# State Fiscal Year 2023 Print Annual Reviews
# Quarter 1

| Count | Category/Medication |
|---|---|
| **1.** | Amyloidosis Medications |
| **2.** | Botulinum Toxins |
| **3.** | Cholbam® (Cholic Acid) |
| **4.** | Chorionic Gonadotropin Medications |
| **5.** | Defitelio® (Defibrotide) |
| **6.** | Dojolvi® (Triheptanoin) |
| **7.** | Gamifant® (Emapalumab-lzsg) |
| **8.** | Hyperkalemia Medications |
| **9.** | Jynarque® (Tolvaptan) |
| **10.** | Keveyis® (Dichlorphenamide) |
| **11.** | Korlym® (Mifepristone) |
| **12.** | Lambert-Eaton Myasthenic Syndrome (LEMS) Medications |
| **13.** | Lidocaine Topical Products |
| **14.** | Nulibry® (Fosdenopterin) |
| **15.** | Ocaliva® (Obeticholic acid) |
| **16.** | Ophthalmic Anti-Inflammatory Products |
| **17.** | Ophthalmic Antibiotic Medications |
| **18.** | Parathyroid Medications |
| **19.** | Revcovi® (Elapegademase-lvlr) |
| **20.** | Thrombocytopenia Medications |

**Fiscal Year 2023** = July 1, 2022 – June 30, 2023

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 print annual review packet to ensure fair and knowledgeable deliberation of the potential impact of the recommendations on this patient population.

# Fiscal Year 2023 Annual Review of Amyloidosis Medications

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Amvuttra® (Vutrisiran) and Onpattro® (Patisiran) Approval Criteria:**

1. An FDA approved indication for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; or
   b. Genetic confirmation of transthyretin (*TTR*) gene mutation (e.g., Val30Met); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must confirm the member does not have severe renal impairment, end-stage renal disease, and/or moderate or severe hepatic impairment; and
7. Prescriber must confirm the member has not undergone a liver transplant; and
8. For Onpattro®, prescriber must confirm the member will be pre-medicated with intravenous (IV) corticosteroid, oral acetaminophen, IV histamine-1 (H1) antagonist, and IV histamine-2 (H2) antagonist 60 minutes prior to administration to reduce the risk of infusion-related reaction(s); and
9. Amvuttra® will not be approved for concomitant use with Onpattro® (patisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
10. Authorization for Amvuttra® will also require a patient-specific, clinically significant reason why the member cannot use Onpattro®; and
11. Onpattro® will not be approved for concomitant use with Amvuttra® (vutrisiran), Tegsedi® (inotersen), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and

12. For Onpattro®, member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
13. For Amvuttra®, a quantity limit of 0.5mL per 90 days will apply; and
14. Approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding well to treatment and member has not undergone a liver transplant.

**Tegsedi® (Inotersen) Approval Criteria:**

1. An FDA approved indication for the treatment of polyneuropathy associated with hereditary transthyretin-mediated (hATTR) amyloidosis; and
2. Diagnosis confirmed by the following:
   a. Tissue (fat pad) biopsy confirming amyloid deposits; or
   b. Genetic confirmation of transthyretin (*TTR*) gene mutation (e.g., Val30Met); and
3. Prescriber must verify member is currently experiencing signs and symptoms of polyneuropathy and other causes of polyneuropathy have been ruled out; and
4. Tegsedi® must be prescribed by or in consultation with a cardiologist, geneticist, or neurologist (or an advanced care practitioner with a supervising physician who is a cardiologist, geneticist, or neurologist); and
5. Prescriber must confirm the member will take the recommended daily allowance of vitamin A; and
6. Prescriber must agree to monitor ALT, AST, and total bilirubin prior to initiation of Tegsedi® and every 4 months during treatment; and
7. Prescriber must confirm the first injection of Tegsedi® administered by the member or caregiver will be performed under the guidance of a health care professional; and
8. Prescriber must confirm the member or caregiver has been trained by a health care professional on the subcutaneous (sub-Q) administration and proper storage of Tegsedi®; and
9. Prescriber must confirm the member has not undergone a liver transplant; and
10. Tegsedi® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), or Vyndaqel® (tafamidis meglumine); and
11. Prescriber, pharmacy, and member must be enrolled in the Tegsedi® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
12. Tegsedi® approvals will be for the duration of 1 year. Reauthorization may be granted if the prescriber documents the member is responding

well to treatment and member has not undergone a liver transplant; and
13. A quantity limit of 4 syringes per 28 days will apply.

**Vyndamax® (Tafamidis) and Vyndaqel® (Tafamidis Meglumine) Approval Criteria:**

1. An FDA approved indication for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization; and
2. Diagnosis confirmed by:
   a. Genetic confirmation of transthyretin (*TTR*) mutation (e.g., Val122Ile) or wild-type amyloidosis; and
   b. Cardiac imaging (e.g., ultrasound, MRI) confirming cardiac involvement; and
3. Presence of amyloid deposits confirmed by:
   a. Nuclear scintigraphy; or
   b. Endomyocardial biopsy; and
4. Member must have medical history of heart failure (NYHA Class I to III); and
5. Prescriber must confirm light-chain amyloidosis (AL) has been ruled out; and
6. Prescriber must confirm the member has not undergone a liver transplant; and
7. Vyndamax® or Vyndaqel® must be prescribed by or in consultation with a cardiologist or geneticist (or an advanced care practitioner with a supervising physician who is a cardiologist or geneticist); and
8. Vyndamax® or Vyndaqel® will not be approved for concomitant use with Amvuttra® (vutrisiran), Onpattro® (patisiran), or Tegsedi® (inotersen); and
9. Initial approvals will be for the duration of 6 months. Reauthorization may be granted if prescriber documents member is responding well to treatment and member has not undergone a liver transplant; and
10. A quantity limit of 1 Vyndamax® capsule or 4 Vyndaqel® capsules per day will apply.

## Utilization of Amyloidosis Medications: Fiscal Year 2023

**Fiscal Year 2023 Utilization: Pharmacy Claims**

| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2023** | 1 | 2 | $41,757.42 | $20,878.71 | $695.96 | 240 | 60 |

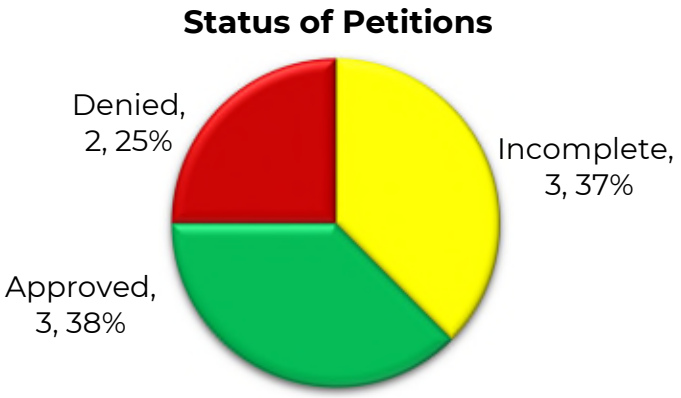
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: There were no paid claims for amyloidosis medications during fiscal year 2022 to allow for a cost comparison.

### Demographics of Members Utilizing Amyloidosis Medications

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

## Prior Authorization of Amyloidosis Medications

There were 8 prior authorization requests submitted for amyloidosis medications during fiscal year 2023. The following chart shows the status of the submitted petitions for calendar year 2023.




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

**Anticipated Patent Expiration(s):**

- Vyndaqel® (tafamidis meglumine): May 2024
- Tegsedi® (inotersen): April 2031
- Onpattro® (patisiran): August 2035
- Vyndamax® (tafamidis): August 2035
- Amvuttra® (vutrisiran): July 2036

**Pipeline:**

- **Acoramidis (AG10):** BridgeBio Pharma announced results from the Phase 3 ATTRibute-CM clinical trial of acoramidis, a small molecule stabilizer of transthyretin (TTR) administered orally twice daily for the treatment of cardiomyopathy of TTR-related amyloidosis (ATTR-CM). The study demonstrated a statistically significant reduction in the frequency of cardiovascular-related hospitalization, reduction in all-cause mortality, improvements in N-terminal pro-B type natriuretic peptide (NT-proBNP) levels, and improvement in distance walked on the 6-minute walk test (6MWT). BridgeBio plans to submit a New Drug Application (NDA) for acoramidis to the U.S. Food and Drug Administration (FDA) by the end of 2023.
- **Eplontersen (ION-682884)**: Ionis Pharmaceuticals announced results from the Phase 3 NEURO-TTRansform clinical trial of eplontersen, a

ligand-conjugated antisense (LICA) medication administered by subcutaneous (sub-Q) injection once every 4 weeks to treat hereditary TTR-mediated amyloid polyneuropathy (hATTR-PN) by inhibiting TTR production. In the study, eplontersen demonstrated a statistically significant reduction in TTR production, a reduction in neuropathy impairment, and a beneficial change in the modified Neuropathy Impairment Score +7 (mNIS+7) and the Norfolk Quality of Life Questionnaire-Diabetic Neuropathy (Norfolk QoL-DN). Ionis and AstraZeneca have submitted an NDA to the FDA for eplontersen for the treatment of ATTR-PN and the Prescription Drug User Fee Act (PDUFA) action date is December 22, 2023. Eplontersen has also been granted Orphan Drug designation by the FDA.

## Recommendations

The College of Pharmacy does not recommend any changes to the current amyloidosis medications prior authorization criteria at this time.

## Utilization Details of Amyloidosis Medications: Fiscal Year 2023

### Pharmacy Claims

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| VYNDAQEL CAP 20MG | 2 | 1 | $41,757.42 | $20,878.71 | 2 | 100% |
| **TOTAL** | **2** | **1*** | **$41,757.42** | **$20,878.71** | **2** | **100%** |

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

[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 08/2023. Last accessed 08/23/2023.
[2] BridgeBio Pharma, Inc. BridgeBio Announces Consistently Positive Results from Phase 3 ATTRibute-CM Study of Acoramidis for Patients with Transthyretin Amyloid Cardiomyopathy (ATTR-CM). Available online at: https://investor.bridgebio.com/news-releases/news-release-details/bridgebio-announces-consistently-positive-results-phase-3. Issued 07/17/2023. Last accessed 08/16/2023.
[3] Ionis Pharmaceuticals, Inc. Ionis Presents Positive Results from Phase 3 NEURO-TTRansform Study at International Symposium on Amyloidosis. *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/ionis-presents-positive-results-from-phase-3-neuro-ttransform-study-at-international-symposium-on-amyloidosis-301618729.html. Issued 09/07/2022. Last accessed 08/23/2023.
[4] Ionis Pharmaceuticals, Inc. Eplontersen Continued to Show Improvement in ATTRv-PN Through 85 Weeks. Available online at: https://ir.ionispharma.com/news-releases/news-release-details/eplontersen-continued-show-improvement-attrv-pn-through-85-weeks. Issued 07/10/2023. Last accessed 09/11/2023.

# Fiscal Year 2023 Annual Review of Botulinum Toxins

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Review**

## Current Prior Authorization Criteria

**Botulinum Toxins Approval Criteria:**

1. For approval of Xeomin® or Myobloc®, a patient-specific, clinically significant reason the member cannot use Botox® or Dysport® must be provided; and
2. Cosmetic indications will not be covered; and
3. A diagnosis of chronic migraine (tension headaches are not a covered diagnosis), neurogenic detrusor overactivity, and non-neurogenic overactive bladder will require manual review (see specific criteria below); and
4. The following indications have been determined to be appropriate and are covered:
    a. Spasticity associated with:
        i. Cerebral palsy; or
        ii. Paralysis; or
        iii. Generalized weakness/incomplete paralysis; or
        iv. Larynx; or
        v. Anal fissure; or
        vi. Esophagus (achalasia and cardiospasms); or
        vii. Eye and eye movement disorders; or
    b. Cervical dystonia.

**Botox® (OnabotulinumtoxinA) Approval Criteria [Chronic Migraine Diagnosis*]:**

1. FDA indications are met:
    a. Member is 18 years of age or older; and
    b. Member has documented chronic migraine headaches:
        i. Frequency of ≥15 headache days per month with ≥8 migraine days per month and occurring for >3 months; and
        ii. Headache duration of ≥4 hours per day; and
2. Non-migraine medical conditions known to cause headache have been ruled out and/or have been treated. This includes, but is not limited to:
    a. Increased intracranial pressure (e.g., tumor, pseudotumor cerebri, central venous thrombosis); and
    b. Decreased intracranial pressure (e.g., post-lumbar puncture headache, dural tear after trauma); and

3. Migraine headache exacerbation secondary to other medical conditions or medication therapies have been ruled out and/or treated. This includes, but is not limited to:
    a. Hormone replacement therapy or hormone-based contraceptives; and
    b. Chronic insomnia; and
    c. Obstructive sleep apnea; and
4. Member has no contraindications to Botox® injections; and
5. The member has failed medical migraine preventative therapy, including ≥2 agents with different mechanisms of action. Trials must be at least 8 weeks in duration (or documented adverse effects) within the last 365 days. This includes, but is not limited to:
    a. Select antihypertensive therapy (e.g., beta blockers); or
    b. Select anticonvulsant therapy; or
    c. Select antidepressant therapy [e.g., tricyclic antidepressants (TCA), serotonin and norepinephrine reuptake inhibitors (SNRI)]; and
6. Member is not frequently taking medications which are known to cause medication overuse headaches (MOH or rebound headaches) in the absence of intractable conditions known to cause chronic pain. MOH are a frequent cause of chronic headaches. A list of prescription or non-prescription medications known to cause MOH includes, but is not limited to:
    a. Decongestants (alone or in combination products) (≥10 days/month for >3 months); and
    b. Combination analgesics containing caffeine and/or butalbital (≥10 days/month for >3 months); and
    c. Opioids (≥10 days/month for >3 months); and
    d. Analgesic medications including acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) (≥15 days/month for >3 months); and
    e. Ergotamine-containing medications (≥10 days/month for >3 months); and
    f. Triptans (≥10 days/month for >3 months); and
7. Member is not taking any medications that are likely to be the cause of the headaches; and
8. Member must have been evaluated within the last 6 months by a neurologist for chronic migraine headaches and Botox® recommended as treatment (not necessarily prescribed or administered by a neurologist); and
9. Prescriber must verify that other aggravating factors that are contributing to the development of chronic migraine headaches are being treated when applicable (e.g., smoking); and

10. Member will not use the requested medication concurrently with a calcitonin gene-related peptide (CGRP) inhibitor for the prevention of migraine headaches.

**Botox® (OnabotulinumtoxinA) Approval Criteria [Neurogenic Detrusor Overactivity (NDO) Diagnosis*]:**

1. Diagnosis of 1 of the following:
    a. Urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury, multiple sclerosis] in adult members; or
    b. NDO in pediatric members; and
2. Underlying pathological dysfunction subtype confirmed by:
    a. Urodynamic studies to determine pathology and serve to provide objective evidence of bladder and external sphincter function; and
    b. A diary of fluid intake, incontinence, voiding, and catheterization times and amounts to provide a record of actual occurrences; and
3. Member must have a clinically significant reason why anticholinergic medications are no longer an option for the member; and
4. Member must be 5 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
5. Botox® must be administered by a urologist.

**Botox® (OnabotulinumtoxinA) Approval Criteria [Non-Neurogenic Overactive Bladder Diagnosis*]:**

1. Member must have severe disease (≥5 urinary incontinence episodes per day on medication) and specific pathology determined via urodynamic studies; and
2. Member must have participated in behavioral therapy for ≥12 weeks that did not yield adequate clinical results; and
3. Member must have had compliant use of ≥3 anti-muscarinic or beta-3 adrenoceptor agonist medications for ≥12 weeks each, alone or in combination with behavioral therapy, that did not yield adequate clinical results. One of those trials must have been an extended-release formulation; and
4. Member must be 18 years of age or older and have adequate hand function and sufficient cognitive ability to know when the bladder needs emptying and to self-catheterize, or have a caregiver able to catheterize the member when necessary; and
5. Botox® must be administered by a urologist.

