State Fiscal Year 2022 Print Annual Reviews
Quarter 1

Count	Category/Medication
1.	Allergen Immunotherapies
2.	Botulinum Toxins
3.	Cholbam® (Cholic Acid)
4.	Chorionic Gonadotropin Medications
5.	Cystadrops® (Cysteamine) and Cystaran® (Cysteamine)
6.	Defitelio® (Defibrotide)
7.	Dry Eye Disease (DED) Medications
8.	Gamifant® (Emapalumab-lzsg)
9.	Hyperkalemia Medications
10.	Jynarque® (Tolvaptan)
11.	Keveyis® (Dichlorphenamide)
12.	Korlym® (Mifepristone)
13.	Lidocaine Topical Products
14.	Ocaliva® (Obeticholic acid)
15.	Ophthalmic Antibiotic Medications
16.	Oxlumo® (Lumasiran)
17.	Parathyroid Medications
18.	Revcovi® (Elapegademase-lvlr)
19.	Tepezza® (Teprotumumab-trbw)
20.	Thrombocytopenia Medications
21.	Vimizim® (Elosulfase alfa)
22.	Zinplava™ (Bezlotoxumab)

Fiscal Year 2022 = July 1, 2021 – June 30, 2022

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 2022 Annual Review of Allergen Immunotherapies

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Grastek® (Timothy Grass Pollen Allergen Extract) Approval Criteria*:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test (labs required) or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies for Timothy grass or cross-reactive grass pollen (cool season grasses); and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of the grass pollen season (November 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy, also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

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

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

Oralair® (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract) Approval Criteria*:

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to 1 of the 5 grass pollens contained in Oralair®; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):

a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and

6. Treatment must begin ≥16 weeks prior to the start of the grass pollen season (October 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 16 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy, also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and
12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

Palforzia® (Peanut Allergen Powder-dnfp) Approval Criteria*:

1. Member must be 4 to 17 years of age to initiate initial dose escalation (maintenance dosing may be continued for members 4 years of age and older); and
2. Member must have a diagnosis of peanut allergy confirmed by a positive skin test, positive *in vitro* test for peanut-specific immunoglobulin E (IgE), or positive clinician-supervised oral food challenge; and
3. Prescriber must confirm member will use Palforzia® with a peanut-avoidant diet; and
4. Member must not have severe uncontrolled asthma; and
5. Member must not have a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
6. Member must not have had severe or life-threatening anaphylaxis within the previous 60 days; and
7. Member or caregiver must be trained in the use of an auto-injectable epinephrine device and have such a device available for immediate use at all times; and
8. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist); and

9. Prescriber, health care setting, and pharmacy must be certified in the Palforzia® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Palforzia® REMS program; and
11. Palforzia® must be administered under the direct observation of a health care provider in a REMS certified health care setting with an observation duration in accordance with the Palforzia® *Prescribing Information*; and
12. After successful completion of initial dose escalation and all levels of up-dosing as documented by the prescriber, initial approvals of maintenance dosing will be for 6 months. For continued approval, the member must be compliant, and prescriber must verify the member is responding well to treatment.

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

1. Member must be 18 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to short ragweed pollen; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and
    b. **Intranasal corticosteroids:** Trials of 2 different products for 21 days each during a previous season; and
6. Treatment must begin ≥12 weeks prior to the start of ragweed pollen season (May 15th) and continue throughout the season; and
7. The first dose must be given in the physician's office, and the member must be observed for at least 30 minutes post dose; and
8. A quantity limit of 1 tablet daily will apply; and
9. Initial approvals will be for the duration of 6 months of therapy to include 12 weeks prior to the season and continue throughout the season; and
10. Member must not be allergic to other allergens for which they are receiving treatment via subcutaneous immunotherapy, also known as "allergy shots"; and
11. Member or family member must be trained in the use of an auto-injectable epinephrine device and have such a device available for use at home; and

12. Prescriber must be an allergist or immunologist (or an advanced care practitioner with a supervising physician who is an allergist or immunologist).

*Current prior authorization criteria are only applicable to allergen immunotherapies with a current federal drug rebate agreement. All criteria, regardless of coverage, are provided in this report for informational purposes.

Utilization of Allergen Immunotherapies: Fiscal Year 2022

Fiscal Year 2022 Utilization: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	1	6	$2,694.24	$449.04	$14.97	180	180

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
Please note: There was no SoonerCare utilization of allergen immunotherapies during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

Demographics of Members Utilizing Allergen Immunotherapies

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

Top Prescriber Specialties of Allergen Immunotherapies by Number of Claims

- The only prescriber specialty listed on paid pharmacy claims for allergen immunotherapies during fiscal year 2022 was allergist.

Prior Authorization of Allergen Immunotherapies

There were 6 prior authorization requests submitted for allergen immunotherapies during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions

Market News and Updates[1,2]

Pipeline:

- **CA002:** CA002 is a peanut protein-based biological drug for oral immunotherapy being developed by Camallergy. The regimen includes a single dose at the initial appointment and a 7-stage dose escalation period completed in 4 months or less with the goal of increasing the dose of peanut protein and then maintaining a steady dose indefinitely. A Phase 2 study showed the safety and efficacy of CA002 compared to standard of care (SOC, peanut avoidance) in children 7 to 16 years of age. In the first phase of the study, of the patients who received CA002, 62% tolerated 1,400mg of peanut protein compared to none of the SOC patients. Of the patients who received CA002, 84% tolerated 800mg. In the second phase, the SOC patients received CA002. Of the patients who received CA002, 54% and 91% tolerated 1,400mg and 800mg, respectively, of peanut protein. Mild side effects occurred in most patients, with gastrointestinal symptoms being the most common (31 patients had nausea and 31 had vomiting). A Phase 3 study is being planned to evaluate the safety and efficacy of CA002 in patients 4 years of age and older with peanut allergy.
- **Omalizumab:** A study called OUtMATCH supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, Genentech, and Novartis Pharmaceuticals Corporation to test the ability of biweekly or monthly injections of omalizumab, alone or together with multi-allergen oral immunotherapy (OIT), to increase a person's ability to tolerate foods to which they are allergic launched in 2019. The NIAID-supported Consortium of Food Allergy Research (CoFAR) is conducting OUtMATCH at 10 clinical sites throughout the United States. The study aims to enroll 225 participants 2 years to younger than 56 years of age with an allergy to peanut and at least 2 other foods, such as cow's milk, egg white, wheat, cashew, hazelnut, or walnut. Data from earlier studies suggested that omalizumab may help prevent allergic reactions to small amounts of food allergens, like those that may be consumed accidentally. Also, NIAID-supported studies indicated that omalizumab, given for a few weeks at the beginning of OIT, may help prevent OIT-induced allergic reactions, which are common. In 2017, a small study of 48 people found that 83% of participants could consume 2 grams of 2 food allergens after receiving omalizumab injections and OIT. In contrast, only 33% of participants in that study who received OIT and a placebo injection could consume the same amount. OUtMATCH will take place in 3 separate stages, with each participant enrolling for about 4 years and 8 months. In 2018, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for

omalizumab for the prevention of severe allergic reactions following accidental exposure to 1 or more foods in people with allergies.

Recommendations

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

Utilization Details of Allergen Immunotherapies: Fiscal Year 2022

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ORALAIR SUB 300 IR	6	1	$2,694.24	$449.04	6
TOTAL	**6**	**1**	**$2,694.24**	**$449.04**	**6**

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

[1] Burke CW. Insight Report: Where is the Peanut Allergy Drug Pipeline Now? *BioSpace*. Available online at: https://www.biospace.com/article/insight-report-where-is-the-peanut-allergy-drug-pipeline-now-/#drug-pipeline. Issued 11/07/2019. Last accessed 09/02/2022.
[2] National Institutes of Health (NIH). News Releases. Clinical Trial to Evaluate Experimental Treatment in People Allergic to Multiple Foods. Available online at: https://www.nih.gov/news-events/news-releases/clinical-trial-evaluate-experimental-treatment-people-allergic-multiple-foods. Issued 08/01/2019. Last accessed 09/02/2022.

Fiscal Year 2022 Annual Review of Botulinum Toxins

Oklahoma Health Care Authority
Fiscal Year 2022 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**

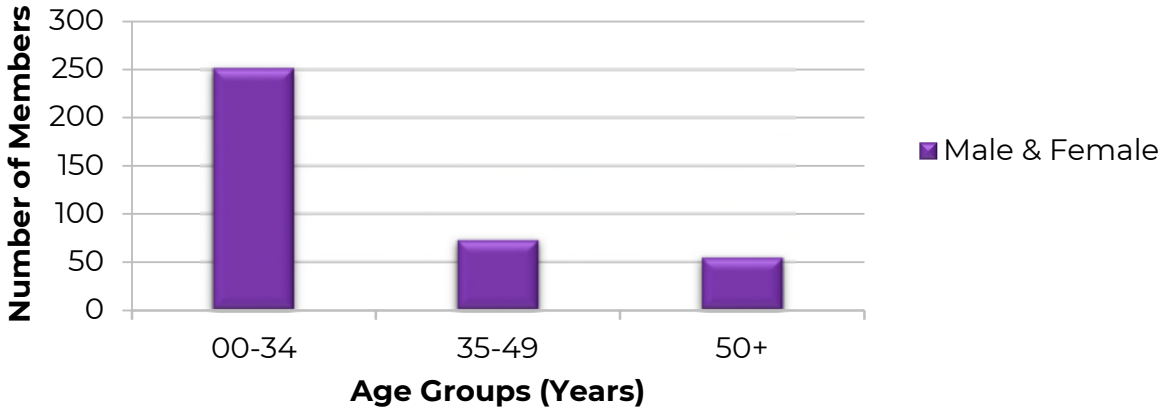
Utilization of Botulinum Toxins: Fiscal Year 2022

Comparison of Fiscal Years: Medical Claims

Fiscal Year	Total Members*	Total Claims†	Total Cost	Cost/ Claim	Total Units
2021	339	589	$851,759.50	$1,446.11	139,631
2022	377	707	$1,000,233.48	$1,414.76	162,343
% Change	**11.21%**	**20.03%**	**17.43%**	**-2.17%**	**16.27%**
Change	**38**	**118**	**$148,473.98**	**-$31.35**	**22,712**

