Dexmedetomidine Hydrochloride Injection	***Currently in Shortage***
Dextrose Monohydrate 10% Injection	***Currently in Shortage***
Dextrose Monohydrate 5% Injection	***Currently in Shortage***
Dextrose Monohydrate 50% Injection	***Currently in Shortage***
Dextrose Monohydrate 70% Injection	***Currently in Shortage***
Dobutamine Hydrochloride Injection	***Currently in Shortage***
Dopamine Hydrochloride Injection	***Currently in Shortage***
Echothiophate Iodide Ophthalmic Solution	***Currently in Shortage***
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	***Currently in Shortage***
Etomidate Injection	***Currently in Shortage***
Fentanyl Citrate Injection	***Currently in Shortage***
Flurazepam Hydrochloride Capsule	***Currently in Shortage***
Furosemide Injection	***Currently in Shortage***
Furosemide Oral Solution	***Currently in Shortage***
Heparin Sodium Injection	***Currently in Shortage***
Hydromorphone Hydrochloride Injection	***Currently in Shortage***
Hydroxocobalamin Injection	***Currently in Shortage***
Ifosfamide Injection	***Currently in Shortage***
Isocarboxazid Tablet	***Currently in Shortage***
Ketorolac Tromethamine Injection	***Currently in Shortage***
Lidocaine Hydrochloride Injection	***Currently in Shortage***
Liraglutide Injection	***Currently in Shortage***
Lisdexamfetamine Dimesylate Capsule	***Currently in Shortage***
Lisdexamfetamine Dimesylate Tablet, Chewable	***Currently in Shortage***
Lorazepam Injection	***Currently in Shortage***
Meperidine Hydrochloride Injection	***Currently in Shortage***
Methotrexate Sodium Injection	***Currently in Shortage***

Methylphenidate Film, Extended Release	***Currently in Shortage***
Methylphenidate Hydrochloride Tablet, Extended Release	***Currently in Shortage***
Methylprednisolone Acetate Injection	***Currently in Shortage***
Metronidazole Injection	***Currently in Shortage***
Midazolam Hydrochloride Injection	***Currently in Shortage***
Morphine Sulfate Injection	***Currently in Shortage***
Peginterferon alfa-2a Injection	***Currently in Shortage***
Penicillin G Benzathine Injection	***Currently in Shortage***
Promethazine Hydrochloride Injection	***Currently in Shortage***
Propranolol Hydrochloride Injection	***Currently in Shortage***
Quinapril Hydrochloride Tablet	***Currently in Shortage***
Quinapril/Hydrochlorothiazide Tablet	***Currently in Shortage***
Remifentanil Hydrochloride Injection	***Currently in Shortage***
Rifampin Capsule	***Currently in Shortage***
Rifampin Injection	***Currently in Shortage***
Rifapentine Tablet, Film Coated	***Currently in Shortage***
Riluzole Oral Suspension	***Currently in Shortage***
Rocuronium Bromide Injection	***Currently in Shortage***
Ropivacaine Hydrochloride Injection	***Currently in Shortage***
Sodium Acetate Injection	***Currently in Shortage***
Sodium Bicarbonate Injection	***Currently in Shortage***
Sterile Water Injection	***Currently in Shortage***
Sterile Water Irrigant	***Currently in Shortage***
Streptozocin Powder, For Solution	***Currently in Shortage***
Sufentanil Citrate Injection	***Currently in Shortage***
Technetium TC-99M Pyrophosphate Kit Injection	***Currently in Shortage***
Triamcinolone Acetonide Injection	***Currently in Shortage***
Triamcinolone Hexacetonide Injection	***Currently in Shortage***
Valproate Sodium Injection	***Currently in Shortage***