***Other botulinum toxins will not be approved for this diagnosis**

## Utilization of Botulinum Toxins: Fiscal Year 2023

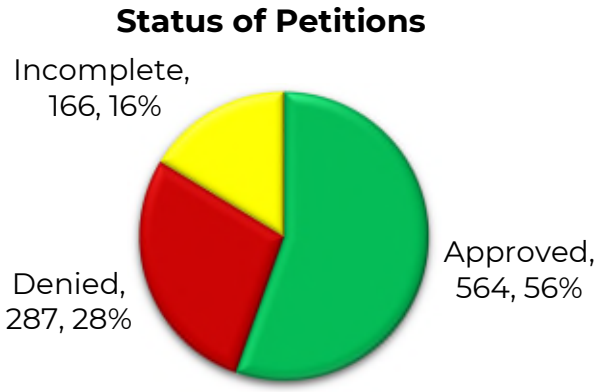
### Comparison of Fiscal Years: Medical Claims

| Fiscal Year | Total Members* | Total Claims† | Total Cost | Cost/ Claim | Total Units |
|---|---|---|---|---|---|
| **2022** | 380 | 721 | $1,015,220.00 | $1,408.07 | 164,808 |
| **2023** | 399 | 747 | $1,060,455.21 | $1,419.62 | 168,733 |
| **% Change** | **5.00%** | **3.61%** | **4.46%** | **0.82%** | **2.38%** |
| **Change** | **19** | **26** | **$45,235.21** | **$11.55** | **3,925** |

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

## Prior Authorization of Botulinum Toxins

There were 1,017 prior authorization requests submitted for botulinum toxins during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.




## Market News and Updates[1]

**Pipeline:**

- **Daxxify® (DaxibotulinumtoxinA-lanm):** In January 2023, the U.S. Food and Drug Administration (FDA) accepted a supplemental Biologics License Application (sBLA) for Daxxify® (daxibotulinumtoxinA-lanm) for the treatment of cervical dystonia in adults. Daxxify® is a peptide formulated neuromodulator that was first FDA approved for cosmetic use for the temporary improvement of moderate to severe glabellar lines in adults. Two Phase 3 clinical studies evaluated the use of Daxxify® for cervical dystonia and found it to be effective and well tolerated across treatment groups.

## Recommendations

The College of Pharmacy does not recommend any changes to the current botulinum toxins prior authorization criteria at this time.

## Utilization Details of Botulinum Toxins: Fiscal Year 2023

**Medical Claims**

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER |
|---|---|---|---|---|---|
| BOTOX (J0585) | 729 | 392 | $1,041,577.00 | $1,428.78 | 1.86 |
| DYSPORT (J0586) | 18 | 8 | $18,878.12 | $1,048.78 | 2.25 |
| **TOTAL** | **747⁺** | **399*** | **$1,060,455.21** | **$1,419.62** | **1.87** |

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

[1] Revance Therapeutics, Inc. Revance Announces U.S. FDA Acceptance of Supplemental Biologics License Application (sBLA) for Daxxify® (DaxibotulinumtoxinA-lanm) for Injection for the Treatment of Cervical Dystonia. Available online: https://investors.revance.com/investors/Press-Releases/news-details/2023/Revance-Announces-U.S.-FDA-Acceptance-of-Supplemental-Biologics-License-Application-sBLA-for-DAXXIFY-DaxibotulinumtoxinA-lanm-for-Injection-for-the-Treatment-of-Cervical-Dystonia-01-06-2023/default.aspx. Issued 01/06/2023. Last accessed 9/5/2023.

# Fiscal Year 2023 Annual Review of Cholbam® (Cholic Acid)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

### Cholbam® (Cholic Acid) Approval Criteria:

1. An FDA approved indication of 1 of the following:
   a. Treatment of bile acid disorders due to single enzyme defects (SEDs); or
   b. Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption; and
2. Treatment with Cholbam® should be initiated and monitored by a hepatologist or pediatric gastroenterologist; and
3. The prescriber must verify that AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR will be monitored every month for the first 3 months, every 3 months for the next 9 months, every 6 months during the next 3 years, and annually thereafter; and
4. Cholbam® should be discontinued if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; and
5. Initial approvals will be for the duration of 3 months to monitor for compliance and liver function tests; and
6. Continuation approvals will be granted for the duration of 1 year; and
7. A quantity limit of 120 capsules per 30 days will apply. Quantity limit requests will be based on the member's recent weight taken within the last 30 days.

## Utilization of Cholbam® (Cholic Acid): Fiscal Year 2023

**Comparison of Fiscal Years: Pharmacy Claims**

| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 1 | 4 | $33,145.64 | $8,286.41 | $276.21 | 120 | 120 |
| **2023** | 1 | 2 | $16,572.82 | $8,286.41 | $276.21 | 60 | 60 |
| **% Change** | **0.0%** | **-50.0%** | **-50.0%** | **0.0%** | **0.0%** | **-50.0%** | **-50.0%** |
| **Change** | **0** | **-2** | **-$16,572.82.41** | **$0.00** | **$0.00** | **-60** | **-60** |

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

### Demographics of Members Utilizing Cholbam® (Cholic Acid)

- Due to the limited number of members utilizing Cholbam® (cholic acid) during fiscal year 2023, detailed demographic information could not be provided.

### Top Prescriber Specialties of Cholbam® (Cholic Acid) by Number of Claims

- The only prescriber specialty listed on paid claims for Cholbam® (cholic acid) during fiscal year 2023 was pediatric gastroenterology.

## Prior Authorization of Cholbam® (Cholic Acid)

There were no prior authorization requests submitted for Cholbam® (cholic acid) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Recommendations

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

## Utilization Details of Cholbam® (Cholic Acid): Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| CHOLBAM CAP 50MG | 2 | 1 | $16,572.82 | $8,286.41 | 2 | 100% |
| **TOTAL** | **2** | **1*** | **$16,572.82** | **$8,286.41** | **2** | **100%** |

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

# Fiscal Year 2023 Annual Review of Chorionic Gonadotropin Medications

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Novarel® and Pregnyl® (Chorionic Gonadotropin) Approval Criteria:**

1. An FDA approved diagnosis of prepubertal cryptorchidism not due to anatomic obstruction or hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency); and
2. Requests for any of the following diagnoses will not be approved:
   a. Ovulation induction; or
   b. Spermatogenesis induction; or
   c. Weight loss; and
3. Member must be male; and
4. For the diagnosis of prepubertal cryptorchidism, member must be 4 to 10 years of age; or
5. For the diagnosis of hypogonadotropic hypogonadism, member must be of peripubertal age; and
   a. A patient-specific, clinically significant reason why testosterone therapy is not appropriate must be provided.

## Utilization of Chorionic Gonadotropin Medications: Fiscal Year 2023

### Fiscal Year 2023 Utilization: Pharmacy Claims

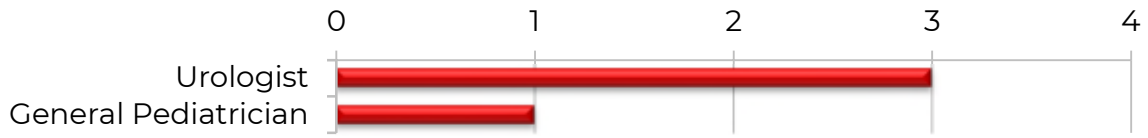
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 1 | 5 | $1,618.30 | $323.66 | $14.07 | 5 | 115 |
| **2023** | 2 | 4 | $1,080.95 | $270.24 | $12.01 | 4 | 90 |
| **% Change** | **100.0%** | **-20.0%** | **-33.2%** | **-16.5%** | **-14.6%** | **-20.0%** | **-21.7%** |
| **Change** | **1** | **-1** | **-$537.35** | **-$53.42** | **-$2.06** | **-1** | **-25** |

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

## Demographics of Members Utilizing Chorionic Gonadotropin Medications

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

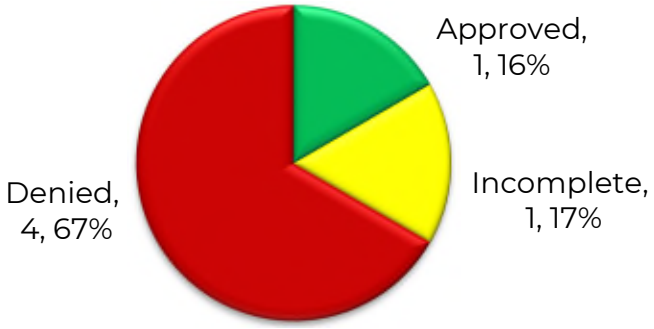
**Top Prescriber Specialties of Chorionic Gonadotropin Medications by Number of Claims**




## Prior Authorization of Chorionic Gonadotropin Medications

There were 6 prior authorization requests submitted for 3 unique members for chorionic gonadotropin medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

**Status of Petitions**




## Recommendations

The College of Pharmacy does not recommend any changes to the current chorionic gonadotropin medications prior authorization criteria at this time.

## Utilization Details of Chorionic Gonadotropin Medications: Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| CHOR GONADOTROPIN INJ 10,000 UNITS | 3 | 1 | $962.98 | $320.99 | 3 | 89.09% |
| PREGNYL INJ 10,000 UNITS | 1 | 1 | $117.97 | $117.97 | 1 | 10.91% |
| **TOTAL** | **4** | **2*** | **$1,080.95** | **$270.24** | **2** | **100%** |

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

# Fiscal Year 2023 Annual Review of Defitelio® (Defibrotide)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Defitelio® (Defibrotide) Approval Criteria:**

1. An FDA approved diagnosis of hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem cell transplantation (HSCT); and
2. Initial approvals will be for 1 month of therapy. An additional month of therapy (maximum total duration of 60 days of therapy) may be granted if the physician documents the continued need for therapy.

## Utilization of Defitelio® (Defibrotide): Fiscal Year 2023

There was no SoonerCare utilization of Defitelio® (defibrotide) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Prior Authorization of Defitelio® (Defibrotide)

There were no prior authorization requests submitted for Defitelio® (defibrotide) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Market News and Updates[1]

**Anticipated Patent Expiration(s):**

- Defitelio® (defibrotide): June 2032

## Recommendations

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

[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 09/2023. Last accessed 09/15/2023.

# Fiscal Year 2023 Annual Review of Dojolvi® (Triheptanoin)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Dojolvi® (Triheptanoin) Approval Criteria:**

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

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

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

## Utilization of Dojolvi® (Triheptanoin): Fiscal Year 2023

### Comparison of Fiscal Years

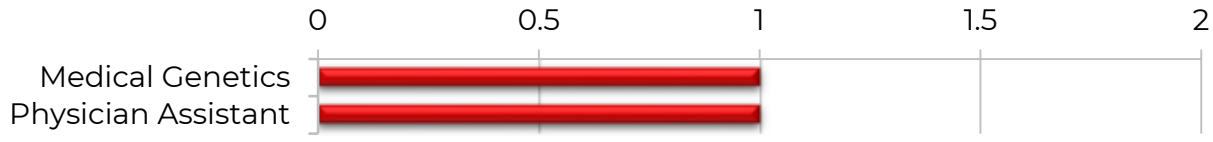
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 2 | 4 | $63,165.71 | $15,791.43 | $535.30 | 6,108 | 118 |
| **2023** | 2 | 2 | $37,276.82 | $18,638.41 | $653.98 | 3,500 | 57 |
| **% Change** | **0.00%** | **-50.00%** | **-41.00%** | **18.00%** | **22.20%** | **-42.70%** | **-51.70%** |
| **Change** | **0** | **-2** | **-$25,888.89** | **$2,846.98** | **$118.68** | **-2,608** | **-61** |

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

### Demographics of Members Utilizing Dojolvi® (Triheptanoin)

- Due to the limited number of members utilizing Dojolvi® (triheptanoin) during fiscal year 2023, detailed demographic information could not be provided.

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




## Prior Authorization of Dojolvi® (Triheptanoin)

There were no prior authorization requests submitted for Dojolvi® (triheptanoin) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Market News and Updates[1]

### Anticipated Patent Expiration(s):

- Dojolvi® (triheptanoin): October 2025

## Recommendations

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

## Utilization Details of Dojolvi® (Triheptanoin): Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| DOJOLVI LIQ 100% | 2 | 2 | $37,276.82 | $18,638.41 | 1 | 100% |
| **TOTAL** | **2** | **2*** | **$37,276.82** | **$18,638.41** | **1** | **100%** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 08/2023. Last accessed 08/21/2023.

# Fiscal Year 2023 Annual Review of Gamifant® (Emapalumab-lzsg)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Gamifant® (Emapalumab-lzsg) Approval Criteria:**

1. An FDA approved indication for the treatment of adult and pediatric members with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or who are intolerant to conventional HLH therapy; and
2. Diagnosis of primary HLH must be confirmed by 1 of the following:
    a. Genetic testing confirming mutation of a gene known to cause primary HLH (e.g., *PRF*, *UNC13D*, *STX11*); or
    b. Family history consistent with primary HLH; or
    c. Member meets 5 of the following 8 diagnostic criteria:
        i. Fever; or
        ii. Splenomegaly; or
        iii. Cytopenias affecting at least 2 of 3 lineages in the peripheral blood (hemoglobin <9g/dL, platelets <100 x $10^9$/L, neutrophils <1 x $10^9$/L); or
        iv. Hypertriglyceridemia (fasting triglycerides >3mmol/L or ≥265mg/dL) and/or hypofibrinogenemia (≤1.5g/L); or
        v. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy; or
        vi. Low or absent natural killer (NK)-cell activity; or
        vii. Hyperferritinemia (ferritin ≥500mcg/L); or
        viii. High levels of soluble interleukin-2 receptor (soluble CD25 ≥2,400U/mL); and
3. Gamifant® must be prescribed by, or in consultation with, a physician who specializes in the treatment of immune deficiency disorders; and
4. Member must have at least 1 of the following:
    a. Failure of at least 1 conventional HLH treatment (e.g., etoposide, dexamethasone, cyclosporine); or
    b. Documentation of progressive disease despite conventional HLH treatment; or
    c. A patient-specific, clinically significant reason why conventional HLH treatment is not appropriate for the member must be provided; and
5. Prescriber must verify dexamethasone dosed at least 5mg/$m^2$/day will be used concomitantly with Gamifant®; and

6. Prescriber must verify member has received or will receive prophylaxis for herpes zoster, *Pneumocystis jirovecii,* and fungal infection(s); and
7. Prescriber must verify member will be monitored for tuberculosis (TB), adenovirus, Epstein-Barr virus (EBV), and cytomegalovirus (CMV) every 2 weeks and as clinically indicated; and
8. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
9. Approvals will be for the duration of 6 months with reauthorization granted if the prescriber documents the member is responding well to treatment, no unacceptable toxicity has occurred, and the member has not received hematopoietic stem cell transplantation (HSCT).

## Utilization of Gamifant® (Emapalumab-lzsg): Fiscal Year 2023

There was no SoonerCare utilization, including pharmacy and medical claims, of Gamifant® (emapalumab-lzsg) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Prior Authorization of Gamifant® (Emapalumab-lzsg)

There were 3 prior authorization requests submitted for 1 unique member for Gamifant® (emapalumab-lzsg) during fiscal year 2023 (07/01/2022 to 06/30/2023), all of which were incomplete.

## Recommendations

The College of Pharmacy does not recommend any changes to the current Gamifant® (emapalumab-lzsg) prior authorization criteria at this time.

# Fiscal Year 2023 Annual Review of Hyperkalemia Medications

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

### Lokelma® (Sodium Zirconium Cyclosilicate) Approval Criteria:

1. An FDA approved diagnosis of hyperkalemia; and
2. Medications known to cause hyperkalemia [e.g., aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to the lowest effective dose where clinically appropriate; and
3. A trial of a potassium-eliminating diuretic or documentation why a diuretic is not appropriate for the member must be provided; and
4. Documentation of a low potassium diet must be provided; and
5. A quantity limit of 30 packets per month will apply. Quantity limit overrides will be granted to allow for initial 3 times daily dosing.

### Veltassa® (Patiromer) Approval Criteria:

1. An FDA approved diagnosis of hyperkalemia; and
2. Medications known to cause hyperkalemia [e.g., aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)] have been discontinued or reduced to lowest effective dose where clinically appropriate; and
3. A trial of a potassium-eliminating diuretic or documentation why a diuretic is not appropriate for the member must be provided; and
4. Documentation of a low potassium diet must be provided; and
5. A quantity limit of 30 packets per month will apply.