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

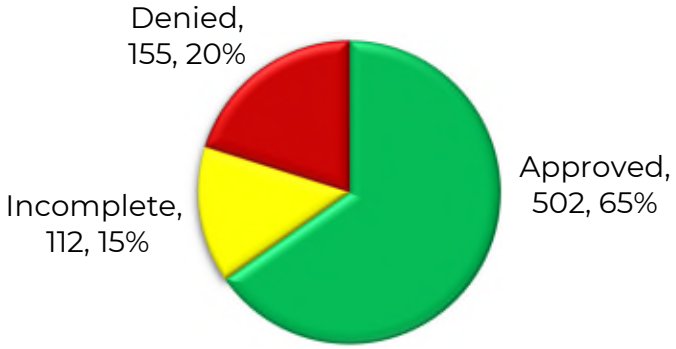
Demographics of Members Utilizing Botulinum Toxins: Medical Claims



Prior Authorization of Botulinum Toxins

There were 769 prior authorization requests submitted for botulinum toxins during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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 2022

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
BOTOX (J0585)	690	371	$979,542.76	$1,419.63	1.86
DYSPORT (J0586)	11	6	$13,710.52	$1,246.41	1.83
XEOMIN (J0588)	4	1	$3,437.20	$859.30	4
MYOBLOC (J0587)	2	1	$3,543.00	$1,771.50	2
TOTAL	**707†**	**377***	**$1,000,233.48**	**$1,414.76**	**1.88**

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 2022 Annual Review of Cholbam® (Cholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2	5	$41,432.05	$8,286.41	$276.21	150	150
2022	1	4	$33,145.64	$8,286.41	$276.21	120	120
% Change	**-50.0%**	**-20.0%**	**-20.0%**	**0.0%**	**0.0%**	**-20.0%**	**-20.0%**
Change	**-1**	**-1**	**-$8,286.41**	**$0.00**	**$0.00**	**-30**	**-30**

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

Demographics of Members Utilizing Cholbam® (Cholic Acid)

- Due to the limited number of members utilizing Cholbam® (cholic acid) during fiscal year 2022, 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 2022 was pediatric gastroenterology.

Prior Authorization of Cholbam® (Cholic Acid)

There were 5 prior authorization requests submitted for Cholbam® (cholic acid) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CHOLBAM CAP 50MG	4	1	$33,145.64	$8,286.41	4	100%
TOTAL	**4**	**1***	**$33,145.64**	**$8,286.41**	**4**	**100%**

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

Fiscal Year 2022 Annual Review of Chorionic Gonadotropin Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Fiscal Year 2022 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

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
Please note: There was no SoonerCare utilization of chorionic gonadotropin medications during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

Demographics of Members Utilizing Chorionic Gonadotropin Medications

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

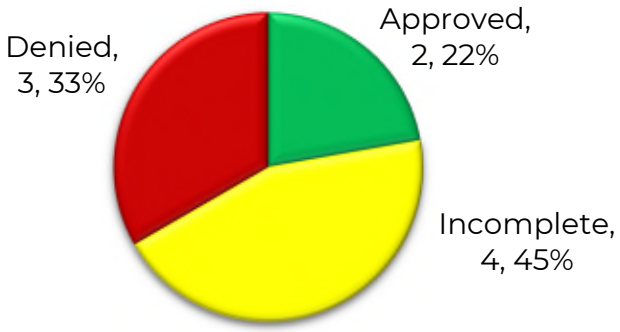
Top Prescriber Specialties of Chorionic Gonadotropin Medications by Number of Claims

- The only prescriber specialty listed on paid claims for chorionic gonadotropin medication during fiscal year 2022 was urology.

Prior Authorization of Chorionic Gonadotropin Medications

There were 9 prior authorization requests submitted for chorionic gonadotropin medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CHOR GONADOTROPIN INJ 10,000 UNITS	5	1	$1,618.30	$323.66	5	100%
TOTAL	**5**	**1***	**$1,618.30**	**$323.66**	**5**	**100%**

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

Fiscal Year 2022 Annual Review of Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Cystadrops® (Cysteamine 0.37% Ophthalmic Solution) and Cystaran® (Cysteamine 0.44% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication for the treatment of corneal cystine crystal accumulation in members with cystinosis; and
2. The requested medication must be prescribed by, or in consultation with, an ophthalmologist; and
3. Prescriber must verify that the member has been counseled on the proper storage of the requested medication; and
4. For Cystadrops®, a patient-specific, clinically significant reason (beyond convenience) why the member cannot use Cystaran® must be provided; and
5. A quantity limit of 4 bottles per month will apply.

Utilization of Cystadrops® and Cystaran®: Fiscal Year 2022

There was no SoonerCare utilization of Cystadrops® or Cystaran® during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Cystadrops® and Cystaran®

There were no prior authorization requests submitted for Cystadrops® or Cystaran® during fiscal year 2022 (07/01/2021 to 06/30/2022).

Market News and Updates[1]

Anticipated Exclusivity Expiration(s):

- Cystadrops® (cysteamine 0.37% ophthalmic solution): August 2023

Recommendations

The College of Pharmacy does not recommend any changes to the current Cystadrops® and Cystaran® 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 07/2022. Last accessed 07/21/2022.

Fiscal Year 2022 Annual Review of Defitelio® (Defibrotide)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

There was no SoonerCare utilization of Defitelio® (defibrotide) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Defitelio® (Defibrotide)

There were no prior authorization requests submitted for Defitelio® (defibrotide) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Market News and Updates[1]

Anticipated Exclusivity Expiration(s):

- Defitelio® (defibrotide): March 2023

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 07/2022. Last accessed 07/28/2022.

Fiscal Year 2022 Annual Review of Dry Eye Disease (DED) Medications

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Cequa™ (Cyclosporine 0.09% Ophthalmic Solution) Approval Criteria:

1. An FDA approved indication to increase tear production in members with keratoconjunctivitis sicca (dry eye); and
2. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided; and
4. A quantity limit of 60 single-use vials (1 box) per 30 days will apply.

Eysuvis® (Loteprednol Etabonate 0.25% Ophthalmic Suspension) Approval Criteria:

1. An FDA approved indication for the short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease (DED); and
2. A documented trial of intermittent or regular artificial tear use within the past 3 months; and
3. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion), which is available without a prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Tier-1 ophthalmic corticosteroids including Lotemax® (loteprednol 0.5% suspension) must be provided; and
5. Member must not have any contraindications to Eysuvis®; and
6. A quantity limit of 8.3mL per 15 days will apply (Eysuvis® for the treatment of DED is not indicated for use beyond 15 days).

Restasis MultiDose® (Cyclosporine 0.05% Ophthalmic Emulsion) Approval Criteria:

1. A patient-specific, clinically significant reason why the member cannot use Restasis® in the individual dosage formulation (single-use vials), which is available without a prior authorization, must be provided; and
2. A patient-specific, clinically significant reason why the member cannot use Xiidra® (lifitegrast 5% ophthalmic solution) must be provided.

Tyrvaya™ (Varenicline Nasal Spray) Approval Criteria:

1. An FDA approved indication for the treatment of the signs and symptoms of dry eye disease (DED) in members 18 years of age or older; and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per product) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A patient-specific, clinically significant reason why the member cannot use all available ophthalmic preparations for the treatment of DED must be provided; and
6. A quantity limit of 8.4mL (2 bottles) per 30 days will apply.

Xiidra® (Lifitegrast) Approval Criteria:

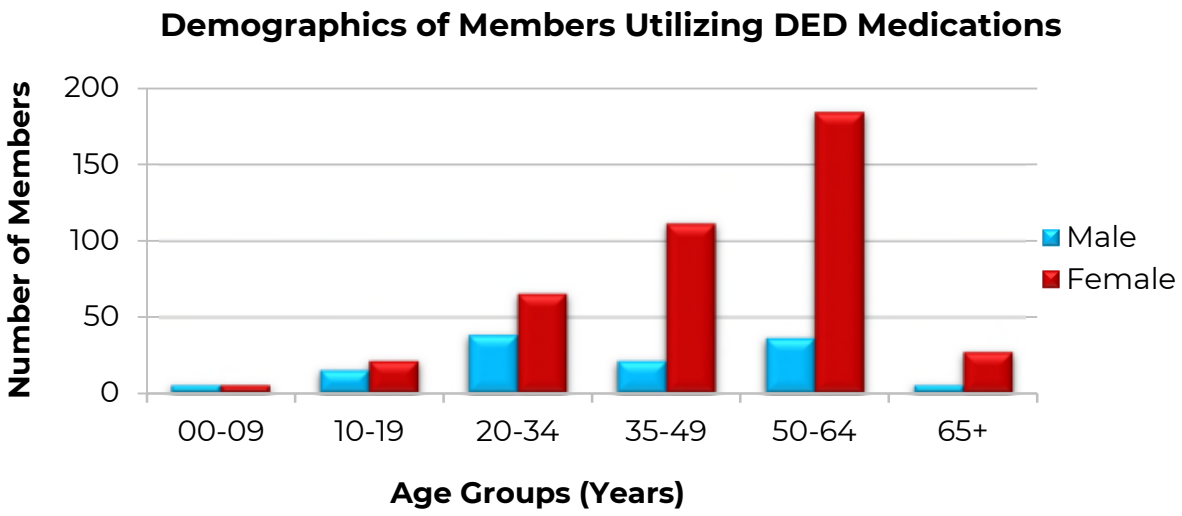
1. Member must be 17 years of age or older and have an FDA approved diagnosis of dry eye disease (DED); and
2. Prescriber must verify that environmental factors (e.g., humidity, fans) have been addressed; and
3. Member must have trials with at least 3 over-the-counter (OTC) products for at least 3 days in duration (per trial) in the last 30 days that failed to relieve signs and symptoms of DED; and
4. A patient-specific, clinically significant reason why the member cannot use Restasis® (cyclosporine ophthalmic emulsion) single-use vials, which are available without a prior authorization, must be provided; and
5. A quantity limit of 2 vials per day will apply.

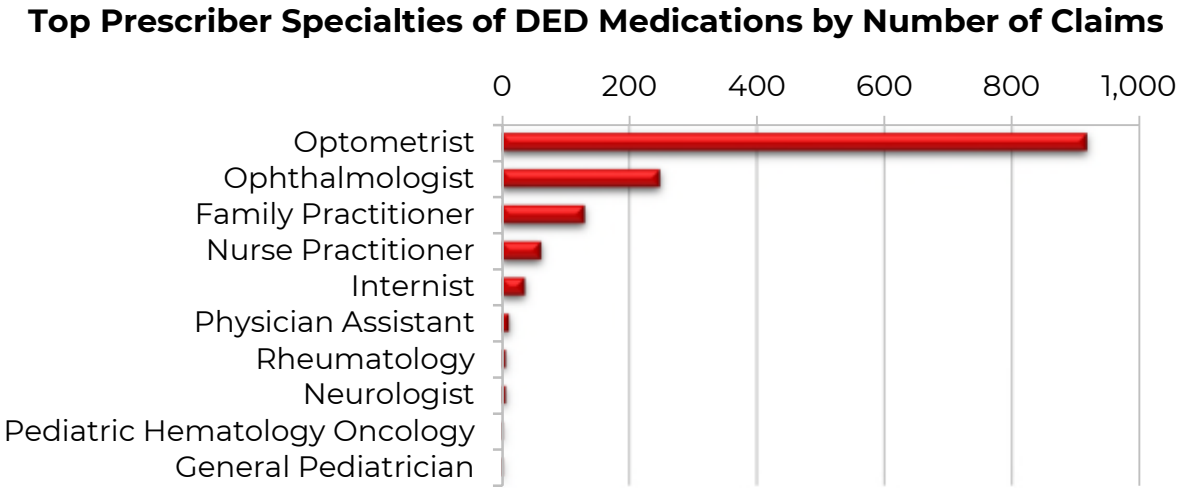
Utilization of DED Medications: Fiscal Year 2022

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	339	998	$542,560.00	$543.65	$18.75	56,040	28,935
2022	533	1,431	$769,570.01	$537.78	$17.89	82,213	43,011
% Change	**57.20%**	**43.40%**	**41.80%**	**-1.10%**	**-4.60%**	**46.70%**	**48.60%**
Change	**194**	**433**	**$227,010.01**	**-$5.87**	**-$0.86**	**26,173**	**14,076**

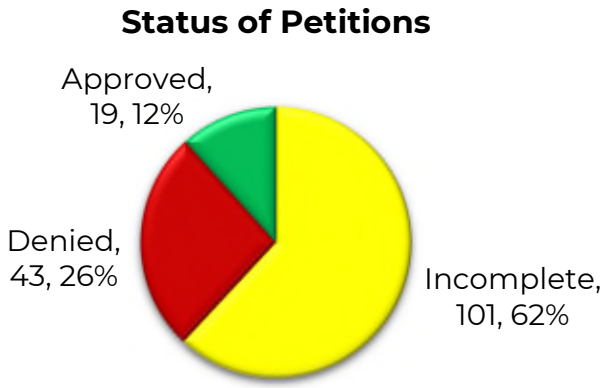
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022





Prior Authorization of DED Medications

There were 163 prior authorization requests submitted for DED medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Market News and Updates[1,2,3]

Anticipated Patent Expiration(s):

- Eysuvis® (loteprednol etabonate 0.25% ophthalmic suspension): May 2033
- Xiidra® (lifitegrast 5% ophthalmic solution): December 2033
- Restasis MultiDose® (cyclosporine 0.05% ophthalmic emulsion): May 2034
- Tyrvaya™ (varenicline nasal spray): October 2035
- Cequa™ (cyclosporine 0.09% ophthalmic solution): February 2037

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

- **February 2022:** The FDA approved the first generic formulation of Restasis® (cyclosporine 0.05% ophthalmic emulsion) single-use vials to increase tear production in patients with keratoconjunctivitis sicca (DED). The FDA approval was granted to Mylan Pharmaceuticals.

Pipeline:

- **Reproxalap:** Aldeyra has been investigating a novel agent for the treatment of DED, reproxalap, which is a small-molecule reactive aldehyde species (RASP) inhibitor. The drug is thought to fight ocular inflammation and improve dry-eye symptoms through a unique mechanism of action. While RASP molecules bind to cellular biomolecules, disrupting their function and activating pro-inflammatory mediators, reproxalap inhibits this inflammation by binding the free aldehydes and reducing RASP levels as a result. In the second quarter of 2021, results were published for the Phase 2b trial studying the effectiveness of reproxalap in reducing dry eye signs and symptoms. The agent demonstrated rapid, broad, and clinically relevant symptomatic control in a cohort of 300 patients with DED over 12 weeks of therapy. It also showed significantly greater improvement in signs of DED vs. vehicle. Results were also published from another Phase 2 clinical trial that compared ocular discomfort and itching symptom scores of reproxalap vs. Xiidra® in 56 patients with DED. They found that both patient-reported ocular discomfort (P=0.002) and itching (P=0.01) were statistically lower with reproxalap than with Xiidra®. Aldeyra is finishing Phase 3 trials to further evaluate the drug.
- **Visomitin:** Visomitin is a novel mitochondrial-targeted antioxidant currently being investigated in the treatment of various inflammatory ocular surface conditions including moderate-to-severe DED. Inhibition of inflammatory breakdown products and mitochondrial metabolism are included in visomitin's mechanism of action. This is thought to produce anti-inflammatory, anti-tear secretory deficiency, and a regenerative effect on the lacrimal accessory gland tissue rejuvenation process, which may apply to other sources of tears such as meibomian

glands, accessory lacrimal glands, and goblet cells. Results from VISTA-1, a Phase 2b/3 clinical trial that enrolled 450 patients, found that relative to the vehicle, visomitin demonstrated a statistically significant reduction of ocular discomfort by week 4 while maintaining an excellent safety and tolerability profile similar to that of an artificial tear product. The more recent VISTA-2 Phase 3 trial, which included 610 patients, had similar outcomes; both VISTA-1 and VISTA-2 demonstrated statistically significant improvement in conjunctival fluorescein staining vs. vehicle and improvement of best corrected visual acuity at week 4. The last trials designed to confirm these outcomes, VISTA-3 and VISTA-4, are scheduled to begin in the second half of 2022.

Recommendations

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

Utilization Details of DED Medications: Fiscal Year 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
CYCLOSPORINE PRODUCTS						
RESTASIS EMU 0.05% OP	1,067	426	$606,735.43	$568.64	2.5	78.84%
CYCLOSPORINE EMU 0.05% OP	297	177	$123,452.37	$415.66	1.68	16.04%
CEQUA SOL 0.09%	1	1	$517.46	$517.46	1	0.07%
SUBTOTAL	**1,365**	**604**	**$730,705.26**	**$535.32**	**2.26**	**94.95%**
LIFITEGRAST PRODUCTS						
XIIDRA DRO 5%	64	14	$38,085.13	$595.08	4.57	4.95%
SUBTOTAL	**64**	**14**	**$38,085.13**	**$595.08**	**4.57**	**4.95%**
LOTEPREDNOL PRODUCTS						
EYSUVIS DRO 0.25%	1	1	$475.57	$475.57	1	0.06%
SUBTOTAL	**1**	**1**	**$475.57**	**$475.57**	**1**	**0.06%**
VARENICLINE PRODUCTS						
TYRVAYA SOL 0.03MG	1	1	$304.05	$304.05	1	0.04%
SUBTOTAL	**1**	**1**	**$304.05**	**$304.05**	**1**	**0.04%**
TOTAL	**1,431**	**533***	**$769,570.01**	**$537.78**	**2.68**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DRO = drop; EMU = emulsion; OP = ophthalmic; SOL = solution
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 09/2022. Last accessed 09/08/2022.
[2] FDA. FDA Approves First Generic of Restasis®. Available online at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-restasis. Issued 02/02/2022. Last accessed 09/27/2022.
[3] Spiegle L. A Glance at the Dry-Eye Pipeline. *Review of Ophthalmology*. Available online at: https://www.reviewofophthalmology.com/article/a-glance-at-the-dryeye-pipeline. Issued 02/10/2022. Last accessed 09/08/2022.

Fiscal Year 2022 Annual Review of Gamifant® (Emapalumab-Izsg)

Oklahoma Health Care Authority
Fiscal Year 2022 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 the Gamifant® *Prescribing Information*; 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 2022

There was no SoonerCare utilization, including pharmacy and medical claims, of Gamifant® (emapalumab-lzsg) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Gamifant® (Emapalumab-lzsg)

There were no prior authorization requests submitted for Gamifant® (emapalumab-lzsg) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Recommendations

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

Fiscal Year 2022 Annual Review of Hyperkalemia Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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., angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), 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., angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), 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.

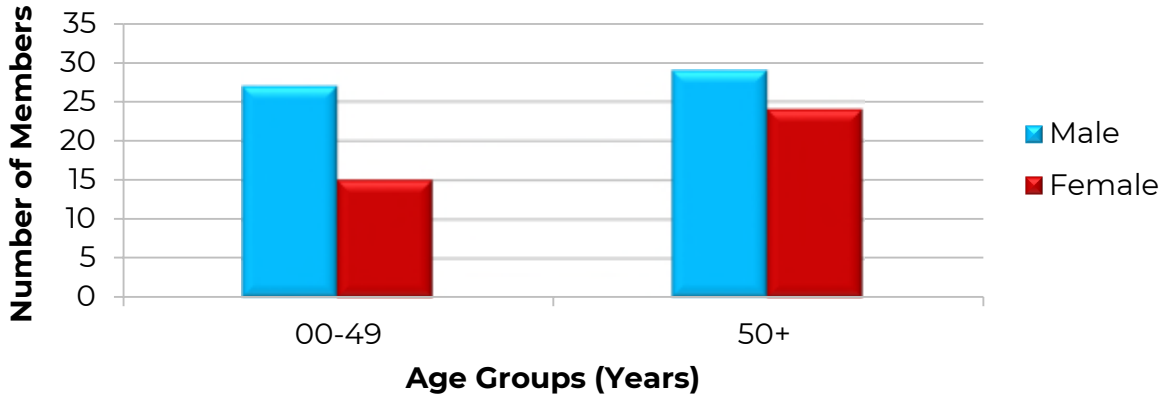
Utilization of Hyperkalemia Medications: Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