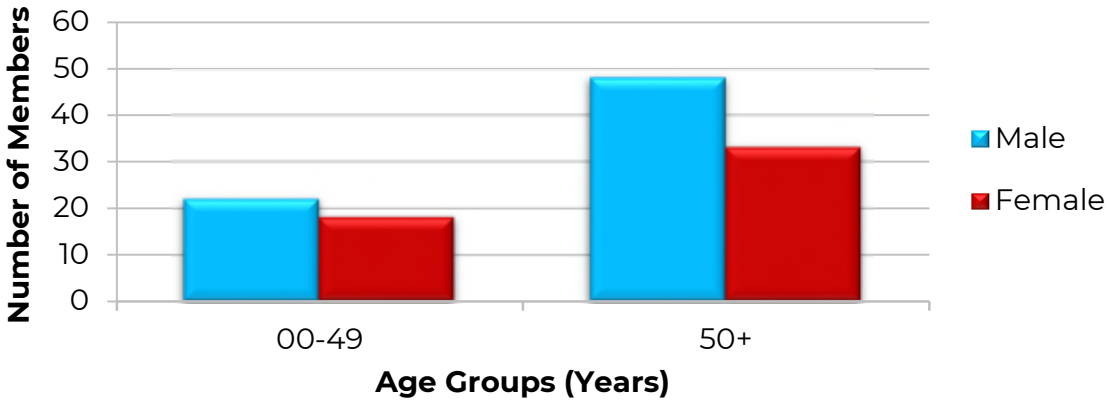
## Utilization of Hyperkalemia Medications: Fiscal Year 2023

**Comparison of Fiscal Years: Pharmacy Claims**

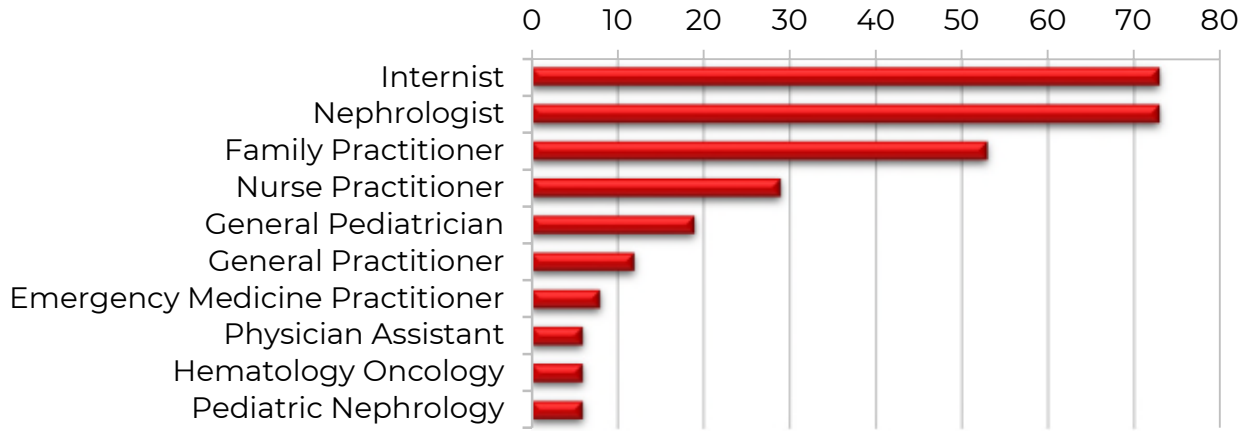
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 96 | 218 | $75,734.35 | $347.41 | $18.27 | 58,141 | 4,145 |
| **2023** | 121 | 300 | $124,753.14 | $415.84 | $18.97 | 75,707 | 6,577 |
| **% Change** | **26.0%** | **37.6%** | **64.7%** | **19.7%** | **3.8%** | **30.2%** | **58.7%** |
| **Change** | **25** | **82** | **$49,018.79** | **$68.43** | **$0.70** | **17,566** | **2,432** |

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

**Demographics of Members Utilizing Hyperkalemia Medications**



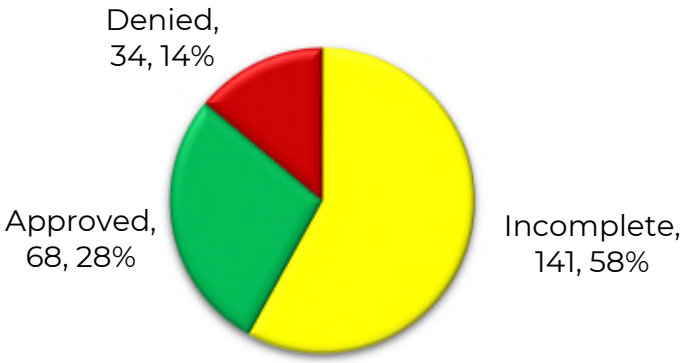

**Top Prescriber Specialties of Hyperkalemia Medications by Number of Claims**




## Prior Authorization of Hyperkalemia Medications

There were 243 prior authorization requests submitted for hyperkalemia medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

**Status of Petitions**



## Market News and Updates[1]

### Anticipated Patent Expiration(s):

- Veltassa® (patiromer): October 2033
- Lokelma® (sodium zirconium cyclosilicate): October 2035

## Recommendations

The College of Pharmacy does not recommend any changes to the current hyperkalemia medications prior authorization criteria at this time.

## Utilization Details of Hyperkalemia Medications: Fiscal Year 2023

### Pharmacy Claims

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| **SODIUM POLYSTYRENE SULFONATE (SPS) PRODUCTS** | | | | | | |
| SPS SUS 15GM/60ML | 113 | 52 | $19,943.27 | $176.49 | 2.17 | 15.99% |
| SPS POW 454GM | 32 | 24 | $1,768.39 | $55.26 | 1.33 | 1.42% |
| **SUBTOTAL** | **145** | **76** | **$21,711.66** | **$149.74** | **1.91** | **17.40%** |
| **SODIUM ZIRCONIUM CYCLOSILICATE PRODUCTS** | | | | | | |
| LOKELMA PAK 10GM | 84 | 30 | $47,887.22 | $570.09 | 2.8 | 38.39% |
| LOKELMA PAK 5GM | 1 | 1 | $745.09 | $745.09 | 1 | 0.60% |
| **SUBTOTAL** | **85** | **31** | **$48,632.31** | **$572.14** | **2.74** | **38.98%** |
| **PATIROMER PRODUCTS** | | | | | | |
| VELTASSA POW 8.4GM | 55 | 16 | $41,140.67 | $748.01 | 3.44 | 32.98% |
| VELTASSA POW 16.8GM | 15 | 8 | $13,268.50 | $884.57 | 1.88 | 10.64% |
| **SUBTOTAL** | **70** | **24** | **$54,409.17** | **$777.27** | **2.92** | **43.61%** |
| **TOTAL** | **300** | **121*** | **$124,753.14** | **$415.84** | **2.48** | **100%** |

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
PAK = packet; POW = powder; SPS = sodium polystyrene sulfonate; SUS = suspension
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 08/2023. Last accessed 08/15/2023.

# Fiscal Year 2023 Annual Review of Jynarque® (Tolvaptan)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Reports**

## Current Prior Authorization Criteria

**Jynarque® (Tolvaptan) Approval Criteria:**

1. An FDA approved indication to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD); and
2. Member must be 18 years of age or older; and
3. Member must not have any contraindications to taking Jynarque® including the following:
    a. Taking any concomitant strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. History of signs or symptoms of significant liver impairment or injury (does not include uncomplicated polycystic liver disease); and
    c. Uncorrected abnormal blood sodium concentrations; and
    d. Unable to sense or respond to thirst; and
    e. Hypovolemia; and
    f. Hypersensitivity to tolvaptan or any of its components; and
    g. Uncorrected urinary outflow obstruction; and
    h. Anuria; and
4. Member must not be taking any of the following medications concomitantly with Jynarque®:
    a. Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan); and
    b. Strong CYP3A inducers (e.g., rifampin); and
    c. OATP1B1/3 and OAT3 transporter substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide); and
    d. BCRP transporter substrates (e.g., rosuvastatin); and
    e. $V_2$-receptor agonists (e.g., desmopressin); and
5. Jynarque® must be prescribed by a nephrologist or specialist with expertise in the treatment of ADPKD (or an advanced care practitioner with a supervising physician who is a nephrologist or specialist with expertise in the treatment of ADPKD); and
6. Prescriber must agree to assess ALT, AST, and bilirubin prior to initiation of Jynarque®, at 2 weeks and 4 weeks after initiation, then monthly for 18 months, and every 3 months thereafter; and

7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Prescriber, pharmacy, and member must be enrolled in the Jynarque® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

## Utilization of Jynarque® (Tolvaptan): Fiscal Year 2023

### Comparison of Fiscal Years

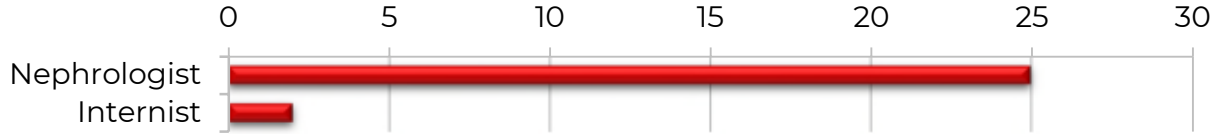
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 7 | 26 | $357,719.85 | $13,758.46 | $496.14 | 1,442 | 721 |
| **2023** | 8 | 27 | $469,470.45 | $17,387.79 | $620.99 | 1,512 | 756 |
| **% Change** | **14.30%** | **3.80%** | **31.20%** | **26.40%** | **25.20%** | **4.90%** | **4.90%** |
| **Change** | **1** | **1** | **$111,750.60** | **$3,629.33** | **$124.85** | **70** | **35** |

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

### Demographics of Members Utilizing Jynarque® (Tolvaptan)

- Due to the limited number of members utilizing Jynarque® (tolvaptan) during fiscal year 2023, detailed demographic information could not be provided.

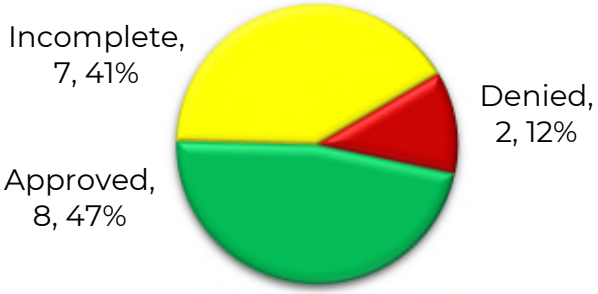
### Top Prescriber Specialties of Jynarque® (Tolvaptan) by Number of Claims




## Prior Authorization of Jynarque® (Tolvaptan)

There were 17 prior authorization requests submitted for Jynarque® (tolvaptan) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

### Status of Petitions



## Market News and Updates[1]

### Anticipated Patent Expiration(s):

- Jynarque® (tolvaptan): April 2030

## Recommendations

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

## Utilization Details of Jynarque® (Tolvaptan): Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| JYNARQUE PAK 45-15MG | 26 | 7 | $461,626.54 | $17,754.87 | 3.71 | 98.33% |
| JYNARQUE PAK 90-30MG | 1 | 1 | $7,843.91 | $7,843.91 | 1 | 1.67% |
| **TOTAL** | **27** | **8*** | **$469,470.45** | **$17,387.79** | **3.38** | **100%** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 09/2023. Last accessed 09/21/2023.

# Fiscal Year 2023 Annual Review of Keveyis® (Dichlorphenamide)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Keveyis® (Dichlorphenamide) Approval Criteria:**

1. An FDA approved indication for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants; and
2. Prescriber documentation that all non-pharmacological treatments failed including the following:
    a. For hyperkalemic periodic paralysis:
        i. Acute attacks can be aborted with sugar or mild exercise; and
        ii. Avoiding foods rich in potassium; and
        iii. Avoiding fasting; and
        iv. High-carbohydrate diet; and
        v. Avoiding strenuous activity; and
        vi. Avoiding prolonged cold exposure; or
    b. For hypokalemic periodic paralysis:
        i. Low-carbohydrate diet (avoiding carbohydrate loading); and
        ii. Avoiding vigorous exercise (some mild attacks can be aborted by low level exercise); and
3. Prescriber documentation of frequent and severe attacks requiring pharmacological treatment (at least 1 attack per week but no more than 3 attacks per day); and
4. A 4-week trial within the last 90 days of acetazolamide in combination with:
    a. Hydrochlorothiazide in hyperkalemic periodic paralysis; or
    b. Spironolactone or triamterene in hypokalemic periodic paralysis; and
5. A quantity limit of 4 tablets per day will apply; and
6. Initial approvals will be for the duration of 3 months after which time compliance will be required for continued approval. Additionally, for continuation the prescriber must include information regarding reduced frequency or severity of attacks.

## Utilization of Keveyis® (Dichlorphenamide): Fiscal Year 2023

### Fiscal Year Comparison: Pharmacy Claims

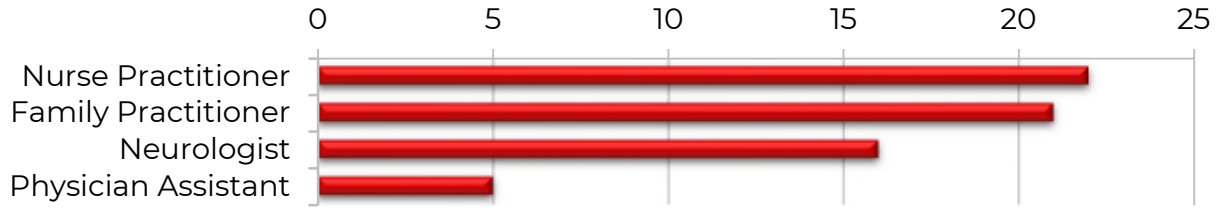
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 5 | 11 | $164,717.32 | $14,974.30 | $499.14 | 600 | 330 |
| **2023** | 9 | 64 | $948,850.54 | $14,825.79 | $494.19 | 3,345 | 1,920 |
| **% Change** | **80.0%** | **481.8%** | **476.0%** | **-1.0%** | **-1.0%** | **457.5%** | **481.8%** |
| **Change** | **4** | **53** | **$784,133.22** | **-$148.51** | **-$4.95** | **2,745** | **1,590** |

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

### Demographics of Members Utilizing Keveyis® (Dichlorphenamide)

- Due to the limited number of members utilizing Keveyis® (dichlorphenamide) during fiscal year 2023, detailed demographic information could not be provided.

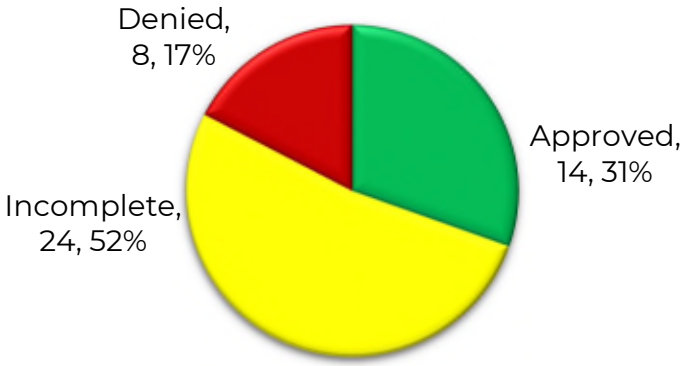
### Top Prescriber Specialties of Keveyis® (Dichlorphenamide) by Number of Claims




## Prior Authorization of Keveyis® (Dichlorphenamide)

There were 46 prior authorization requests submitted for Keveyis® (dichlorphenamide) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

### Status of Petitions



## Market News and Updates[1]

**News:**

- **April 2023:** The first generic formulation of dichlorphenamide was launched by Torrent Pharma in April 2023. Generic dichlorphenamide is available as 50mg tablets in 30- and 100-count bottles and is indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

## Recommendations

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

## Utilization Details of Keveyis® (Dichlorphenamide): Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| KEVEYIS TAB 50MG | 64 | 9 | $948,850.54 | $14,825.79 | 7.11 | 100% |
| **TOTAL** | **64** | **9*** | **$948,850.54** | **$14,825.79** | **7.11** | **100%** |

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

[1] Park B. First Generic Version of Keveyis® Now Available. *Medical Professional Reference (MPR)*. Available online at: https://www.empr.com/home/news/first-generic-version-of-keveyis-now-available/. Issued 04/06/2023. Last accessed 09/21/2023.