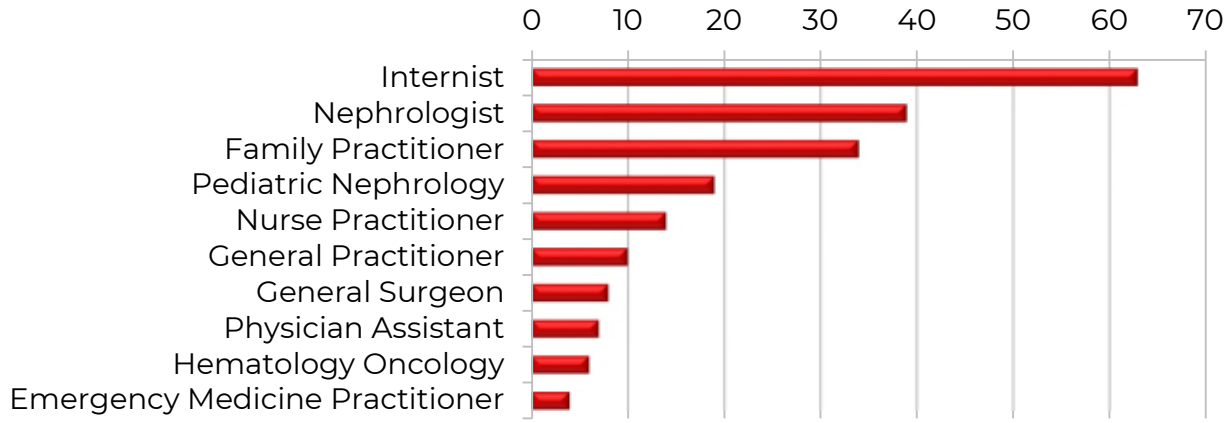
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	80	217	$62,841.19	$289.59	$16.27	40,993	3,862
2022	95	216	$75,573.33	$349.88	$18.26	57,668	4,138
% Change	**18.8%**	**-0.5%**	**20.3%**	**20.8%**	**12.2%**	**40.7%**	**7.1%**
Change	**15**	**-1**	**$12,732.14**	**$60.29**	**$1.99**	**16,675**	**276**

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

Demographics of Members Utilizing Hyperkalemia Medications



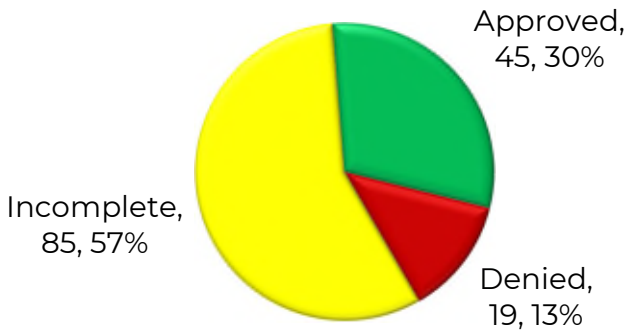
Top Prescriber Specialties of Hyperkalemia Medications by Number of Claims



Prior Authorization of Hyperkalemia Medications

There were 149 prior authorization requests submitted for hyperkalemia medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

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

News:

- **November 2021:** AstraZeneca was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for Lokelma® (sodium zirconium cyclosilicate) to reduce arrhythmia-related cardiovascular (CV) outcomes in patients on chronic hemodialysis with recurrent hyperkalemia. The designation is based on the potential of Lokelma® to reduce serious adverse CV outcomes in this patient population, addressing a significant unmet medical need. This is being investigated in an ongoing Phase 3 trial with results expected in 2024.

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SODIUM POLYSTYRENE SULFONATE (SPS) PRODUCTS						
SPS SUS 15GM/60ML	92	45	$10,643.79	$115.69	2.04	14.08%
SPS POW 454GM	27	19	$2,109.82	$78.14	1.42	2.79%
SUBTOTAL	**119**	**64**	**$12,753.61**	**$107.17**	**1.86**	**16.87%**
PATIROMER PRODUCTS						
VELTASSA POW 8.4GM	46	14	$28,288.20	$614.96	3.29	37.43%
VELTASSA POW 16.8GM	6	3	$4,635.03	$772.51	2	6.13%
VELTASSA POW 25.2GM	1	1	$949.77	$949.77	1	1.26%
SUBTOTAL	**53**	**18**	**$33,873.00**	**$639.11**	**2.94**	**44.82%**
SODIUM ZIRCONIUM CYCLOSILICATE PRODUCTS						
LOKELMA PACKET 10GM	44	17	$28,946.72	$657.88	2.59	38.30%
SUBTOTAL	**44**	**17**	**$28,946.72**	**$657.88**	**2.59**	**38.30%**
TOTAL	**216**	**95***	**$75,573.33**	**$349.88**	**2.27**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
POW = powder; SPS = sodium polystyrene sulfonate; SUS = suspension
Fiscal Year 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 07/2022. Last accessed 07/28/2022.
[2] AstraZeneca. Lokelma® Granted Fast Track Designation in the US to Reduce Cardiovascular Outcomes in Patients on Chronic Hemodialysis with Hyperkalemia. Available online at: https://www.astrazeneca.com/media-centre/medical-releases/lokelma-granted-fast-track-designation-in-the-us-to-reduce-cardiovascular-outcomes-in-patients-on-chronic-haemodialysis-with-hyperkalaemia.html. Issued 11/17/2021. Last accessed 07/28/2022.

Fiscal Year 2022 Annual Review of Jynarque® (Tolvaptan)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	2	13	$200,725.69	$15,440.44	$551.44	728	364
2022	7	26	$357,719.85	$13,758.46	$496.14	1,442	721
% Change	**250.0%**	**100.0%**	**78.20%**	**-10.90%**	**-10.00%**	**98.10%**	**98.10%**
Change	**5**	**13**	**$156,994.16**	**-$1,681.98**	**-$55.30**	**714**	**357**

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

Demographics of Members Utilizing Jynarque® (Tolvaptan)

- Due to the limited number of members utilizing Jynarque® (tolvaptan) during fiscal year 2022, detailed demographic information could not be provided.

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

- The only prescriber specialty listed on paid pharmacy claims for Jynarque® (tolvaptan) during fiscal year 2022 was nephrologist.

Prior Authorization of Jynarque® (Tolvaptan)

There were 21 prior authorization requests submitted for Jynarque® (tolvaptan) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions

Market News and Updates[1]

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
JYNARQUE PAK 45-15MG	12	5	$175,258.19	$14,604.85	2.4	48.99%
JYNARQUE PAK 90-30MG	7	1	$113,725.07	$16,246.44	7	31.79%
JYNARQUE PAK 30-15MG	4	2	$66,558.44	$16,639.61	2	18.61%
JYNARQUE PAK 15MG	3	1	$2,178.15	$726.05	3	0.61%
TOTAL	**26**	**7***	**$357,719.85**	**$13,758.46**	**3.71**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2022. Last accessed 08/01/2022.

Fiscal Year 2022 Annual Review of Keveyis® (Dichlorphenamide)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Fiscal Year 2022 Utilization: Pharmacy Claims

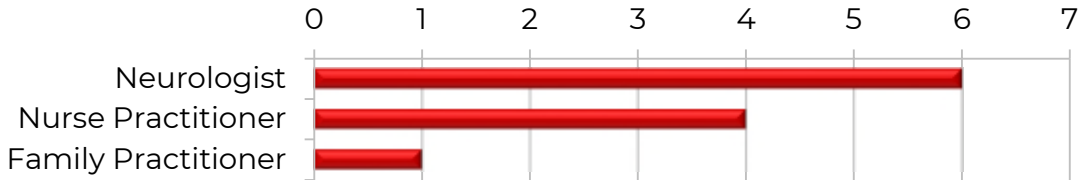
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2022	5	11	$164,717.32	$14,974.30	$499.14	600	330

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
Please note: There was no SoonerCare utilization of Keveyis® (dichlorphenamide) during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

Demographics of Members Utilizing Keveyis® (Dichlorphenamide)

- Due to the limited number of members utilizing Keveyis® (dichlorphenamide) during fiscal year 2022, detailed demographic information could not be provided.

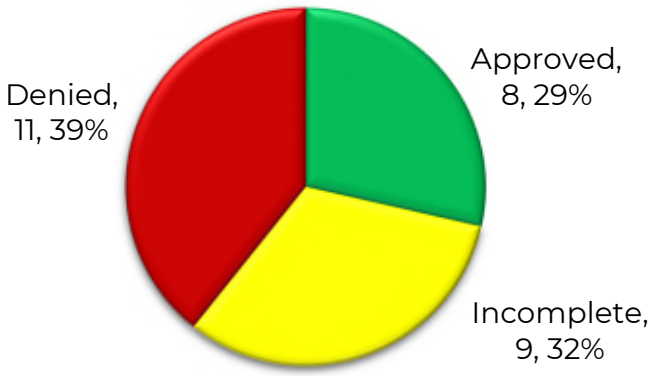
Top Prescriber Specialties of Keveyis® (Dichlorphenamide) by Number of Claims



Prior Authorization of Keveyis® (Dichlorphenamide)

There were 28 prior authorization requests submitted for Keveyis® (dichlorphenamide) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Keveyis® (dichlorphenamide): August 2022

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
KEVEYIS TAB 50MG	11	5	$164,717.32	$14,974.30	2.2	100%
TOTAL	**11**	**5***	**$164,717.32**	**$14,974.30**	**2.2**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2022. Last accessed 08/09/2022.

Fiscal Year 2022 Annual Review of Korlym® (Mifepristone)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Korlym® (Mifepristone) Approval Criteria:

1. An FDA approved indication to control hyperglycemia secondary to hypercortisolism in adult members 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 advancer 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 2022

Comparison of Fiscal Years

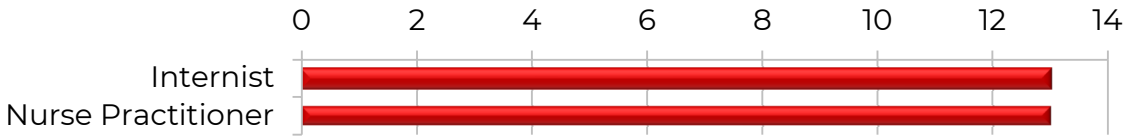
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	3	22	$556,954.95	$25,316.13	$881.26	1,050	632
2022	4	26	$898,968.04	$34,575.69	$1,231.46	1,588	730
% Change	**33.3%**	**18.2%**	**61.4%**	**36.6%**	**39.7%**	**51.2%**	**15.5%**
Change	**1**	**4**	**$342,013.09**	**$9,259.56**	**$350.20**	**538**	**98**

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

Demographics of Members Utilizing Korlym® (Mifepristone)

- There were 4 unique members utilizing Korlym® (mifepristone) during fiscal year 2022. Due to the limited number of utilizing members, detailed demographic information could not be provided.