# Fiscal Year 2023 Annual Review of Korlym® (Mifepristone)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Korlym® (Mifepristone) Approval Criteria:**

1. An FDA approved indication to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus (T2DM) or glucose intolerance; and
2. Member must have failed surgery intended to correct the cause of endogenous Cushing's syndrome or not be a candidate for surgery that is expected to correct the cause of endogenous Cushing's syndrome; and
3. Member must be 18 years of age or older; and
4. Korlym® must be prescribed by, or in consultation with, an endocrinologist (or an advanced care practitioner with a supervising physician who is an endocrinologist); and
5. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
6. Female members of reproductive potential must use a non-hormonal, medically acceptable method of contraception (unless member has undergone surgical sterilization) during treatment with Korlym® and for at least 1 month after discontinuing treatment; and
7. Member must not have any contraindications to taking Korlym® including the following:
    a. Taking drugs metabolized by CYP3A (e.g., simvastatin, lovastatin) and CYP3A substrates with narrow therapeutic ranges (e.g., cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus); and
    b. Receiving systemic corticosteroids for lifesaving purposes (e.g., immunosuppression after organ transplantation); and
    c. Female members must not have a history of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma; and
    d. Known hypersensitivity to mifepristone or to any of the product components; and
8. Authorizations will be for the duration of 12 months; and
9. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

## Utilization of Korlym® (Mifepristone): Fiscal Year 2023

### Comparison of Fiscal Years: Pharmacy Claims

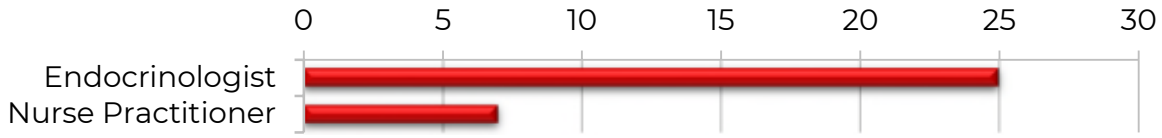
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 4 | 26 | $898,968.04 | $34,575.69 | $1,231.46 | 1,588 | 730 |
| **2023** | 3 | 32 | $1,636,636.75 | $51,144.90 | $1,826.60 | 2,688 | 896 |
| **% Change** | **-25.00%** | **23.10%** | **82.10%** | **47.90%** | **48.30%** | **69.30%** | **22.70%** |
| **Change** | **-1** | **6** | **$737,668.71** | **$16,569.21** | **$595.14** | **1,100** | **166** |

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

### Demographics of Members Utilizing Korlym® (Mifepristone)

- There were 3 unique members utilizing Korlym® (mifepristone) during fiscal year 2023. Due to the limited number of utilizing members, detailed demographic information could not be provided.

### Top Prescriber Specialties of Korlym® (Mifepristone) by Number of Claims




## Prior Authorization of Korlym® (Mifepristone)

There were 7 prior authorization requests submitted for Korlym® (mifepristone) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

### Status of Petitions


## Market News and Updates[1,2]

### Anticipated Patent Expiration(s):

- Korlym® (mifepristone tablet): August 2038

**Pipeline:**

- **Relacorilant:** Relacorilant is being studied to reduce the effects of high cortisol in all forms of Cushing's syndrome. There are currently 2 Phase 3 trials, GRACE and GRADIENT, that are studying these effects. The GRACE trial has completed enrollment and enrollment in the GRADIENT trial is nearly complete. Data is expected next year, and a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) is possible in the second quarter of 2024.

## Recommendations

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

## Utilization Details of Korlym® (Mifepristone): Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| KORLYM TAB 300MG | 32 | 3 | $1,636,636.75 | $51,144.90 | 10.67 | 100% |
| **TOTAL** | **32** | **3*** | **$1,636,636.75** | **$51,144.90** | **10.67** | **100%** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 08/2023. Last accessed 08/15/2023.
[2] Shapiro L. Trial Data for Corcept's Relacorilant, Korlym® Expected Next Year. *Cushing's Disease News.* Available online at: https://cushingsdiseasenews.com/news/trial-data-cushings-treatments-relacorilant-korlym-due-next-year/. Issued 08/04/2023. Last accessed 08/17/2023.

# Fiscal Year 2023 Annual Review of Lambert-Eaton Myasthenic Syndrome (LEMS) Medications

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Firdapse® (Amifampridine) Approval Criteria:**

1. An FDA approved diagnosis of Lambert-Eaton myasthenic syndrome (LEMS); and
2. LEMS diagnosis must be confirmed by 1 of the following:
   a. A high titer anti-P/Q-type voltage-gated calcium channel (VGCC) antibody assay; or
   b. A confirmatory electrodiagnostic study [e.g., repetitive nerve stimulation (RNS), needle electromyography (EMG), single-fiber electromyography (SFEMG)]; and
3. The requested medication must be prescribed by, or in consultation with, a neurologist or oncologist; and
4. Member must not have a history of seizures or be taking medications that lower the seizure threshold (e.g., bupropion, tramadol, amphetamines, theophylline); and
5. A quantity limit of 240 tablets per 30 days will apply; and
6. Initial approvals will be for 6 months. Continued authorization will require the prescriber to indicate that the member is responding well to treatment and continues to require treatment with the requested medication.

## Utilization of LEMS Medications: Fiscal Year 2023

**Comparison of Fiscal Years**

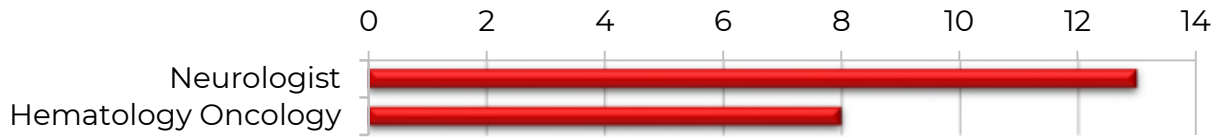
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 1 | 15 | $396,643.95 | $26,442.93 | $986.68 | 2,010 | 402 |
| **2023** | 2 | 21 | $785,924.96 | $37,425.00 | $1,247.50 | 3,684 | 630 |
| **% Change** | **100.00%** | **40.00%** | **98.10%** | **41.50%** | **26.40%** | **83.30%** | **56.70%** |
| **Change** | **1** | **6** | **$389,281.01** | **$10,982.07** | **$260.82** | **1,674** | **228** |

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

### Demographics of Members Utilizing LEMS Medications

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

### Top Prescriber Specialties of LEMS Medications by Number of Claims




## Prior Authorization of LEMS Medications

There were 8 prior authorization requests submitted for 2 unique members for Firdapse® (amifampridine) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

### Status of Petitions


## Market News and Updates[1,2]

**Anticipated Patent Expiration(s):**

- Firdapse® (amifampridine): February 2037

**News:**

- **August 2023:** Catalyst Pharmaceuticals, the manufacturer of Firdapse®, announced the submission of a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking an increase to the maximum daily dose of Firdapse® from 80mg per day to 100mg per day for the treatment of LEMS. No Prescription Drug User Fee Act (PDUFA) date has been announced for the sNDA.

## Recommendations

The College of Pharmacy does not recommend any changes to the current LEMS medications prior authorization criteria at this time.

## Utilization Details of LEMS Medications: Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| **AMIFAMPRIDINE PRODUCTS** | | | | | | |
| FIRDAPSE TAB 10MG | 21 | 2 | $785,924.96 | $37,425.00 | 10.5 | 100% |
| **TOTAL** | **21** | **2*** | **$785,924.96** | **$37,425.00** | **10.5** | **100%** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cf. Last revised 09/2023. Last accessed 09/21/2023.
[2] Catalyst Pharmaceuticals, Inc. Catalyst Pharmaceuticals Reports Strong Second Quarter 2023 Financial Results and Provides Corporate Update. Available online at: https://ir.catalystpharma.com/news-releases/news-release-details/catalyst-pharmaceuticals-reports-strong-second-quarter-2023. Issued 08/09/2023. Last accessed 08/21/2023.

# Fiscal Year 2023 Annual Review of Lidocaine Topical Products

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Lidotral® (Lidocaine 3.88% Topical Cream) Approval Criteria:**

1. A patient-specific, clinically significant reason why the member cannot use other formulations of lidocaine including lidocaine 3% topical cream, which is available without prior authorization, must be provided.

**Synera® (Lidocaine/Tetracaine Patch) Approval Criteria:**

1. Member must be 3 years of age or older; and
2. Member must have an FDA approved need for local dermal analgesia for superficial venous access or superficial dermatological procedures; and
3. A patient-specific, clinically significant reason why the member cannot use EMLA® (lidocaine/prilocaine) cream, which is available without a prior authorization, must be provided; and
4. The total number of procedures must be provided on the prior authorization request; and
5. A quantity limit of 2 patches per day will apply.

**ZTlido® (Lidocaine 1.8% Topical System) Approval Criteria:**

1. An FDA approved diagnosis of pain due to postherpetic neuralgia (PHN); and
2. Documented treatment attempts, at recommended dosing, of at least 1 agent from 2 of following drug classes that failed to provide adequate relief or contraindication(s) to all of the following classes:
    a. Tricyclic antidepressants; or
    b. Anticonvulsants; or
    c. Topical or oral analgesics; and
3. A patient-specific, clinically significant reason why the member cannot use lidocaine 5% topical patches, which are available without prior authorization, must be provided; and
4. A quantity limit of 3 patches per day with a maximum of 90 patches per 30 days will apply.

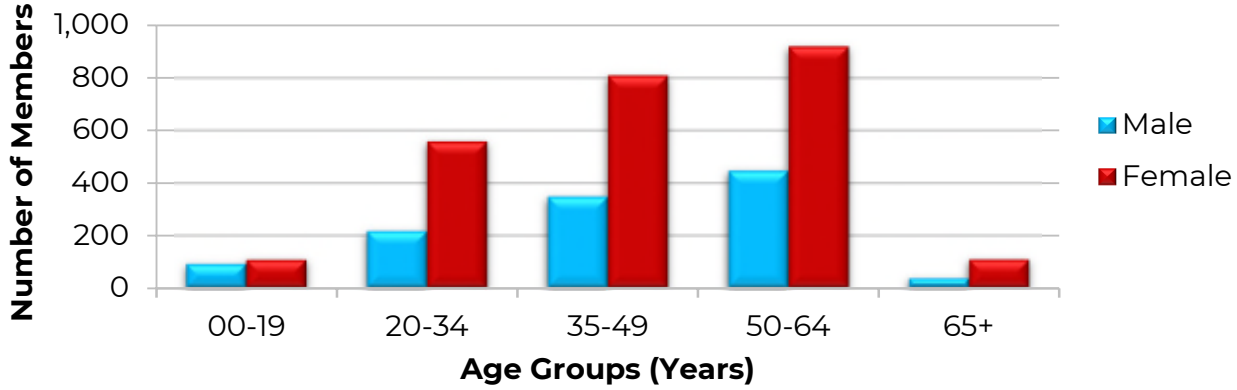
## Utilization of Lidocaine Topical Products: Fiscal Year 2023

### Comparison of Fiscal Years: Pharmacy Claims

| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 2,242 | 3,893 | $281,469.84 | $72.30 | $2.70 | 121,514 | 104,124 |
| **2023** | 3,622 | 6,258 | $409,387.88 | $65.42 | $2.47 | 195,680 | 165,543 |
| **% Change** | **61.6%** | **60.8%** | **45.4%** | **-9.5%** | **-8.5%** | **61.0%** | **59.0%** |
| **Change** | **1,380** | **2,365** | **$127,918.04** | **-$6.88** | **-$0.23** | **74,166** | **61,419** |

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

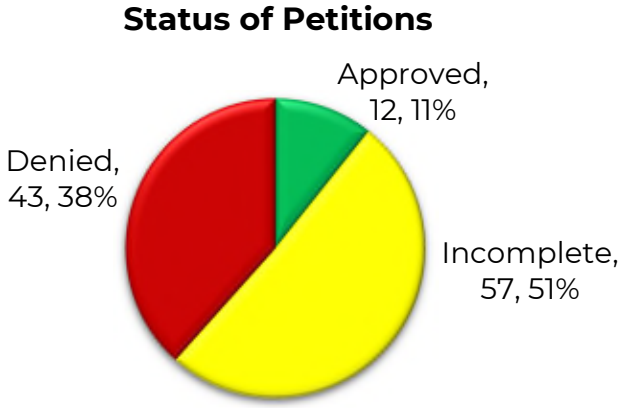
### Demographics of Members Utilizing Lidocaine Topical Products




### Top Prescriber Specialties of Lidocaine Topical Products by Number of Claims

## Prior Authorization of Lidocaine Topical Products

There were 112 prior authorization requests submitted for lidocaine topical products during fiscal year 2023. The following chart shows the status of the submitted petitions.




## Market News and Updates[1]

### Anticipated Patent Expiration(s):

- ZTlido® (lidocaine 1.8% topical system): May 2031

## Recommendations

The College of Pharmacy does not recommend any changes to the current lidocaine topical products prior authorization criteria at this time.

## Utilization Details of Lidocaine Topical Products: Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| **LIDOCAINE PRODUCTS** | | | | | | |
| LIDOCAINE PAD 5% | 6,254 | 3,621 | $408,080.43 | $65.25 | 1.73 | 99.68% |
| ZTLIDO PAD 1.8% | 4 | 1 | $1,307.45 | $326.86 | 4 | 0.32% |
| **TOTAL** | **6,258** | **3,622*** | **$409,387.88** | **$65.42** | **1.73** | **100%** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 09/2023. Last accessed 09/21/2023.

# Fiscal Year 2023 Annual Review of Nulibry® (Fosdenopterin)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Nulibry® (Fosdenopterin) Approval Criteria:**

1. An FDA approved indication to reduce the risk of mortality in members with molybdenum cofactor deficiency (MoCD) Type A; and
2. MoCD Type A must be confirmed by genetic testing; and
    a. If the member is presumed to have MoCD Type A, Nulibry® can be approved for 1 month until genetic testing can be performed; and
    b. Nulibry® will be discontinued if genetic testing results do not confirm MoCD Type A; and
3. Nulibry® must be administered by a health care provider, or the prescriber must verify the member or member's caregiver has been trained by a health care professional on proper storage, preparation, and intravenous (IV) administration of Nulibry®; and
4. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing according to package labeling; and
5. Approval quantities will be dependent on the member's age, weight, and dosing based on package labeling.

## Utilization of Nulibry® (Fosdenopterin): Fiscal Year 2023

There was no utilization of Nulibry® (fosdenopterin) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Prior Authorization of Nulibry® (Fosdenopterin)

There were no prior authorization requests submitted for Nulibry® (fosdenopterin) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Market News and Updates[1]

**Anticipated Patent Expiration(s):**

- Nulibry® (fosdenopterin): January 2025

## Recommendations

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

[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 09/2023. Last accessed 09/21/2023.

# Fiscal Year 2023 Annual Review of Ocaliva® (Obeticholic Acid)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Ocaliva® (Obeticholic Acid) Approval Criteria:**

1. An FDA approved diagnosis of primary biliary cholangitis (PBC); and
2. Member must have taken ursodeoxycholic acid (UDCA) at an appropriate dose for at least 1 year and prescriber must confirm a lack of improvement in liver function tests; and
3. The prescriber must also confirm all of the following:
   a. PBC is not caused by a superimposed liver disease; and
   b. If the member has a superimposed liver disease, it is being adequately treated; and
   c. Proper timing of bile acid sequestrants if co-administered with UDCA (4 hours before or 4 hours after) and patient compliance with UDCA; and
4. Ocaliva® must be taken in combination with UDCA. For Ocaliva® monotherapy consideration, the prescriber must document a patient-specific, clinically significant reason why the member is unable to take UDCA; and
5. A quantity limit of 1 tablet per day will apply.

## Utilization of Ocaliva® (Obeticholic Acid): Fiscal Year 2023

### Comparison of Fiscal Years: Pharmacy Claims

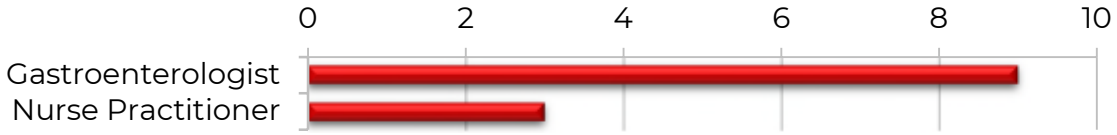
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 2 | 10 | $77,854.12 | $7,785.41 | $259.51 | 300 | 300 |
| **2023** | 2 | 12 | $100,468.08 | $8,372.34 | $279.08 | 360 | 360 |
| **% Change** | **0.0%** | **20.0%** | **29.0%** | **7.5%** | **7.5%** | **20.0%** | **20.0%** |
| **Change** | **0** | **2** | **$22,613.96** | **$586.93** | **$19.57** | **60** | **60** |

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

### Demographics of Members Utilizing Ocaliva® (Obeticholic Acid)

- There were 2 unique members utilizing Ocaliva® during fiscal year 2023. Due to the limited number of utilizing members, detailed demographic information could not be provided.

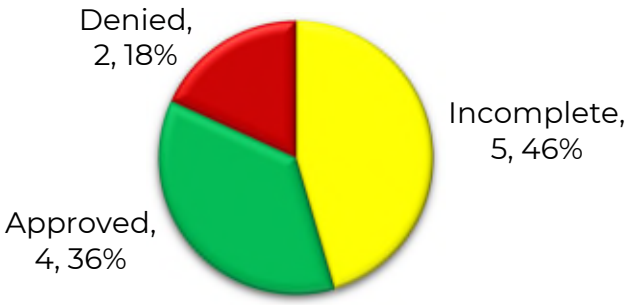
**Top Prescriber Specialties of Ocaliva® (Obeticholic Acid) by Number of Claims**




## Prior Authorization of Ocaliva® (Obeticholic Acid)

There were 11 prior authorization requests submitted for Ocaliva® (obeticholic acid) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

**Status of Petitions**




## Market News and Updates[1,2]

**Anticipated Patent Expiration(s):**

- Ocaliva® (obeticholic acid): April 2036

**News:**

- **June 2023:** Intercept Pharmaceuticals received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for obeticholic acid for the treatment of pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis (NASH). The CRL indicated the FDA completed the review of the New Drug Application (NDA) for obeticholic acid but stated it could not be approved for the indication. It was stated that any resubmission would require completion of long-term outcomes phase of the current trial. Based on this, Intercept made the decision to discontinue its NASH-related investments at this time.

## Recommendations

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

## Utilization Details of Ocaliva® (Obeticholic Acid): Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| OCALIVA TAB 5MG | 12 | 2 | $100,468.08 | $8,372.34 | 6 | 100% |
| **TOTAL** | **12** | **2*** | **$100,468.08** | **$8,372.34** | **6** | **100%** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2023. Last accessed 08/28/2023.
[2] Intercept Pharmaceuticals Inc. Intercept Receives Complete Response Letter from FDA for Obeticholic Acid as a Treatment for Pre-Cirrhotic Fibrosis due to NASH. Available online at: https://ir.interceptpharma.com/news-releases/news-release-details/intercept-receives-complete-response-letter-fda-obeticholic-0. Issued 06/22/2023. Last accessed 08/16/2023.

# Fiscal Year 2023 Annual Review of Ophthalmic Anti-Inflammatory Products

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

| Ophthalmic Corticosteroids | |
|---|---|
| **Tier-1** | **Tier-2** |
| dexamethasone 0.1% sus (Maxidex®) | fluorometholone 0.25% sus (FML Forte®) |
| dexamethasone sodium phosphate 0.1% sol | fluorometholone 0.1% oint (FML S.O.P®) |
| difluprednate 0.05% emu (Durezol®) – **Brand Preferred** | loteprednol 1% sus (Inveltys®) |
| fluorometholone 0.1% sus (Flarex®) | loteprednol 0.38% gel (Lotemax® SM) |
| fluorometholone 0.1% sus (FML Liquifilm®) | prednisolone acetate 1% sus (Pred Forte®) |
| loteprednol 0.5% gel, oint, sus (Lotemax®) – **Brand Preferred** | |
| prednisolone acetate 1% sus (Omnipred®) | |
| prednisolone acetate 0.12% sus (Pred Mild®) | |
| prednisolone sodium phosphate 1% sol | |

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)
emu = emulsion; oint = ointment; sol = solution; sus = suspension

### Ophthalmic Corticosteroids Tier-2 Approval Criteria:

1. Documented trials of all Tier-1 ophthalmic corticosteroids (from different product lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower-tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic corticosteroids lack.

### Dextenza® (Dexamethasone Ophthalmic Insert) Approval Criteria (Medical Only):

1. An FDA approved indication for the treatment of ocular inflammation and pain following ophthalmic surgery; and
2. Prescriber must verify that Dextenza® will be placed by a physician immediately following ophthalmic surgery; and
3. Date of ophthalmic surgery must be provided; and
4. A patient-specific, clinically significant reason why corticosteroid ophthalmic preparations, such as solution or suspension, typically used following ophthalmic surgery are not appropriate for the member must be provided; and
5. A quantity limit of 1 insert per eye every 30 days will apply.

**Iluvien® (Fluocinolone Intravitreal Implant) Approval Criteria (Medical Only):**

1. An FDA approved diagnosis of diabetic macular edema in members who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure; and
2. Iluvien® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. A patient-specific, clinically significant reason why the member requires Iluvien® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A quantity limit of 1 implant per eye every 36 months will apply.

**Oxervate® (Cenegermin-bkbj) Approval Criteria:**

1. An FDA approved diagnosis of neurotrophic keratitis; and
2. Oxervate® must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has persistent epithelial defect (PED) (stage 2 disease) or corneal ulceration (stage 3 disease) of at least 2 weeks duration that is refractory to 1 or more conventional non-surgical treatments for neurotrophic keratitis; and
    a. Specific non-surgical treatments and dates of trials must be listed on the prior authorization request; and
4. Prescriber must verify that the member has evidence of decreased corneal sensitivity within the area of the PED or corneal ulcer and outside of the area of the defect in at least 1 corneal quadrant; and
5. Prescriber must verify the member has been counseled on the proper administration and storage of Oxervate®; and
6. Approvals will be for a maximum duration of 8 weeks of total therapy per eye; and
7. A quantity limit of 2 weekly kits per 14 days will apply. A quantity limit override will be approved for 4 weekly kits per 14 days with prescriber documentation of treatment in both eyes.

**Ozurdex® (Dexamethasone Intravitreal Implant) Approval Criteria (Medical Only):**

1. An FDA approved indication for 1 of the following:
    a. Treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO); or
    b. Treatment of non-infectious uveitis affecting the posterior segment of the eye; or
    c. Treatment of diabetic macular edema; and
2. Ozurdex® must be administered by an ophthalmologist; and

3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Ozurdex® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A quantity limit of 1 implant per eye every 3 months will apply.

**Retisert® (Fluocinolone Intravitreal Implant) Approval Criteria (Medical Only):**

1. An FDA approved diagnosis of chronic non-infectious posterior uveitis; and
2. Retisert® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. Prescriber must agree to periodically monitor the integrity of the implant by visual inspection; and
5. A patient-specific, clinically significant reason why the member requires Retisert® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
6. A patient-specific, clinically significant reason why the member requires Retisert® in place of Ozurdex® or Yutiq® must be provided; and
7. A quantity limit of 1 implant per eye every 30 months will apply.

**Xipere® (Triamcinolone Acetonide Injection) Approval Criteria (Medical Only):**

1. An FDA approved indication for the treatment of macular edema associated with non-infectious uveitis; and
2. Member must be 18 years of age or older; and
3. Xipere® must be administered by an ophthalmologist; and
4. Prescriber must confirm that the member does not have an active ocular or periocular infection; and
5. Prescriber must confirm member does not have untreated ocular hypertension or uncontrolled glaucoma; and
6. A patient-specific, clinically significant reason why the member cannot use corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
7. A patient-specific, clinically significant reason the member cannot use Triesence® (triamcinolone acetonide injection) must be provided; and
8. Initial authorization will be for 12 weeks, with an additional dose approved at or after 12 weeks if the prescriber documents improvement from baseline in visual acuity.

**Yutiq® (Fluocinolone Acetonide Intravitreal Implant) Approval Criteria (Medical Only):**

1. An FDA approved diagnosis of chronic, non-infectious uveitis affecting the posterior segment of the eye; and
2. Yutiq® must be administered by an ophthalmologist; and
3. Prescriber must verify that the member will be monitored for increased intraocular pressure, endophthalmitis, and cataract development; and
4. A patient-specific, clinically significant reason why the member requires Yutiq® in place of corticosteroid ophthalmic preparations, such as solution or suspension, must be provided; and
5. A patient-specific, clinically significant reason why the member requires Yutiq® in place of Ozurdex® must be provided; and
6. A quantity limit of 1 implant per eye every 36 months will apply.

| Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) | |
|---|---|
| **Tier-1** | **Tier-2** |
| diclofenac 0.1% sol (Voltaren®) | bromfenac 0.09% sol (Bromday®) |
| flurbiprofen 0.03% sol$^{\Delta}$ (Ocufen®) | bromfenac 0.075% sol (BromSite®) |
| ketorolac 0.5% sol (Acular®) | bromfenac 0.07% sol (Prolensa®) |
| | ketorolac 0.4% sol (Acular LS®) |
| | ketorolac 0.45% sol (Acuvail®) |
| | nepafenac 0.1% sus (Nevanac®) |
| | nepafenac 0.3% sus (Ilevro®) |

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).
sol = solution; sus = suspension
$^{\Delta}$Not a required Tier-1 trial; does not have to be attempted for approval of a Tier-2 medication.

**Ophthalmic Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Tier-2 Approval Criteria:**

1. Documented trials of all Tier-1 ophthalmic NSAIDs (from different medication lines) in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
2. Contraindication(s) to all lower tiered medications; or
3. A unique indication for which the Tier-1 ophthalmic NSAIDs lack.

## Utilization of Ophthalmic Anti-Inflammatory Products: Fiscal Year 2023

### Comparison of Fiscal Years: Ophthalmic Corticosteroids (Pharmacy Claims)

| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 3,548 | 5,231 | $373,039.14 | $71.31 | $2.60 | 35,524 | 143,604 |
| **2023** | 4,702 | 6,741 | $425,486.81 | $63.12 | $2.28 | 46,553 | 186,403 |
| **% Change** | **32.5%** | **28.9%** | **14.1%** | **-11.5%** | **-12.3%** | **31.0%** | **29.8%** |
| **Change** | **1,154** | **1,510** | **$52,447.67** | **-$8.19** | **-$0.32** | **11,029** | **42,799** |

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

## Fiscal Year 2023 Utilization: Ophthalmic Corticosteroids (Medical Claims)

| Fiscal Year | *Total Members | †Total Claims | Total Cost | Cost/ Claim | Claims/ Member |
|---|---|---|---|---|---|
| **2023** | 18 | 36 | $115,581.20 | $3,210.59 | 2 |

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

## Comparison of Fiscal Years: Oxervate® (Cenegermin-bkbj) (Pharmacy Claims)

| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 1 | 8 | $101,245.98 | $12,655.75 | $1,807.96 | 56 | 56 |
| **2023** | 4 | 13 | $564,075.05 | $43,390.39 | $3,099.31 | 308 | 182 |
| **% Change** | **300%** | **62.5%** | **457.1%** | **242.9%** | **71.4%** | **450%** | **225%** |
| **Change** | **3** | **5** | **$462,829.07** | **$30,734.64** | **$1,291.35** | **252** | **126** |

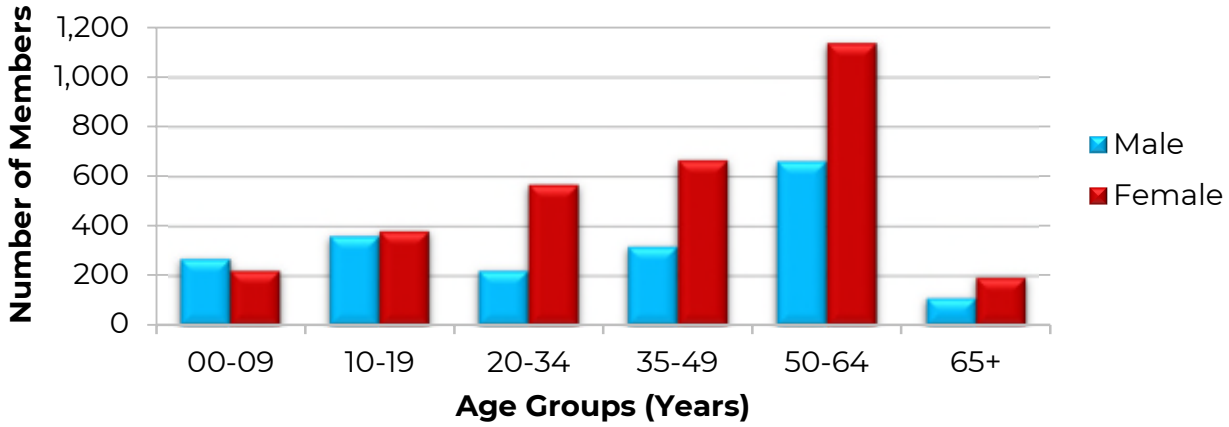
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

## Comparison of Fiscal Years: Ophthalmic NSAIDs (Pharmacy Claims)

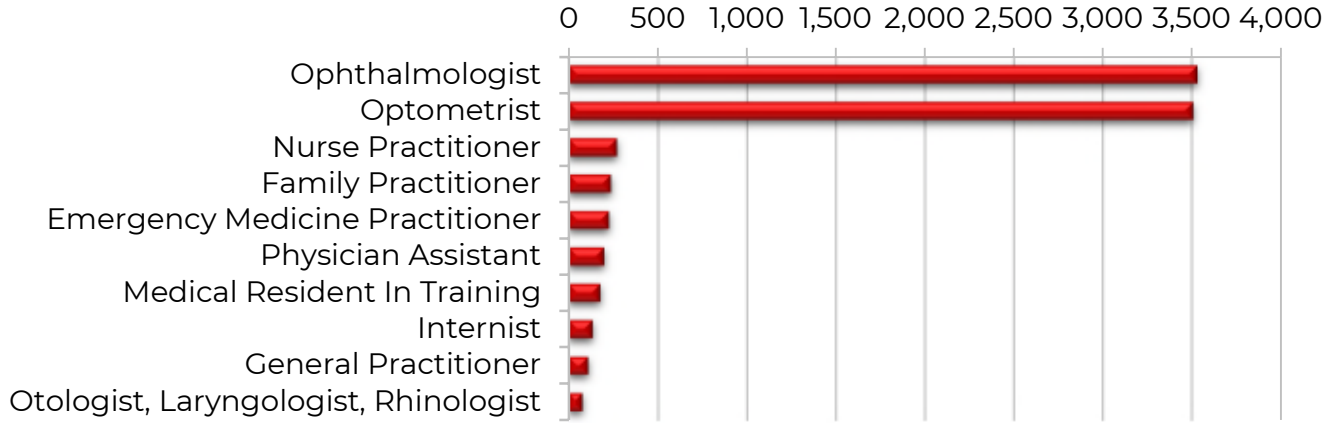
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 1,130 | 1,533 | $47,048.24 | $30.69 | $1.20 | 8,215 | 39,234 |
| **2023** | 1,452 | 1,993 | $35,913.94 | $18.02 | $0.71 | 11,362 | 50,771 |
| **% Change** | **28.5%** | **30.0%** | **-23.7%** | **-41.3%** | **-40.8%** | **38.3%** | **29.4%** |
| **Change** | **322** | **460** | **-$11,134.30** | **-$12.67** | **-$0.49** | **3,147** | **11,537** |

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

## Demographics of Members Utilizing Ophthalmic Anti-Inflammatory Products



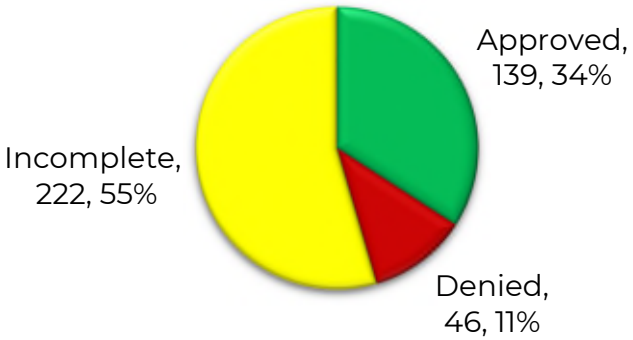
**Top Prescriber Specialties of Ophthalmic Anti-Inflammatory Products by Number of Claims**




## Prior Authorization of Ophthalmic Anti-Inflammatory Products

There were 407 prior authorization requests submitted for ophthalmic anti-inflammatory products during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

**Status of Petitions**




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

**Anticipated Patent Expiration(s):**

- Ozurdex® (dexamethasone intravitreal implant): November 2023
- Nevanac® (nepafenac 0.1% ophthalmic suspension): January 2027
- Iluvien® (fluocinolone intravitreal implant): August 2027
- Acular LS® (ketorolac 0.4% ophthalmic solution): November 2027
- Yutiq® (fluocinolone intravitreal implant): January 2028
- Acuvail® (ketorolac 0.45% ophthalmic solution): August 2029
- BromSite® (bromfenac 0.075% ophthalmic solution): August 2029
- Ilevro® (nepafenac 0.3% ophthalmic suspension): March 2032
- Inveltys® (loteprednol 1% ophthalmic suspension): May 2033

- Prolensa® (bromfenac 0.07% ophthalmic solution): November 2033
- Xipere® (triamcinolone acetonide injectable suspension): May 2034
- Lotemax® SM (loteprednol 0.38% ophthalmic gel): December 2036
- Dextenza® (dexamethasone ophthalmic insert): November 2037

**Pipeline:**

- **SVT-15473:** Salvat Laboratories has developed IMPACT-SVT, a patented nanoemulsion drug delivery technology that improves drug penetration and bio-adhesion. SVT-15473 is a new ophthalmic formulation of clobetasol 0.05% made using this nanoemulsion technology. Previously, clobetasol has not been available as an ophthalmic formulation. The new drug is currently being reviewed by the U.S. Food and Drug Administration (FDA) for the treatment of inflammation and pain after ocular surgery, and a decision by the FDA was initially expected in the summer of 2023. However, in July 2023 Salvat announced they have initiated an additional clinical study in pediatric patients 0 to 3 years of age with cataracts. The new study was agreed upon with the FDA to provide complementary data as part of the review process. A Prescription Drug User Fee Act (PDUFA) date has not been announced.