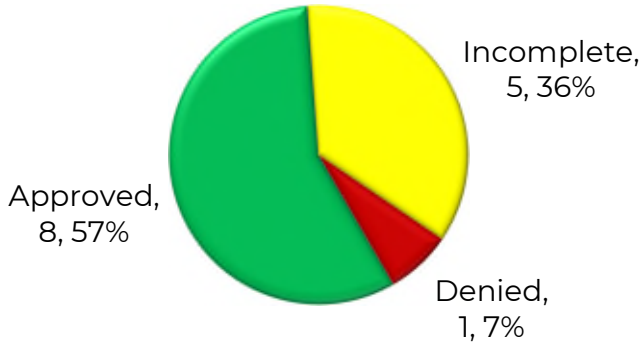
Top Prescriber Specialties of Korlym® (Mifepristone) by Number of Claims



Prior Authorization of Korlym® (Mifepristone)

There were 14 prior authorization requests submitted for Korlym® (mifepristone) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Korlym® (mifepristone tablet): August 2038

Pipeline:

- **Relacorilant:** Corcept Therapeutics is conducting 2 Phase 3 clinical trials to test the safety and efficacy of relacorilant, an oral medication designed to block the glucocorticoid receptor, thereby decreasing the effects of excess cortisol levels. The GRADIENT trial will evaluate patients with Cushing's syndrome caused by a tumor in the adrenal glands while the GRACE trial will evaluate patients with Cushing's syndrome who also have type 2 diabetes, impaired glucose tolerance, and/or high blood pressure, which is similar to Corcept's current therapy, Korlym®. Corcept Therapeutics is anticipating submission of a New Drug Application (NDA) for relacorilant to the U.S. Food and Drug Administration (FDA) by 2023.

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
KORLYM TAB 300MG	26	4	$898,968.04	$34,575.69	6.50	100%
TOTAL	**26**	**4***	**$898,968.04**	**$34,575.69**	**6.50**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/. Last revised 08/2022. Last accessed 08/16/2022.
[2] Wexler, MS. Corcept Will Seek FDA Approval of Relacorilant in 2023. *Cushing's Disease News*. Available online at: https://cushingsdiseasenews.com/news/corcept-cushings-syndrome-experimental-therapy-relacorilant-fda-approval/. Issued 02/18/2022. Last accessed 08/16/2022.

Fiscal Year 2022 Annual Review of Lidocaine Topical Products

Oklahoma Health Care Authority
Fiscal Year 2022 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.

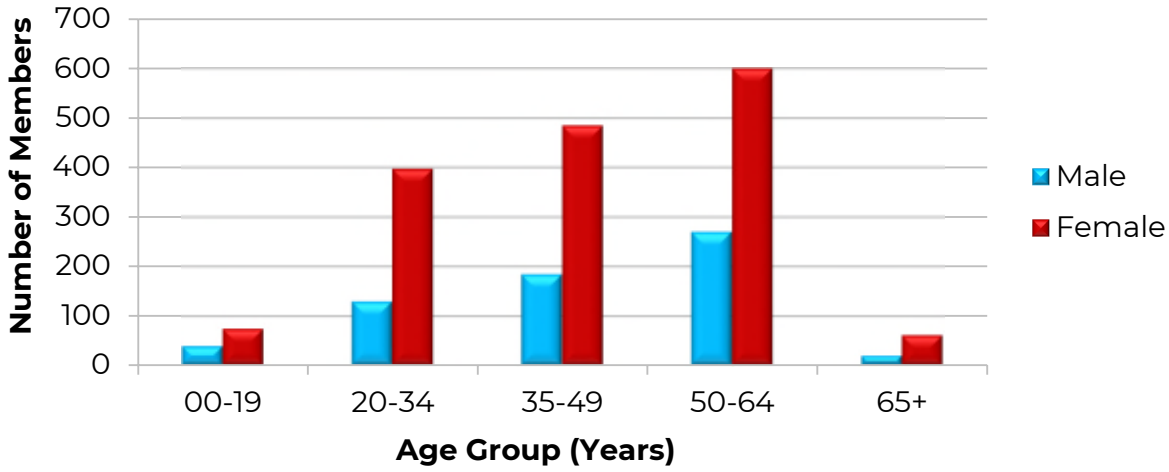
Utilization of Lidocaine Topical Products: Fiscal Year 2022

Comparison of Fiscal Years: Pharmacy Claims

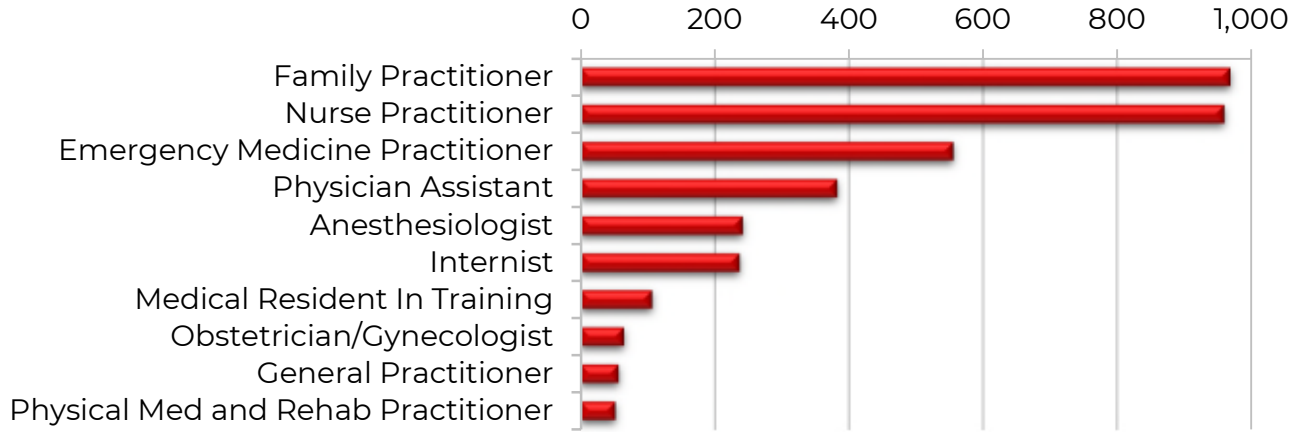
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1,180	2,304	$187,448.20	$81.38	$3.06	72,720	61,356
2022	2,249	3,905	$282,157.91	$72.26	$2.70	121,879	104,414
% Change	**90.60%**	**69.50%**	**50.50%**	**-11.20%**	**-11.80%**	**67.50%**	**70.20%**
Change	**1,069**	**1,601**	**$94,669.71**	**-$9.12**	**-$0.36**	**49,099**	**43,058**

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

Demographics of Members Utilizing Lidocaine Topical Products

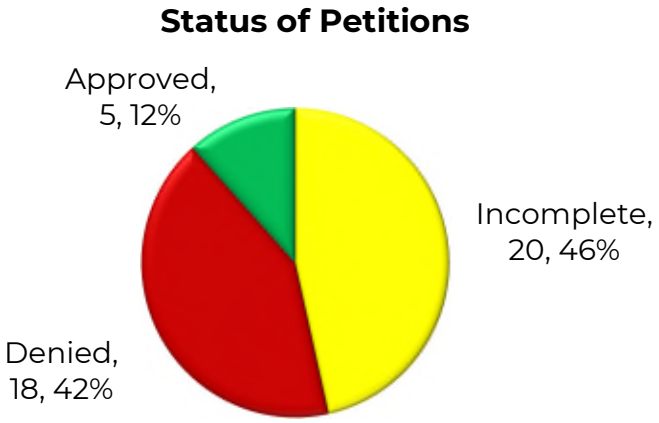


Top Prescriber Specialties of Lidocaine Topical Products by Number of Claims



Prior Authorization of Lidocaine Topical Products

There were 43 prior authorization requests submitted for lidocaine topical products during fiscal year 2022. 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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
LIDOCAINE PRODUCTS						
LIDOCAINE PAD 5%	3,905	2,249	$282,157.91	$72.26	1.74	100%
TOTAL	**3,905**	**2,249***	**$282,157.91**	**$72.26**	**1.74**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 07/2022. Last accessed 07/20/2022.

Fiscal Year 2022 Annual Review of Ocaliva® (Obeticholic Acid)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Comparison of Fiscal Years: Pharmacy Claims

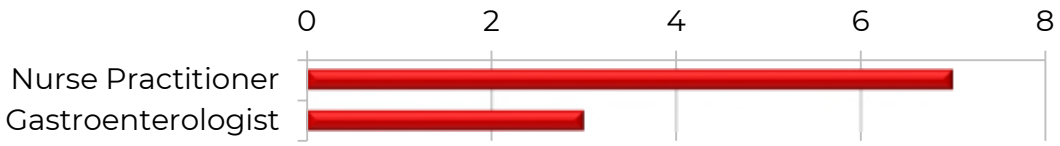
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	1	6	$44,578.68	$7,429.78	$247.66	180	180
2022	2	10	$77,854.12	$7,785.41	$259.51	300	300
% Change	**100%**	**66.7%**	**74.6%**	**4.8%**	**4.8%**	**66.7%**	**66.7%**
Change	**1**	**4**	**$33,275.44**	**$355.63**	**$11.85**	**120**	**120**

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

Demographics of Members Utilizing Ocaliva® (Obeticholic Acid)

- There were 2 unique members utilizing Ocaliva® during fiscal year 2022. Due to the limited number of utilizing members, detailed demographic information could not be provided.