## Recommendations

The College of Pharmacy does not recommend changes to the current ophthalmic anti-inflammatory products prior authorization criteria at this time.

## Utilization Details of Ophthalmic Corticosteroids: Fiscal Year 2023

### Pharmacy Claims

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER |
|---|---|---|---|---|---|
| **TIER-1 UTILIZATION** | | | | | |
| **PREDNISOLONE PRODUCTS** | | | | | |
| PREDNISOLONE SUS 1% OP | 5,332 | 3,763 | $237,199.05 | $44.49 | 1.42 |
| PRED SOD PHO SOL 1% OP | 25 | 23 | $1,469.26 | $58.77 | 1.09 |
| PRED MILD SUS 0.12% OP | 16 | 16 | $4,258.35 | $266.15 | 1 |
| **SUBTOTAL** | **5,373** | **3,802** | **$242,926.66** | **$45.21** | **1.41** |
| **FLUOROMETHOLONE PRODUCTS** | | | | | |
| FLUOROMETHOLONE SUS 0.1% OP | 336 | 247 | $28,915.70 | $86.06 | 1.36 |
| FLAREX SUS 0.1% OP | 67 | 43 | $8,637.96 | $128.92 | 1.56 |
| FML LIQUIFLM SUS 0.1% OP | 22 | 17 | $5,295.69 | $240.71 | 1.29 |
| **SUBTOTAL** | **425** | **307** | **$42,849.34** | **$100.82** | **1.38** |
| **DEXAMETHASONE PRODUCTS** | | | | | |
| DEXAMETH PHO SOL 0.1% OP | 400 | 367 | $20,671.05 | $51.68 | 1.09 |
| MAXIDEX SUS 0.1% OP | 17 | 13 | $1,613.60 | $94.92 | 1.31 |

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER |
|---|---|---|---|---|---|
| **SUBTOTAL** | **417** | **380** | **$22,284.65** | **$53.44** | **1.1** |
| **LOTEPREDNOL PRODUCTS** | | | | | |
| LOTEMAX SUS 0.5% | 162 | 135 | $48,874.32 | $301.69 | 1.2 |
| LOTEMAX GEL 0.5% | 67 | 49 | $15,337.95 | $228.92 | 1.37 |
| LOTEPREDNOL GEL 0.5% | 58 | 40 | $9,016.82 | $155.46 | 1.45 |
| LOTEMAX OIN 0.5% | 28 | 18 | $8,890.24 | $317.51 | 1.56 |
| LOTEPREDNOL SUS 0.5% | 3 | 1 | $449.01 | $149.67 | 3 |
| **SUBTOTAL** | **318** | **243** | **$82,568.34** | **$259.65** | **1.31** |
| **DIFLUPREDNATE PRODUCTS** | | | | | |
| DIFLUPREDNATE EMU 0.05% | 112 | 70 | $13,836.45 | $123.54 | 1.6 |
| DUREZOL EMU 0.05% | 96 | 83 | $21,021.36 | $218.97 | 1.16 |
| **SUBTOTAL** | **208** | **153** | **$34,857.81** | **$167.59** | **1.36** |
| **TIER-1 SUBTOTAL** | **6,741** | **4,885** | **$425,486.81** | **$63.12** | **1.43** |
| **TOTAL** | **6,741** | **4,702*** | **$425,486.81** | **$63.12** | **1.43** |

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DEXAMETH = dexamethasone; EMU = emulsion; OIN = ointment; OP = ophthalmic; PHO = phosphate; PRED = prednisolone; SOD = sodium; SOL = solution; SUS = suspension
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

### Medical Claims

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER |
|---|---|---|---|---|---|
| OZURDEX® (J7312) | 28 | 16 | $40,606.86 | $1,450.25 | 1.75 |
| ILUVIEN® (J7313) | 6 | 3 | $55,968.30 | $9,328.05 | 2 |
| YUTIQ® (J7314) | 2 | 2 | $18,653.04 | $9,326.52 | 1 |
| **TOTAL** | **36+** | **18*** | **$115,581.20** | **$3,210.59** | **2** |

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

## Utilization Details of Oxervate® (Cenegermin-bkbj): Fiscal Year 2023

### Pharmacy Claims

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER |
|---|---|---|---|---|---|
| OXERVATE SOL 20MCG/ML | 13 | 4 | $564,075.05 | $43,390.39 | 3.25 |
| **TOTAL** | **13** | **4*** | **$564,075.05** | **$43,390.39** | **3.25** |

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

## Utilization Details of Ophthalmic NSAIDs: Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER |
|---|---|---|---|---|---|
| **TIER-1 UTILIZATION** | | | | | |
| KETOROLAC SOL 0.5% | 1,856 | 1,353 | $32,342.57 | $17.43 | 1.37 |
| DICLOFENAC SOL 0.1% OP | 130 | 103 | $2,425.02 | $18.65 | 1.26 |
| FLURBIPROFEN SOL 0.03% | 4 | 3 | $129.46 | $32.37 | 1.33 |
| **TIER-1 SUBTOTAL** | **1,990** | **1,459** | **$34,897.05** | **$17.54** | **1.36** |
| **TIER-2 UTILIZATION** | | | | | |
| ILEVRO DRO 0.3% OP | 3 | 1 | $1,016.89 | $338.96 | 3 |
| **TIER-2 SUBTOTAL** | **3** | **1** | **$1,016.89** | **$338.96** | **3** |
| **TOTAL** | **1,993** | **1,452*** | **$35,913.94** | **$18.02** | **1.37** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 08/2023. Last accessed 09/01/2023.
[2] Salvat Laboratories. Salvat Laboratories Presents Phase 3 Clinical Trials Results of Clobetasol Nanoemulsion for Treating Inflammation and Pain After Ocular Surgery. *Eyewire*. Available online at: https://eyewire.news/news/salvat-laboratories-presents-phase-3-clinical-trials-results-of-clobetasol-nanoemulsion-for-treating-inflammation-and-pain-after-ocular-surgery?c4src=article:infinite-scroll. Issued 05/08/2023. Last accessed 09/05/2023.
[3] Salvat Laboratories. Salvat Laboratories Initiates a Pioneering Pediatric Study in Europe with its Innovative Drug SVT-15473, for the Treatment of Inflammation and Pain Following Ocular Surgery. Available online at: https://svt.com/en/salvat-laboratories-initiates-a-pioneering-pediatric-study-in-europe-with-its-innovative-drug-svt-15473-for-the-treatment-of-inflammation-and-pain-following-ocular-surgery/. Issued 07/07/2023. Last accessed 09/29/2023.

# Fiscal Year 2023 Annual Review of Ophthalmic Antibiotic Medications

## Oklahoma Health Care Authority
## Fiscal Year 2023 Print Report

### Current Prior Authorization Criteria

| Ophthalmic Antibiotic Medications: Liquids | | |
|---|---|---|
| **Tier-1** | **Tier-2** | **Tier-3** |
| ciprofloxacin (Ciloxan®) | levofloxacin (Quixin®) | azithromycin (Azasite®) |
| gentamicin (Gentak®) | | besifloxacin (Besivance®) |
| neomycin/polymyxin B/gramicidin (Neosporin®) | | gatifloxacin (Zymaxid®) |
| ofloxacin (Ocuflox®) | | moxifloxacin (Vigamox®, Moxeza®) |
| polymyxin B/trimethoprim (Polytrim®) | | |
| sulfacetamide sodium (Bleph-10®) | | |
| tobramycin (Tobrex®) | | |

| Ophthalmic Antibiotic Medications: Ointments | |
|---|---|
| **Tier-1** | **Tier-2** |
| bacitracin/polymyxin B (AK-Poly-Bac®, Polycin®) | bacitracin (AK-Tracin®) |
| erythromycin (Ilotycin™, Romycin®) | ciprofloxacin (Ciloxan®) |
| gentamicin (Gentak®) | sodium sulfacetamide (Bleph-10®) |
| neomycin/polymyxin B/bacitracin (Neosporin®) | |
| tobramycin (Tobrex®) | |

| Ophthalmic Antibiotic/Steroid Combination Products | |
|---|---|
| **Tier-1** | **Tier-2** |
| neomycin/polymyxin B/dexamethasone (Maxitrol®) susp & oint | bacitracin/polymyxin B/neomycin/ hydrocortisone (Neo-Polycin® HC) oint |
| sulfacetamide/prednisolone 10%/0.23% solution | gentamicin/prednisolone (Pred-G®) susp & oint |
| tobramycin/dexamethasone 0.3%/0.1% (Tobradex®) susp – **Brand Preferred** | neomycin/polymyxin B/hydrocortisone (Cortisporin®) susp |
| tobramycin/dexamethasone 0.3%/0.05% (Tobradex® ST) oint | sulfacetamide/prednisolone (Blephamide®) susp & oint |
| | tobramycin/dexamethasone (Tobradex®) oint |
| | tobramycin/loteprednol (Zylet®) susp |

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).
HC= hydrocortisone; oint= ointment; susp= suspension

**Ophthalmic Antibiotic Medications Tier-2 Approval Criteria:**

1. An FDA approved indication/suspected infection by an organism not known to be covered by Tier-1 products, or failure of a Tier-1 product; or
2. Known contraindication to all indicated Tier-1 medications; or
3. Prescription written by an optometrist or ophthalmologist; or
4. When requested medication is being used for pre/post-operative prophylaxis.

**Ophthalmic Antibiotic Medications Tier-3 Approval Criteria:**

1. An FDA approved indication/suspected infection by an organism not known to be covered by Tier-2 products, or failure of a Tier-2 product; or
2. Known contraindication to all indicated Tier-2 medications; or
3. Prescription written by an optometrist or ophthalmologist; or
4. When requested medication is being used for pre/post-operative prophylaxis.

**Ophthalmic Antibiotic/Steroid Combination Products Tier-2 Approval Criteria:**

1. Prescription written by an optometrist or ophthalmologist; or
2. When requested medication is being used for pre/post-operative prophylaxis.

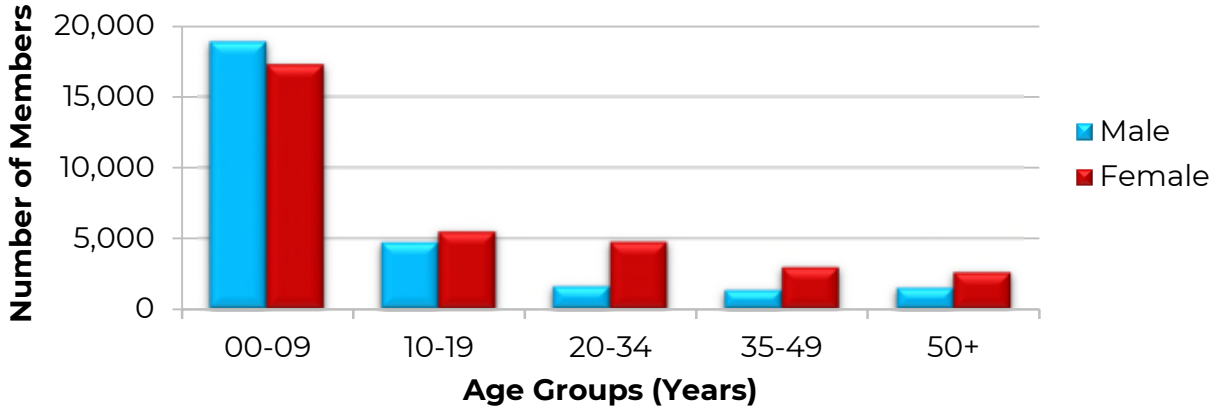
## Utilization of Ophthalmic Antibiotic Medications: Fiscal Year 2023

**Comparison of Fiscal Years**

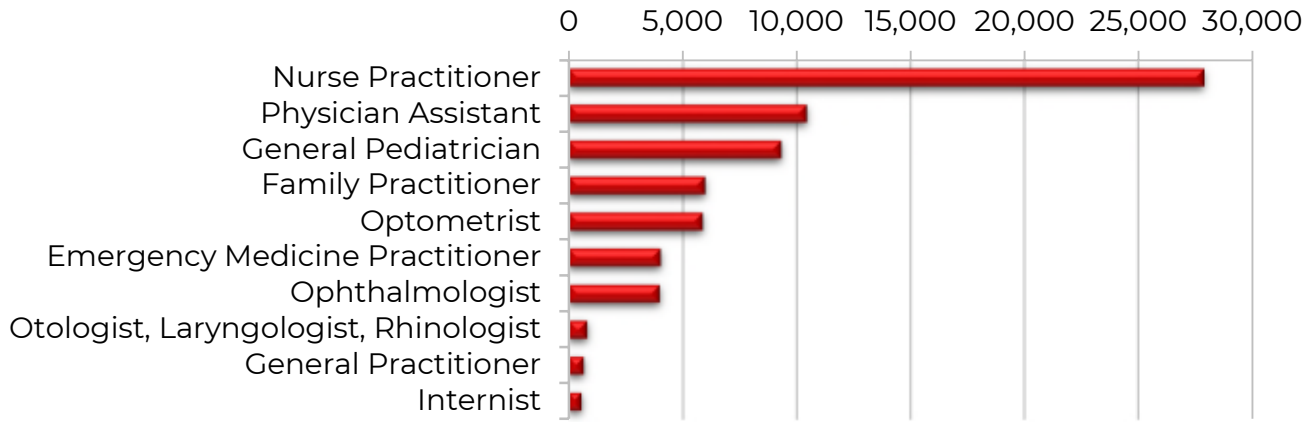
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 41,160 | 48,491 | $1,012,565.86 | $20.88 | $1.46 | 313,370 | 694,933 |
| **2023** | 60,883 | 72,119 | $1,408,387.27 | $19.53 | $1.42 | 454,105 | 994,780 |
| **% Change** | **47.90%** | **48.70%** | **39.10%** | **-6.50%** | **-2.70%** | **44.90%** | **43.10%** |
| **Change** | **19,723** | **23,628** | **$395,821.41** | **-$1.35** | **-$0.04** | **140,735** | **299,847** |

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

**Demographics of Members Utilizing Ophthalmic Antibiotic Medications**



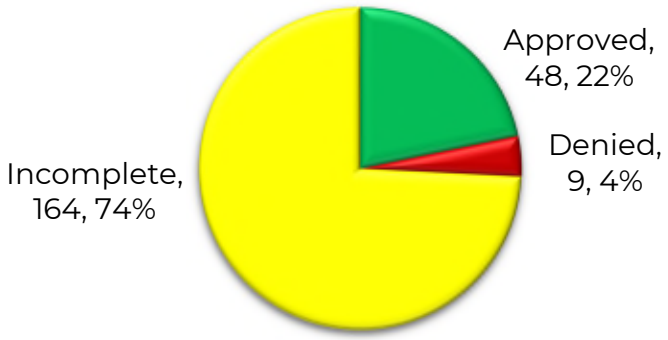

**Top Prescriber Specialties of Ophthalmic Antibiotic Medications by Number of Claims**




## Prior Authorization of Ophthalmic Antibiotic Medications

There were 221 prior authorization requests submitted for ophthalmic antibiotic medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

**Status of Petitions**



## Market News and Updates[1]

### Anticipated Patent Expiration(s):

- Tobradex® ST (tobramycin/dexamethasone ophthalmic suspension): August 2028
- Moxeza® (moxifloxacin ophthalmic solution): May 2029
- Besivance® (besifloxacin ophthalmic suspension): January 2031

## Recommendations

The College of Pharmacy does not recommend any changes to the ophthalmic antibiotic medications Product Based Prior Authorization (PBPA) category at this time.

## Utilization Details of Ophthalmic Antibiotic Medications: Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| **OPHTHALMIC ANTIBIOTIC LIQUIDS** | | | | | | |
| **TIER-1 PRODUCTS** | | | | | | |
| OFLOXACIN DRO 0.3% OP | 18,006 | 16,413 | $364,915.72 | $20.27 | 1.1 | 25.91% |
| POLYMYXIN B/TRIMETH SOL | 17,006 | 16,316 | $263,805.68 | $15.51 | 1.04 | 18.73% |
| TOBRAMYCIN SOL 0.3% OP | 5,258 | 4,984 | $75,331.87 | $14.33 | 1.05 | 5.35% |
| CIPROFLOXACIN SOL 0.3% OP | 3,657 | 3,418 | $67,444.58 | $18.44 | 1.07 | 4.79% |
| GENTAMICIN SOL 0.3% OP | 3,547 | 3,343 | $50,362.16 | $14.20 | 1.06 | 3.58% |
| SULFACET SOD SOL 10% OP | 589 | 576 | $24,599.41 | $41.76 | 1.02 | 1.75% |
| NEO/POLY/GRAM SOL OP | 60 | 58 | $3,228.65 | $53.81 | 1.03 | 0.23% |
| TRIMETH/POLYMYXN SOL | 36 | 36 | $548.05 | $15.22 | 1 | 0.04% |
| **SUBTOTAL** | **48,159** | **45,144** | **$850,236.12** | **$17.65** | **1.07** | **60.37%** |
| **TIER-3 PRODUCTS** | | | | | | |
| MOXIFLOXACIN SOL HCL 0.5% | 1,286 | 904 | $25,785.33 | $20.05 | 1.42 | 1.83% |
| BESIVANCE SUS 0.6% | 106 | 90 | $20,930.44 | $197.46 | 1.18 | 1.49% |
| GATIFLOXACIN SOL 0.5% | 80 | 64 | $2,517.74 | $31.47 | 1.25 | 0.18% |
| MOXIFLOXACIN SOL 0.5% | 7 | 7 | $139.05 | $19.86 | 1 | 0.01% |
| AZASITE SOL 1% | 4 | 4 | $952.70 | $238.18 | 1 | 0.07% |
| MOXIFLOXACIN SOL 0.5% BID | 1 | 1 | $102.87 | $102.87 | 1 | 0.01% |
| **SUBTOTAL** | **1,484** | **1,070** | **$50,428.13** | **$33.98** | **1.39** | **3.58%** |
| **LIQUID SUBTOTAL** | **49,643** | **43,974*** | **$900,664.25** | **$18.14** | **1.13** | **63.95%** |
| **OPHTHALMIC ANTIBIOTIC OINTMENTS** | | | | | | |
| **TIER-1 PRODUCTS** | | | | | | |
| ERYTHROMYCIN OIN 5MG/GM | 15,838 | 14,545 | $280,445.91 | $17.71 | 1.09 | 19.91% |
| BACITRACIN/POLY OIN OP | 208 | 179 | $4,388.97 | $21.10 | 1.16 | 0.31% |
| TOBREX OIN 0.3% OP | 56 | 50 | $12,966.87 | $231.55 | 1.12 | 0.92% |
| NEO/BAC/POLY OIN OP | 50 | 45 | $1,403.67 | $28.07 | 1.11 | 0.10% |
| AK-POLY-BAC OIN OP | 3 | 3 | $64.03 | $21.34 | 1 | 0.00% |
| **SUBTOTAL** | **16,155** | **14,822** | **$299,269.45** | **$18.52** | **1.09** | **21.25%** |

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| **TIER-2 PRODUCTS** | | | | | | |
| BACITRACIN OIN OP | 7 | 7 | $814.71 | $116.39 | 1 | 0.06% |
| CILOXAN OIN 0.3% OP | 2 | 2 | $257.49 | $128.75 | 1 | 0.02% |
| **SUBTOTAL** | **9** | **9** | **$1,072.20** | **$119.13** | **1** | **0.08%** |
| **OINTMENT SUBTOTAL** | **16,164** | **14,800*** | **$300,341.65** | **$18.58** | **1.09** | **21.33%** |
| **OPHTHALMIC ANTIBIOTIC/STEROID COMBINATION PRODUCTS** | | | | | | |
| **TIER-1 PRODUCTS** | | | | | | |
| NEO/POLY/DEX SUS 0.1% OP | 4,729 | 4,400 | $92,268.59 | $19.51 | 1.07 | 6.55% |
| NEO/POLY/DEX OIN 0.1% OP | 1,070 | 938 | $21,232.18 | $19.84 | 1.14 | 1.51% |
| TOBRADEX SUS 0.3-0.1% | 337 | 308 | $57,412.56 | $170.36 | 1.09 | 4.08% |
| TOBRADEX ST SUS 0.3-0.05 | 49 | 42 | $11,414.40 | $232.95 | 1.17 | 0.81% |
| SULFACET/PRED NA SOL 10-0.23% OP | 32 | 25 | $725.60 | $22.68 | 1.28 | 0.05% |
| **SUBTOTAL** | **6,217** | **5,713** | **$183,053.33** | **$29.44** | **1.09** | **13.00%** |
| **TIER-2 PRODUCTS** | | | | | | |
| TOBRADEX OIN 0.3-0.1% | 62 | 58 | $15,110.07 | $243.71 | 1.07 | 1.07% |
| ZYLET SUS 0.5-0.3% | 30 | 28 | $9,011.07 | $300.37 | 1.07 | 0.64% |
| NEO/POLY/BAC/HC OIN 1% OP | 2 | 1 | $73.78 | $36.89 | 2 | 0.01% |
| NEO/POLY/HC SUS OP | 1 | 1 | $133.12 | $133.12 | 1 | 0.01% |
| **SUBTOTAL** | **95** | **88** | **$24,328.04** | **$256.08** | **1.08** | **1.73%** |
| **COMBINATION SUBTOTAL** | **6,312** | **5,661*** | **$207,381.37** | **$32.86** | **1.11** | **14.72%** |
| **TOTAL** | **72,119** | **60,883*** | **$1,408,387.27** | **$19.53** | **1.18** | **100%** |

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BAC = bacitracin; BID = twice daily formulation; DEX = dexamethasone; DRO = drops; GRAM = gramicidin; HC = hydrocortisone; HCL = hydrochloride; NA = sodium; NEO = neomycin; OIN = ointment; OP = ophthalmic; POLY = polymyxin; PRED = prednisolone; SOD = sodium; SOL = solution; ST = suspension technology; SULFACET = sulfacetamide; SUS = suspension; TRIMETH = trimethoprim
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2023. Last Accessed 08/18/2023.

# Fiscal Year 2023 Annual Review of Parathryoid Medications

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Hectorol® (Doxercalciferol Capsule) Approval Criteria:**

1. An FDA approved diagnosis; and
2. Member must have a documented failure or a clinically significant reason why the member cannot use calcitriol.

**Natpara® (Parathyroid Hormone Injection) Approval Criteria:**

1. An FDA approved indication for use as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism; and
   a. Natpara® is not FDA approved for hypoparathyroidism caused by calcium-sensing receptor mutations; and
   b. Natpara® is not FDA approved for hypoparathyroidism due to acute post-surgery; and
2. Magnesium deficiency must be ruled out; and
3. Member must have pretreatment serum calcium >7.5mg/dL before starting Natpara®; and
4. Prescriber must verify the member has sufficient 25-hydroxyvitamin D level per standard of care; and
5. Member must be unable to be adequately well controlled on calcium supplements and active forms of vitamin D alone; and
6. Health care provider and dispensing pharmacy must be certified through the Natpara® Risk Evaluation and Mitigation Strategies (REMS) program; and
7. A quantity limit of 2 cartridges [each package contains (2) 14-day cartridges] per 28 days will apply. The maximum covered dose will be 100mcg per day.

**Parsabiv® (Etelcalcetide Injection) Approval Criteria:**

1. An FDA approved indication for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on hemodialysis; and
2. Parsabiv® will not be approved for parathyroid carcinoma, primary hyperparathyroidism, or in patients with CKD who are not on hemodialysis (Parsabiv® is not recommended for use in these populations); and

3. Member's corrected serum calcium should be at or above the lower limit of normal (≥8.3mg/dL) prior to initiation, dose increase, or re-initiation of Parsabiv®; and
4. Parsabiv® must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
5. Member must have a documented failure or a clinically significant reason why the member cannot use available generic vitamin D analogs including calcitriol; and
6. Member must have a documented failure or a clinically significant reason why the member cannot use Sensipar® (cinacalcet); and
7. A quantity limit of 12 vials per month will apply.

**Rayaldee® [Calcifediol Extended-Release (ER) Capsule] Approval Criteria:**

1. An FDA approved indication for the treatment of secondary hyperparathyroidism (SHPT) in adults with chronic kidney disease (CKD) stage 3 or 4; and
2. Member must not have CKD stage 5 or end-stage renal disease on dialysis; and
3. Member should have a serum total 25-hydroxyvitamin D level <30ng/mL before starting treatment; and
4. Member should have a serum calcium level <9.8mg/dL before initiating treatment; and
5. Rayaldee® must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
6. Member must have a documented failure or clinically-significant reason why the member cannot use available generic vitamin D analogs including calcitriol; and
7. Initial approval will be for 30mcg daily for 3 months; and
    a. After 3 months, approval for 60mcg daily for 12 months can be considered if intact parathyroid hormone (iPTH) is above the treatment goal and serum calcium is <9.8mg/dL, phosphorus is <5.5mg/dL, and 25-hydroxyvitamin D is <100ng/mL; and
    b. Additional approvals will not be granted if iPTH is persistently abnormally low, serum calcium is consistently above the normal range, or serum 25-hydroxyvitamin D is consistently >100ng/mL; and
8. A quantity limit of 60 capsules per 30 days will apply.

**Zemplar® (Paricalcitol Capsule) Approval Criteria:**

1. Member must be 10 years of age or older; and
2. An FDA approved indication for the prevention and treatment of secondary hyperparathyroidism (SHPT) associated with 1 of the following:
    a. Chronic kidney disease (CKD) stage 3 or 4; or

b. CKD stage 5 in members on hemodialysis or peritoneal dialysis; and
    i. Members with CKD stage 5 should have a corrected total serum calcium ≤9.5mg/dL before initiating treatment; and
3. Zemplar® must be prescribed by a nephrologist, endocrinologist, or provider who specializes in the treatment of SHPT; and
4. Member must have a documented failure or a clinically significant reason why the member cannot use other generic vitamin D analogs available without prior authorization including calcitriol and Zemplar® injection; and
5. A quantity limit of 30 capsules per 30 days will apply.

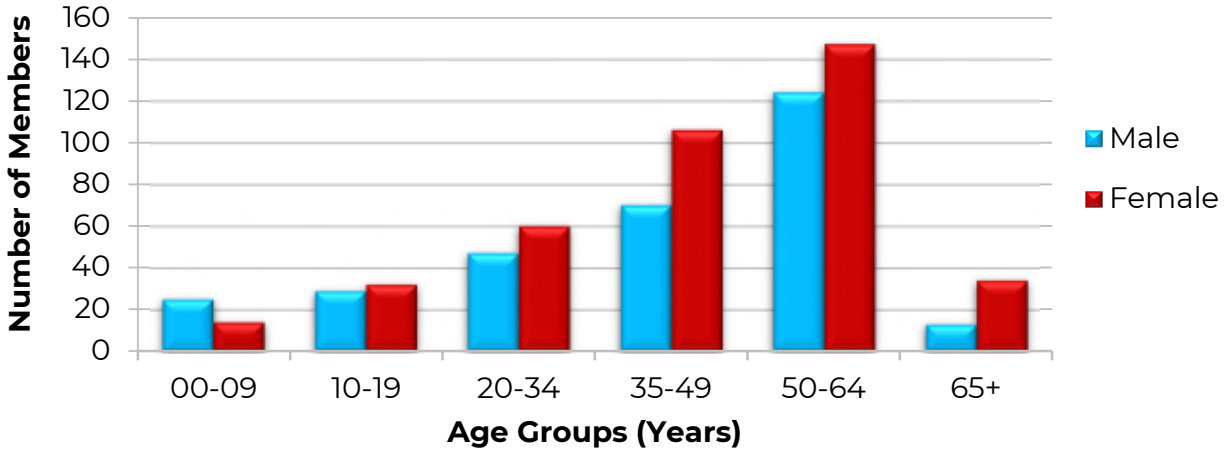
## Utilization of Parathyroid Medications: Fiscal Year 2023

### Comparison of Fiscal Years: Calcimimetics and Vitamin D Analogs

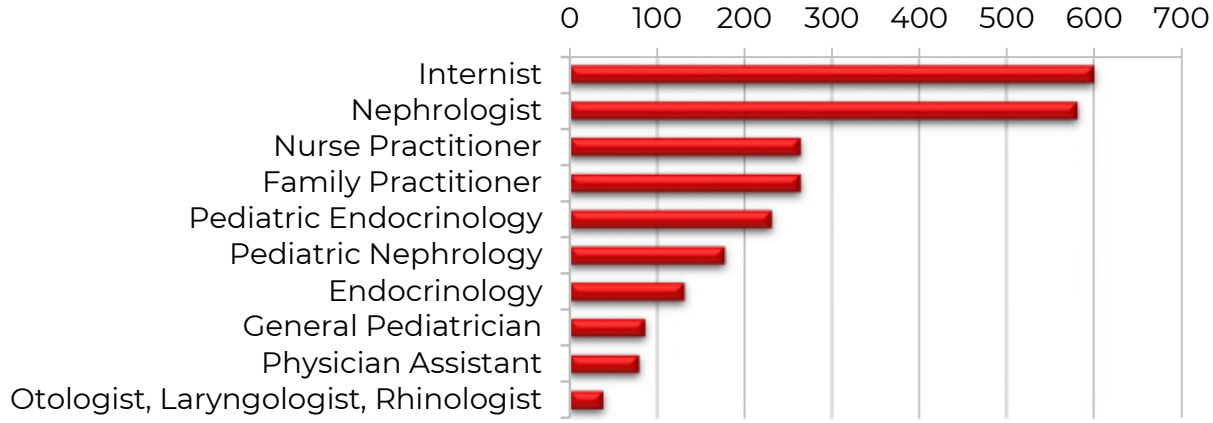
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 549 | 2,187 | $89,412.38 | $40.88 | $1.00 | 101,060 | 89,097 |
| **2023** | 701 | 2,630 | $91,617.01 | $34.84 | $0.84 | 127,769 | 109,054 |
| **% Change** | **27.7%** | **20.3%** | **2.5%** | **-14.8%** | **-16.0%** | **26.4%** | **22.4%** |
| **Change** | **152** | **443** | **$2,204.63** | **-$6.04** | **-$0.16** | **26,709** | **19,957** |

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023
Please note: There were no paid claims for Natpara® during fiscal years 2022 or 2023.