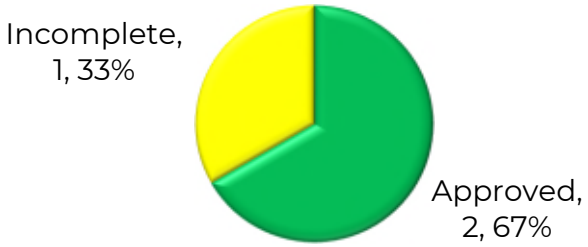
Top Prescriber Specialties of Ocaliva® (Obeticholic Acid) by Number of Claims



Prior Authorization of Ocaliva® (Obeticholic Acid)

There were 3 prior authorization requests submitted for Ocaliva® (obeticholic acid) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Ocaliva® (obeticholic acid): April 2036

News:

- **July 2022:** Intercept Pharmaceuticals announced positive topline results from a new interim analysis of its ongoing Phase 3 trial of obeticholic acid (OCA) in patients with liver fibrosis due to nonalcoholic steatohepatitis (NASH). This is the second analysis of OCA that had met the primary endpoint of achieving at least 1 stage of fibrosis improvement with no worsening of NASH at month 18. Based on these results, Intercept plans to resubmit its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for OCA in liver fibrosis due to NASH.

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OCALIVA TAB 10MG	7	1	$53,686.36	$7,669.48	7	68.96%
OCALIVA TAB 5MG	3	1	$24,167.76	$8,055.92	3	31.04%
TOTAL	**10**	**2***	**$77,854.12**	**$7,785.41**	**5**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2022. Last accessed 08/28/2022.
[2] Intercept Pharmaceuticals, Inc. Intercept Announces Positive Data in Fibrosis due to NASH from a New Analysis of its Phase 3 REGENERATE Study of Obeticholic Acid (OCA). Available online at: https://www.globenewswire.com/news-release/2022/07/07/2475765/23024/en/Intercept-Announces-Positive-Data-in-Fibrosis-due-to-NASH-from-a-New-Analysis-of-its-Phase-3-REGENERATE-Study-of-Obeticholic-Acid-OCA.html. Issued 07/07/2022. Last accessed 08/28/2022.

Fiscal Year 2022 Annual Review of Ophthalmic Antibiotic Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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.

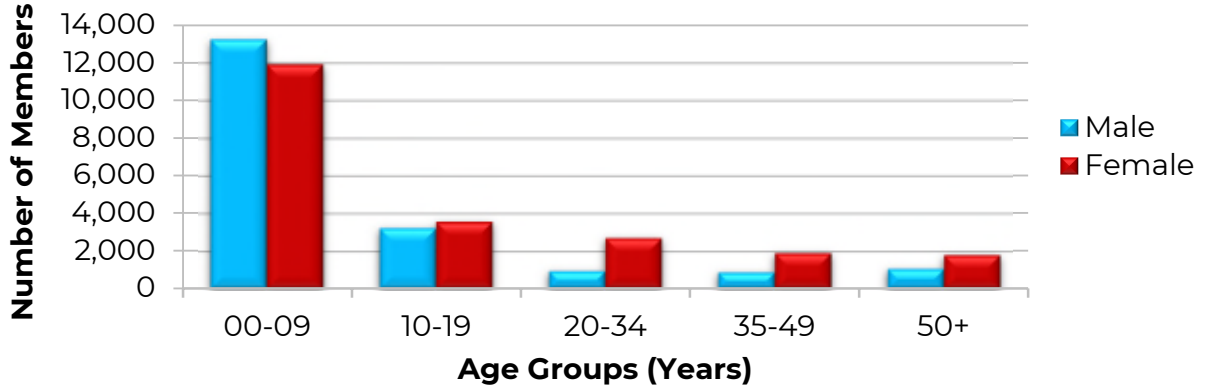
Utilization of Ophthalmic Antibiotic Medications: Fiscal Year 2022

Comparison of Fiscal Years

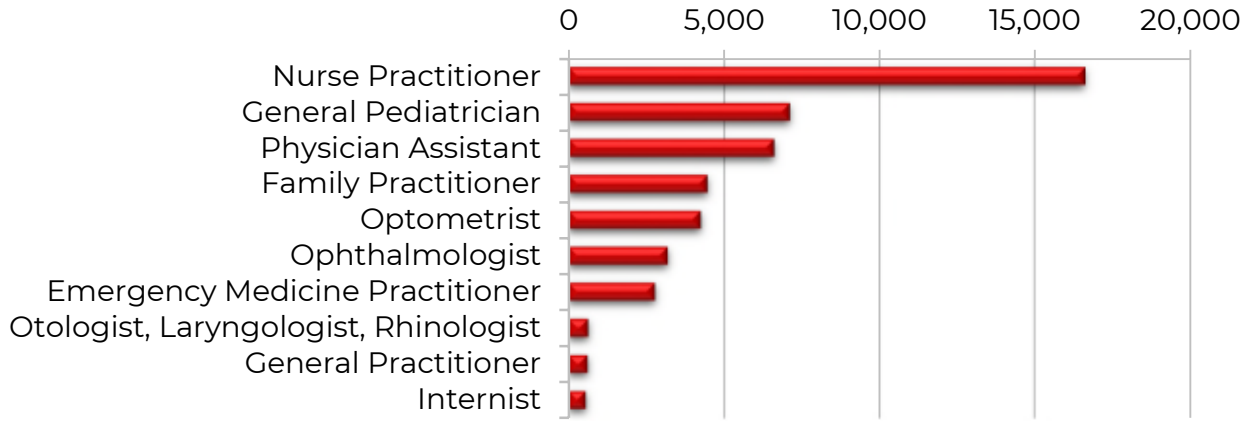
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	21,871	26,102	$606,960.43	$23.25	$1.75	159,348	345,995
2022	41,173	48,509	$1,013,009.61	$20.88	$1.46	313,493	695,112
% Change	**88.30%**	**85.80%**	**66.90%**	**-10.20%**	**-16.60%**	**96.70%**	**100.90%**
Change	**19,302**	**22,407**	**$406,049.18**	**-$2.37**	**-$0.29**	**154,145**	**349,117**

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

Demographics of Members Utilizing Ophthalmic Antibiotic Medications



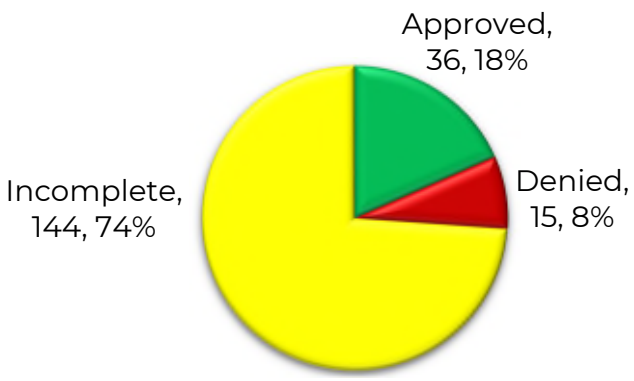
Top Prescriber Specialties of Ophthalmic Antibiotic Medications by Number of Claims



Prior Authorization of Ophthalmic Antibiotic Medications

There were 195 prior authorization requests submitted for ophthalmic antibiotic medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OPHTHALMIC ANTIBIOTIC LIQUIDS						
TIER-1 PRODUCTS						
POLYMYXIN B/TRIMETH SOL	13,317	12,729	$210,972.10	$15.84	1.05	20.83%
OFLOXACIN DRO 0.3% OP	10,183	9,108	$214,957.24	$21.11	1.12	21.22%
TOBRAMYCIN SOL 0.3% OP	3,295	3,106	$47,655.48	$14.46	1.06	4.70%
GENTAMICIN SOL 0.3% OP	2,418	2,264	$34,743.95	$14.37	1.07	3.43%
CIPROFLOXACIN SOL 0.3% OP	2,220	2,053	$41,966.96	$18.90	1.08	4.14%
SULFACET SOD SOL 10% OP	933	897	$37,361.81	$40.04	1.04	3.69%
NEO/POLY/GRAM SOL OP	33	31	$1,762.86	$53.42	1.06	0.17%
TRIMETH/POLYMYXIN SOL	26	25	$412.37	$15.86	1.04	0.04%
BLEPH-10 SOL 10% OP	1	1	$20.50	$20.50	1	0.00%
SUBTOTAL	**32,426**	**30,214**	**$589,853.27**	**$18.19**	**1.07**	**58.23%**
TIER-3 PRODUCTS						
MOXIFLOXACIN HCL SOL 0.5%	874	629	$20,853.06	$23.86	1.39	2.06%
BESIVANCE SUS 0.6%	164	131	$31,872.13	$194.34	1.25	3.15%
GATIFLOXACIN SOL 0.5%	61	57	$2,461.91	$40.36	1.07	0.24%
MOXIFLOXACIN SOL 0.5%	14	7	$327.28	$23.38	2	0.03%
AZASITE SOL 1%	7	7	$1,495.42	$213.63	1	0.15%
SUBTOTAL	**1,120**	**831**	**$57,009.80**	**$50.90**	**1.35**	**5.63%**
LIQUID SUBTOTAL	**33,546**	**29,843***	**$646,863.07**	**$19.28**	**1.12**	**63.86%**
OPHTHALMIC ANTIBIOTIC OINTMENTS						
TIER-1 PRODUCTS						
ERYTHROMYCIN OIN 5MG/GM	10,302	9,420	$198,130.94	$19.23	1.09	19.56%
BACITRACIN/POLY OIN OP	163	156	$3,560.18	$21.84	1.04	0.35%
GENTAK OIN 0.3% OP	61	59	$2,014.85	$33.03	1.03	0.20%
NEO/BAC/POLY OIN OP	41	41	$1,626.11	$39.66	1	0.16%
TOBREX OIN 0.3% OP	40	37	$8,475.47	$211.89	1.08	0.84%
POLYCIN OIN OP	1	1	$23.79	$23.79	1	0.00%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SUBTOTAL	**10,608**	**9,714**	**$213,831.34**	**$20.16**	**1.09**	**21.11%**
TIER-2 PRODUCTS						
BACITRACIN OIN 500 UNIT/GM OP	7	7	$711.26	$101.61	1	0.07%
CILOXAN OIN 0.3% OP	3	3	$651.29	$217.10	1	0.06%
SUBTOTAL	**10**	**10**	**$1,362.55**	**$136.26**	**1**	**0.13%**
OINTMENT SUBTOTAL	**10,618**	**9,692***	**$215,193.89**	**$20.27**	**1.1**	**21.24%**
OPHTHALMIC ANTIBIOTIC/STEROID COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
NEO/POLY/DEX SUS 0.1% OP	3,050	2,822	$58,170.99	$19.07	1.08	5.74%
NEO/POLY/DEX OIN 0.1% OP	879	754	$18,114.36	$20.61	1.17	1.79%
TOBRADEX SUS 0.3-0.1%	256	224	$39,459.26	$154.14	1.14	3.90%
TOBRADEX ST SUS 0.3-0.05%	41	30	$9,514.11	$232.05	1.37	0.94%
SULFACET/PRED NA SOL 10-0.23% OP	12	9	$275.14	$22.93	1.33	0.03%
SUBTOTAL	**4,238**	**3,839**	**$125,533.86**	**$29.62**	**1.1**	**12.39%**
TIER-2 PRODUCTS						
TOBRADEX OIN 0.3-0.1%	78	72	$17,621.68	$225.92	1.08	1.74%
ZYLET SUS 0.5-0.3%	25	24	$6,977.02	$279.08	1.04	0.69%
BLEPHAMIDE SUS 10-0.2% OP	2	1	$643.66	$321.83	2	0.06%
NEO/POLY/BAC/HC OIN 1% OP	1	1	$41.04	$41.04	1	0.00%
NEO/POLY/HC SUS OP	1	1	$135.39	$135.39	1	0.01%
SUBTOTAL	**107**	**99**	**$25,418.79**	**$237.56**	**1.08**	**2.51%**
COMBINATION SUBTOTAL	**4,345**	**3,808***	**$150,952.65**	**$34.74**	**1.14**	**14.90%**
TOTAL	**48,509**	**41,173***	**$1,013,009.61**	**$20.88**	**1.18**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 07/2022. Last Accessed 07/25/2022.