### Demographics of Members Utilizing Parathyroid Medications



**Top Prescriber Specialties of Parathyroid Medications by Number of Claims**




## Prior Authorization of Parathyroid Medications

There were 59 prior authorization requests submitted for parathyroid medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

**Status of Petitions**


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

**Anticipated Patent Expiration(s):**

- Sensipar® (cinacalcet tablets): September 2026
- Rayaldee® [calcifediol extended-release (ER) capsules]: March 2034
- Parsabiv® (etelcalcetide injection): June 2034

**Pipeline:**

- **TransCon PTH:** TransCon PTH is an investigational, once-daily, long-acting prodrug of parathyroid hormone (PTH) that is currently in development as a treatment for hypoparathyroidism in adults. TransCon PTH is designed to restore PTH at physiologic levels for 24 hours daily and address both short-term symptoms and long-term complications. In October 2022, the U.S. Food and Drug Administration (FDA) granted Priority Review to a New Drug Application (NDA) for

TransCon PTH, but the FDA issued a Complete Response Letter (CRL) in May 2023 due to concerns related to the manufacturing control strategies. There were no concerns about the clinical data that was submitted. Ascendis plans to request a meeting with the FDA to assess what is needed to move forward.

## Recommendations

The College of Pharmacy does not recommend any changes to the current parathyroid medications prior authorization criteria at this time.

## Utilization Details of Parathyroid Medications: Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| **VITAMIN-D ANALOG PRODUCTS** | | | | | | |
| **CALCITRIOL PRODUCTS** | | | | | | |
| CALCITRIOL CAP 0.25MCG | 1,262 | 406 | $22,784.88 | $18.05 | 3.11 | 24.87% |
| CALCITRIOL CAP 0.5MCG | 509 | 154 | $13,333.72 | $26.20 | 3.31 | 14.55% |
| CALCITRIOL SOL 1MCG/ML | 176 | 47 | $15,990.25 | $90.85 | 3.74 | 17.45% |
| ROCALTROL SOL 1MCG/ML | 1 | 1 | $226.06 | $226.06 | 1 | 0.25% |
| **SUBTOTAL** | **1,948** | **608** | **$52,334.91** | **$26.87** | **3.2** | **57.12%** |
| **PARICALCITOL PRODUCTS** | | | | | | |
| PARICALCITOL CAP 1MCG | 21 | 4 | $849.31 | $40.44 | 5.25 | 0.93% |
| PARICALCITOL CAP 2MCG | 9 | 2 | $899.19 | $99.91 | 4.5 | 0.98% |
| PARICALCITOL INJ 5MCG/ML | 4 | 1 | $1,195.64 | $298.91 | 4 | 1.31% |
| **SUBTOTAL** | **34** | **7** | **$2,944.14** | **$86.59** | **4.86** | **3.22%** |
| **CALCIFEDIOL PRODUCTS** | | | | | | |
| RAYALDEE CAP 30MCG | 6 | 1 | $6,659.63 | $1,109.94 | 6 | 7.27% |
| **SUBTOTAL** | **6** | **1** | **$6,659.63** | **$1,109.94** | **6** | **7.27%** |
| **VITAMIN D ANALOG SUBTOTAL** | **1,988** | **616** | **$61,938.68** | **$31.16** | **3.23** | **67.61%** |
| **CALCIMIMETIC PRODUCTS** | | | | | | |
| **CINACALCET PRODUCTS** | | | | | | |
| CINACALCET TAB 30MG | 437 | 121 | $10,861.04 | $24.85 | 3.61 | 11.85% |
| CINACALCET TAB 60MG | 144 | 41 | $5,744.72 | $39.89 | 3.51 | 6.27% |
| CINACALCET TAB 90MG | 58 | 16 | $3,125.67 | $53.89 | 3.63 | 3.41% |
| **SUBTOTAL** | **639** | **178** | **$19,731.43** | **$30.88** | **3.59** | **21.53%** |
| **ETELCALCETIDE PRODUCTS** | | | | | | |
| PARSABIV INJ 2.5MG/0.5ML | 3 | 1 | $9,946.90 | $3,315.63 | 3 | 10.86% |
| **SUBTOTAL** | **3** | **1** | **$9,946.90** | **$3,315.63** | **3** | **10.86%** |
| **CALCIMIMETIC SUBTOTAL** | **642** | **179** | **$29,678.33** | **$46.23** | **3.59** | **32.39%** |
| **TOTAL** | **2,630** | **701*** | **$91,617.01** | **$34.84** | **3.75** | **100%** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2023. Last accessed 08/18/2023.
[2] Ascendis Pharma. TransCon PTH. Available online at: https://ascendispharma.com/pipeline/endocrinology/transcon-pth/. Last accessed 08/18/2023.
[3] Ascendis Pharma. FDA Accepts for Priority Review Ascendis Pharma's NDA for TransCon™ PTH in Adult Patients with Hypoparathyroidism. *Globe Newswire*. Available online at: https://www.globenewswire.com/news-release/2022/10/31/2544511/0/en/FDA-Accepts-for-Priority-Review-Ascendis-Pharma-s-NDA-for-TransCon-PTH-in-Adult-Patients-with-Hypoparathyroidism.html. Issued 10/31/2022. Last accessed 08/18/2023.
[4] Ascendis Pharma. U.S. Food & Drug Administration Issues Complete Response Letter for TransCon™ PTH in Hypoparathyroidism. Available online at: https://investors.ascendispharma.com/news-releases/news-release-details/us-food-drug-administration-issues-complete-response-letter. Issued 05/01/2023. Last accessed 08/18/2023.

# Fiscal Year 2023 Annual Review of Revcovi® (Elapegademase-lvlr)

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Revcovi® (Elapegademase-lvlr) Approval Criteria:**

1. An FDA approved diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult members; and
    a. Diagnosis of ADA deficiency should be confirmed by genetic testing demonstrating biallelic mutations in the *ADA* gene; and
2. Revcovi® must be prescribed by, or in consultation with, a physician who specializes in the treatment of immune deficiency disorders; and
3. The member must have failed to respond to a bone marrow transplant or not be a current suitable candidate for a bone marrow transplant; and
4. Prescriber must agree to monitor trough plasma ADA activity, trough dAXP levels, and/or total lymphocyte counts to ensure efficacy and compliance and to monitor for neutralizing antibodies when suspected; 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; and
6. Initial approvals will be for the duration of 6 months, at which time the prescriber must confirm improvement or stabilization in ADA activity or dAXP levels or improvement in immune function. Subsequent approvals will require the prescriber to verify the member is still not a current suitable candidate for a bone marrow transplant.

## Utilization of Revcovi® (Elapegademase-lvlr): Fiscal Year 2023

There was no SoonerCare utilization of Revcovi® (elapegademase-lvlr) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Prior Authorization of Revcovi® (Elapegademase-lvlr)

There were no prior authorization requests submitted for Revcovi® (elapegademase-lvlr) during fiscal year 2023 (07/01/2022 to 06/30/2023).

## Recommendations

The College of Pharmacy does not recommend any changes to the current Revcovi® (elapegademase-lvlr) prior authorization criteria at this time.

# Fiscal Year 2023 Annual Review of Thrombocytopenia Medications

**Oklahoma Health Care Authority**
**Fiscal Year 2023 Print Report**

## Current Prior Authorization Criteria

**Cablivi® (Caplacizumab-yhdp) Approval Criteria:**

1. An FDA approved indication for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive therapy; and
2. Member must be undergoing plasma exchange therapy; and
    a. Dates of initiation of plasma exchange therapy must be listed on the prior authorization request; and
    b. Authorizations will be for the duration of plasma exchange and for 30 days after discontinuation of plasma exchange; and
3. Member must be utilizing immunosuppressant therapy; and
4. Cablivi® must be prescribed by, or in consultation with, a hematologist; and
5. A quantity limit of 11mg per day will apply. Initial approvals will be for the duration of plasma exchange plus 30 days. Reauthorization, after completing 30 days post-plasma exchange, may be considered if the prescriber documents sign(s) of persistent underlying disease remain. Reauthorization will be for a maximum of 28 days.

**Doptelet® (Avatrombopag) Approval Criteria [Chronic Immune Thrombocytopenia (ITP) Diagnosis]:**

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic ITP who have had an insufficient response to a previous treatment; and
2. Member must be 18 years of age or older; and
3. Previous insufficient response with at least 1 of the following treatments:
    a. Corticosteroids; or
    b. Immunoglobulins; or
    c. Splenectomy; and
4. A patient-specific, clinically significant reason why the member cannot use an alternative thrombopoietin (TPO) receptor agonist available without a prior authorization must be provided; and
5. Prescriber must verify the degree of thrombocytopenia and clinical condition increase the risk for bleeding; and

6. Prescriber must verify platelet counts will be assessed weekly until a stable platelet count >50 x $10^9$/L has been achieved, and then obtained monthly thereafter; and
7. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
8. Doptelet® must not be used in an attempt to normalize platelet counts; and
9. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
10. Prescriber must verify female member is not breastfeeding; and
11. A quantity limit of 60 tablets per 30 days will apply.

**Doptelet® (Avatrombopag) Approval Criteria [Thrombocytopenia in Chronic Liver Disease (CLD) Diagnosis]:**

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with CLD who are scheduled to undergo a procedure; and
2. Date of procedure must be listed on the prior authorization request; and
3. Prescriber must verify the member will have the procedure within 5 to 8 days after the member receives the last dose of Doptelet®; and
4. Member must have a baseline platelet count <50 x $10^9$/L (recent baseline platelet count must be provided); and
5. Must be prescribed by, or in consultation with, a hematologist, gastroenterologist, or hepatologist; and
6. Doptelet® must not be used in an attempt to normalize platelet counts; and
7. Female members must not be pregnant and must have a negative pregnancy test prior to therapy initiation; and
8. Prescriber must verify female member is not breastfeeding; and
9. A quantity limit of 15 tablets per scheduled procedure will apply.

**Mulpleta® (Lusutrombopag) Approval Criteria:**

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic liver disease (CLD) who are scheduled to undergo a procedure; and
2. Date of procedure must be listed on the prior authorization request; and
3. Prescriber must verify the member will have the procedure 2 to 8 days after the member receives the last dose of Mulpleta®; and
4. Member must have a baseline platelet count <50 x $10^9$/L (recent baseline platelet count must be provided); and
5. Must be prescribed by, or in consultation with, a hematologist, gastroenterologist, or hepatologist; and

6. Mulpleta® must not be used in an attempt to normalize platelet counts; and
7. A quantity limit of 7 tablets per scheduled procedure will apply.

**Tavalisse® (Fostamatinib) Approval Criteria:**

1. An FDA approved indication for the treatment of thrombocytopenia in adult members with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment; and
2. Member must be 18 years of age or older (Tavalisse® is not recommended for use in patients younger than 18 years of age because adverse effects on actively growing bones were observed in nonclinical studies); and
3. Member must have a clinical diagnosis of persistent/chronic ITP for at least 3 months; and
4. Previous insufficient response with at least 2 of the following treatments:
    a. Corticosteroids; or
    b. Immunoglobulins; or
    c. Splenectomy; or
    d. Thrombopoietin (TPO) receptor agonists; and
5. Prescriber must verify degree of thrombocytopenia and clinical condition increase the risk for bleeding; and
6. Must be prescribed by, or in consultation with, a hematologist or oncologist; and
7. Prescriber must verify the member's complete blood count (CBC), including platelet counts, will be monitored monthly until a stable platelet count (at least 50 x $10^9$/L) is achieved and will be monitored regularly thereafter; and
8. Prescriber must verify liver function tests (LFTs) (e.g., ALT, AST, bilirubin) will be monitored monthly; and
9. Prescriber must verify member's blood pressure will be monitored every 2 weeks until establishment of a stable dose, then monthly thereafter; and
10. 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 for at least 1 month after therapy completion; and
11. Prescriber must verify female member is not breastfeeding; and
12. Member must not be taking strong CYP3A4 inducers (e.g., rifampicin) concurrently with Tavalisse®; and
13. Initial approvals will be for the duration of 12 weeks; and
14. Discontinuation criteria:

a. Platelet count does not increase to a level sufficient to avoid clinically important bleeding after 12 weeks of therapy; and

15. A quantity limit of 2 tablets per day will apply.

## Utilization of Thrombocytopenia Medications: Fiscal Year 2023

### Comparison of Fiscal Years: Pharmacy Claims

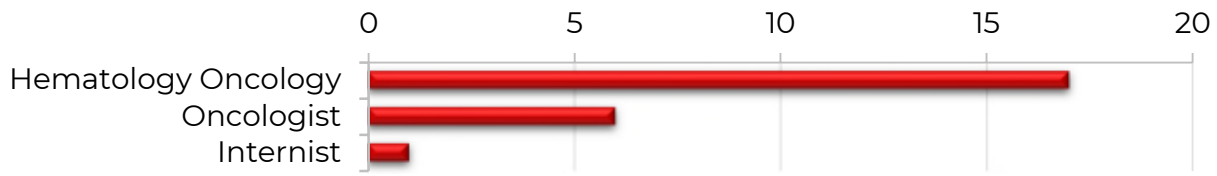
| Fiscal Year | *Total Members | Total Claims | Total Cost | Cost/ Claim | Cost/ Day | Total Units | Total Days |
|---|---|---|---|---|---|---|---|
| **2022** | 7 | 23 | $273,954.01 | $11,911.04 | $444.01 | 1,232 | 617 |
| **2023** | 8 | 25 | $457,588.60 | $18,303.54 | $817.12 | 980 | 560 |
| **% Change** | **14.3%** | **8.7%** | **67.0%** | **53.7%** | **84.0%** | **-20.5%** | **-9.2%** |
| **Change** | **1** | **2** | **$183,634.59** | **$6,392.50** | **$373.11** | **-252** | **-57** |

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

### Demographics of Members Utilizing Thrombocytopenia Medications

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

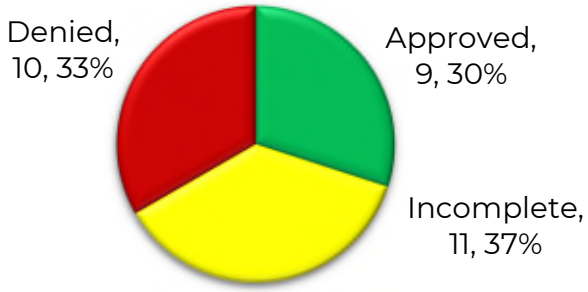
### Top Prescriber Specialties of Thrombocytopenia Medications by Number of Claims




## Prior Authorization of Thrombocytopenia Medications

There were 30 prior authorization requests submitted for thrombocytopenia medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

### Status of Petitions



## Market News and Updates[1]

### Anticipated Patent Expiration(s):

- Doptelet® (avatrombopag): May 2025
- Mulpleta® (lusutrombopag): September 2031
- Tavalisse® (fostamatinib): July 2032

## Recommendations

The College of Pharmacy does not recommend any changes to the current thrombocytopenia medications prior authorization criteria at this time.

## Utilization Details of Thrombocytopenia Medications: Fiscal Year 2023

| PRODUCT UTILIZED | TOTAL CLAIMS | TOTAL MEMBERS | TOTAL COST | COST/ CLAIM | CLAIMS/ MEMBER | % COST |
|---|---|---|---|---|---|---|
| **FOSTAMATINIB PRODUCTS** | | | | | | |
| TAVALISSE TAB 150MG | 11 | 2 | $147,206.51 | $13,382.41 | 5.5 | 32.17% |
| TAVALISSE TAB 100MG | 4 | 1 | $39,869.64 | $9,967.41 | 4 | 8.71% |
| **SUBTOTAL** | **15** | **3** | **$187,076.15** | **$12,471.74** | **5** | **40.88%** |
| **AVATROMBOPAG PRODUCTS** | | | | | | |
| DOPTELET TAB 20MG | 9 | 4 | $42,745.04 | $4,749.45 | 2.25 | 9.34% |
| **SUBTOTAL** | **9** | **4** | **$42,745.04** | **$4,749.45** | **2.25** | **9.34%** |
| **CAPLACIZUMAB PRODUCTS** | | | | | | |
| CABLIVI KIT 11MG | 1 | 1 | $227,767.41 | $227,767.41 | 1 | 49.78% |
| **SUBTOTAL** | **1** | **1** | **$227,767.41** | **$227,767.41** | **1** | **49.78%** |
| **TOTAL** | **25** | **8*** | **$457,588.60** | **$18,303.54** | **3.13** | **100%** |

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 09/2023. Last accessed 09/21/2023.