Fiscal Year 2022 Annual Review of Oxlumo® (Lumasiran)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Oxlumo® (Lumasiran) Approval Criteria:

1. An FDA approved indication for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels. Diagnosis of PH1 must be confirmed by:
   a. Molecular genetic testing identifying biallelic pathogenic variants in the *AGXT* gene; or
   b. Liver biopsy confirming alanine-glyoxylate aminotransferase (AGT) catalytic deficiency if the results of genetic testing are not diagnostic; and
2. Oxlumo® must be prescribed by a nephrologist, geneticist, or other specialist with expertise in the treatment of PH1 (or an advanced care practitioner with a supervising physician who is a nephrologist, geneticist, or other specialist with expertise in the treatment of PH1); and
3. Prescriber must verify the member has an estimated glomerular filtration rate (eGFR) of ≥30mL/min/1.73m^2 prior to starting Oxlumo® and must agree to monitor renal function regularly during treatment with Oxlumo®; and
4. Member must not have a history of liver transplant; and
5. Member must not have evidence of systemic oxalosis; and
6. Prescriber must verify that Oxlumo® will be administered by a health care professional; and
7. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to the Oxlumo® *Prescribing Information*; and
8. Initial approvals will be for the duration of 6 months. Further approval may be granted if the prescriber documents that the member is responding well to treatment as indicated by a reduction in urinary oxalate excretion.

Utilization of Oxlumo® (Lumasiran): Fiscal Year 2022

There was no SoonerCare utilization of Oxlumo® (lumasiran) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Oxlumo® (Lumasiran)

There were no prior authorization requests submitted for Oxlumo® (lumasiran) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Market News and Updates[1,2]

Anticipated Patent Expiration(s):

- Oxlumo® (lumasiran): November 2038

Pipeline:

- **Lumasiran:** In May 2022, Alnylam Pharmaceuticals, the manufacturer of Oxlumo®, announced the U.S. Food and Drug Administration (FDA) has accepted its supplemental New Drug Application (sNDA) for Oxlumo® for the treatment of advanced primary hyperoxaluria type 1 (PH1). The sNDA submission is supported by data from the Phase 3 ILLUMINATE-C study which enrolled patients with PH1 with an estimated glomerular filtration rate (eGFR) ≤45mL/min/1.73m^2, including patients on dialysis. The study demonstrated reductions in plasma oxalate level in these patients with decreased renal function due to PH1. Previous Phase 3 studies of lumasiran had enrolled patients with PH1 with relatively preserved renal function. The Prescription Drug User Fee Act (PDUFA) action date for the sNDA is October 6, 2022.

Recommendations

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

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[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 07/2022. Last accessed 07/25/2022.

[2] Alnylam Pharmaceuticals, Inc. Alnylam Announces U.S. Food and Drug Administration Acceptance of Supplemental New Drug Application for Oxlumo® for the Treatment of Advanced Primary Hyperoxaluria Type 1. Available online at: https://investors.alnylam.com/press-release?id=26566. Issued 03/01/2022. Last accessed 07/25/2022.

Fiscal Year 2022 Annual Review of Parathyroid Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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 members 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.

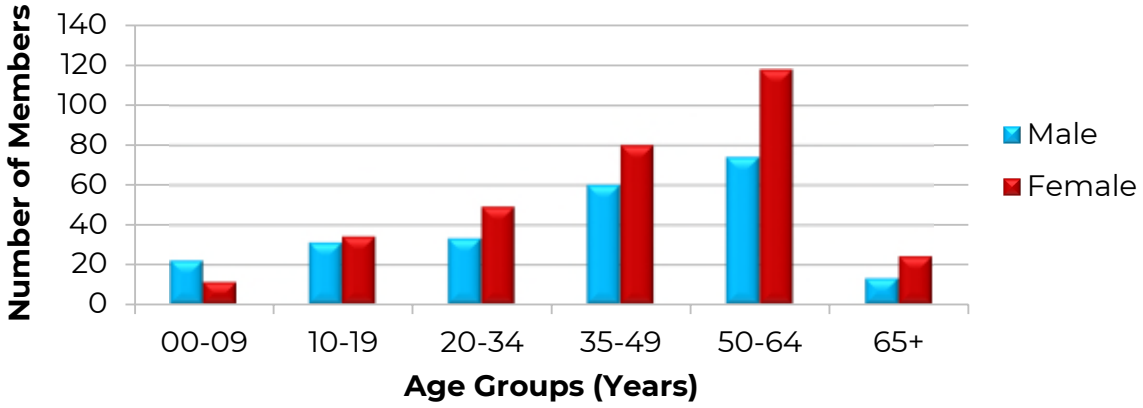
Utilization of Parathyroid Medications: Fiscal Year 2022

Comparison of Fiscal Years: Calcimimetics and Vitamin D Analogs

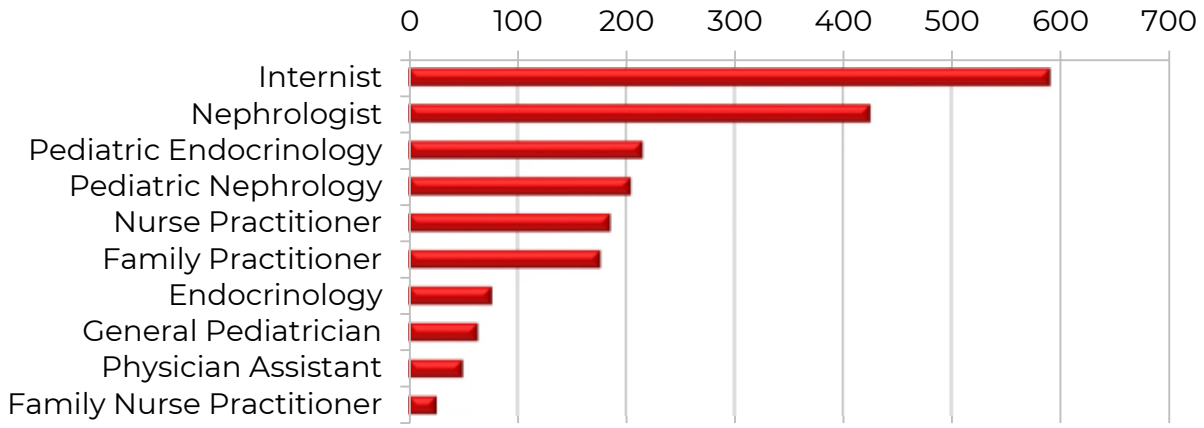
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	416	1,810	$215,620.50	$119.13	$2.96	79,510	72,770
2022	549	2,188	$89,438.29	$40.88	$1.00	101,073	89,187
% Change	**32.0%**	**20.9%**	**-58.5%**	**-65.7%**	**-66.2%**	**27.1%**	**22.6%**
Change	**133**	**378**	**-$126,182.21**	**-$78.25**	**-$1.96**	**21,563**	**16,417**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021; Fiscal Year 2022 = 07/01/2021 to 06/30/2022
Please note: There were no paid claims for Natpara® during fiscal years 2021 or 2022.

Demographics of Members Utilizing Parathyroid Medications



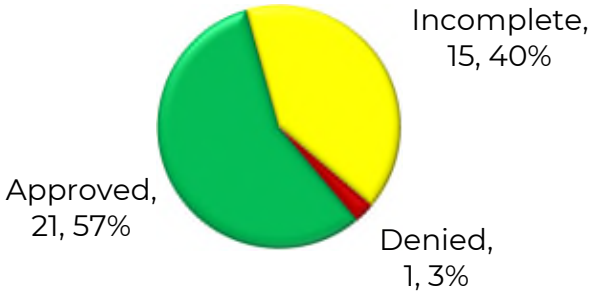
Top Prescriber Specialties of Parathyroid Medications by Number of Claims



Prior Authorization of Parathyroid Medications

There were 37 prior authorization requests submitted for parathyroid medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1,2]

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. Ascendis Pharma recently announced data from the Phase 3 PaTHway trial that demonstrated statistically significant improvement compared to placebo on the primary composite endpoint of serum calcium levels in the normal range and independence from conventional therapy. Ascendis plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) during the third quarter of 2022.

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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VITAMIN D ANALOG PRODUCTS						
CALCITRIOL PRODUCTS						
CALCITRIOL CAP 0.25MCG	927	299	$16,975.21	$18.31	3.1	18.98%
CALCITRIOL CAP 0.5MCG	428	120	$11,410.74	$26.66	3.57	12.76%
CALCITRIOL SOL 1MCG/ML	170	38	$13,344.09	$78.49	4.47	14.92%
SUBTOTAL	**1,525**	**457**	**$41,730.04**	**$27.36**	**3.34**	**46.66%**
PARICALCITOL PRODUCTS						
PARICALCITOL CAP 1MCG	39	6	$1,518.03	$38.92	6.5	1.70%
PARICALCITOL INJ 5MCG/ML	8	1	$2,491.28	$311.41	8	2.79%
PARICALCITOL CAP 2MCG	2	1	$468.54	$234.27	2	0.52%
SUBTOTAL	**49**	**8**	**$4,477.85**	**$91.38**	**6.125**	**5.01%**
CALCIFEDIOL PRODUCTS						
RAYALDEE CAP 30MCG	3	1	$5,515.13	$1,838.38	3	6.17%
SUBTOTAL	**3**	**1**	**$5,515.13**	**$1,838.38**	**3**	**6.17%**
VITAMIN D ANALOG SUBTOTAL	**1,577**	**466**	**$51,723.02**	**$32.80**	**3.38**	**57.83%**
CALCIMIMETIC PRODUCTS						
CINACALCET PRODUCTS						
CINACALCET TAB 30MG	423	110	$19,042.70	$45.02	3.85	21.29%
CINACALCET TAB 60MG	112	33	$6,736.75	$60.15	3.39	7.53%
CINACALCET TAB 90MG	74	16	$8,735.28	$118.04	4.63	9.77%
SENSIPAR TAB 30MG	2	1	$3,200.54	$1,600.27	2	3.58%
SUBTOTAL	**611**	**160**	**$37,715.27**	**$61.73**	**3.82**	**42.17%**
CALCIMIMETIC SUBTOTAL	**611**	**160**	**$37,715.27**	**$61.73**	**3.82**	**42.17%**
TOTAL	**2,188**	**549***	**$89,438.29**	**$40.88**	**16.29**	**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 2022 = 07/01/2021 to 06/30/2022

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm. Last revised 08/2022. Last accessed 08/28/2022.

[2] Ascendis Pharma. Ascendis Pharma A/S Announces Phase 3 PaTHway Trial of TransCon™ PTH in Adults with Hypoparathyroidism Met Primary and All Key Secondary Endpoints. Available online at: https://investors.ascendispharma.com/news-releases/news-release-details/ascendis-pharma-announces-phase-3-pathway-trial-transcontm-pth. Issued 03/13/2022. Last accessed 08/30/2022.

Fiscal Year 2022 Annual Review of Revcovi® (Elapegademase-lvlr)

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

There was no SoonerCare utilization of Revcovi® (elapegademase-lvlr) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Revcovi® (Elapegademase-lvlr)

There were no prior authorization requests submitted for Revcovi® (elapegademase-lvlr) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Recommendations

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

Fiscal Year 2022 Annual Review of Tepezza® (Teprotumumab-trbw)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Tepezza® (Teprotumumab-trbw) Approval Criteria:

1. An FDA approved indication for the treatment of thyroid eye disease in adult members 18 years of age and older; and
    a. Member must be experiencing eye symptoms related to thyroid eye disease; and
    b. Member must have thyroid blood levels in the normal range or must be undergoing active treatment working toward normal range; and
2. Female members must not be pregnant and must have a negative pregnancy test prior to initiation of therapy; and
3. Female members of reproductive potential must be willing to use effective contraception prior to initiation, during treatment with Tepezza®, and for at least 6 months after the last dose of Tepezza®; and
4. Member must not have had prior surgical treatment for thyroid eye disease; and
    a. A prior authorization request with patient-specific information may be submitted for consideration of Tepezza® for members who have had prior surgical treatment for thyroid eye disease, including but not limited to patient-specific, clinically significant information regarding the member's prior surgery and the need for Tepezza®; and
5. Medical supervision by an ophthalmologist in conjunction with an endocrinologist for the treatment of thyroid eye disease; and
    a. The name of the ophthalmologist and endocrinologist recommending treatment with Tepezza® must be provided on the prior authorization request; and
6. Tepezza® must be administered as an intravenous (IV) infusion at the recommended infusion rate per package labeling, with appropriate pre-medication(s) based on the member's risk of infusion reactions; and
7. Tepezza® must be administered by a health care professional. Prior authorization requests must indicate how Tepezza® will be administered; and
    a. Tepezza® must be shipped via cold chain supply to the facility where the member is scheduled to receive treatment; or

b. Tepezza® must be shipped via cold chain supply to the member's home and administered by a home health care provider and the member (or the member's caregiver) must be trained on the proper storage of Tepezza®; and

8. The member's current 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 a maximum of 8 total infusions.

Utilization of Tepezza® (Teprotumumab-trbw): Fiscal Year 2022

Fiscal Year 2022 Utilization: Medical Claims

Fiscal Year	Total Members*	Total Claims+	Total Cost	Cost/ Claim	Total Units
2022	15	83	$4,432,744.04	$53,406.55	14,033

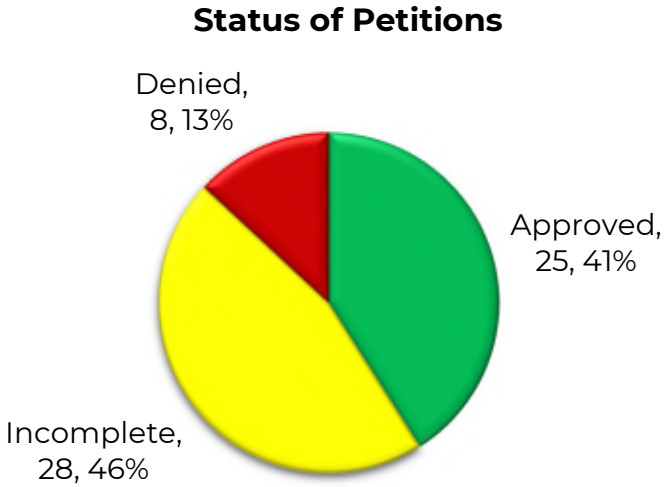
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
+Total number of unduplicated claims.
Fiscal Year 2022 = 07/01/2021 to 06/30/2022
Please note: There were no paid pharmacy claims for Tepezza® during fiscal year 2022. Further, there were no paid medical claims for Tepezza® during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

Demographics of Members Utilizing Tepezza® (Teprotumumab-trbw)

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

Prior Authorization of Tepezza® (Teprotumumab-trbw)

There were 61 prior authorization requests for Tepezza® (teprotumumab-trbw) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.



Recommendations

The College of Pharmacy does not recommend any changes to the current Tepezza® (teprotumumab-trbw) prior authorization criteria at this time.

Utilization Details of Tepezza® (Teprotumumab-trbw): Fiscal Year 2022

Medical Claims

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TEPEZZA INJ 500MG (J3241)	83	15	$4,432,744.04	$53,406.55	5.53
TOTAL	**83**	**15**	**$4,432,744.04**	**$53,406.55**	**5.53**

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

Fiscal Year 2022 Annual Review of Thrombocytopenia Medications

Oklahoma Health Care Authority
Fiscal Year 2022 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 2022

Comparison of Fiscal Years: Pharmacy Claims

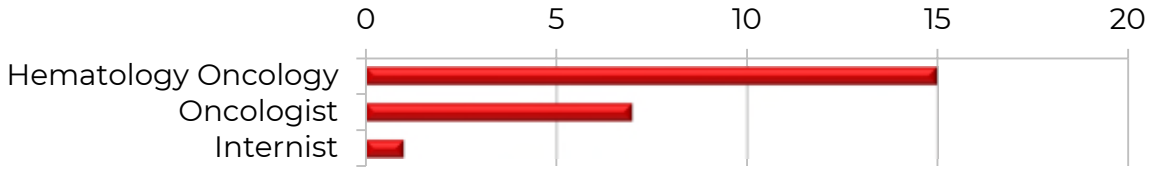
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2021	3	5	$50,541.05	$10,108.21	$404.33	250	125
2022	7	23	$273,954.01	$11,911.04	$444.01	1,232	617
% Change	**133.3%**	**360.0%**	**442.0%**	**17.8%**	**9.8%**	**392.8%**	**393.6%**
Change	**4**	**18**	**$223,412.96**	**$1,802.83**	**$39.68**	**982**	**492**

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

Demographics of Members Utilizing Thrombocytopenia Medications

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

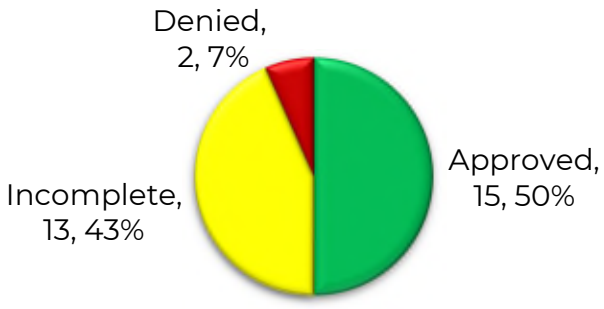
Top Prescriber Specialties of Thrombocytopenia Medications by Number of Claims



Prior Authorization of Thrombocytopenia Medications

There were 30 prior authorization requests submitted for thrombocytopenia medications during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



Market News and Updates[1]

Anticipated Patent Expiration(s):

- Doptelet® (avatrombopag): May 2025
- Promacta® (eltrombopag): February 2028
- 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 2022

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
FOSTAMATINIB PRODUCTS						
TAVALISSE TAB 150MG	10	2	$125,939.60	$12,593.96	5	45.97%
TAVALISSE TAB 100MG	8	3	$88,879.96	$11,109.99	2.67	32.44%
SUBTOTAL	**18**	**5**	**$214,819.56**	**$23,706.95**	**7.67**	**78.41%**
AVATROMBOPAG PRODUCTS						
DOPTELET TAB 20MG	4	3	$50,627.04	$12,656.76	1.33	18.48%
SUBTOTAL	**4**	**3**	**$50,627.04**	**$12,656.76**	**1.33**	**18.48%**
LUSUTROMBOPAG PRODUCTS						
MULPLETA TAB 3MG	1	1	$8,507.41	$8,507.41	1	3.11%
SUBTOTAL	**1**	**1**	**$8,507.41**	**$8,507.41**	**1**	**3.11%**
TOTAL	**23**	**7***	**$273,954.01**	**$11,911.04**	**3.29**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 08/2022. Last accessed 08/03/2022.

Fiscal Year 2022 Annual Review of Vimizim® (Elosulfase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Vimizim® (Elosulfase Alfa) Approval Criteria:

1. An FDA approved diagnosis of Morquio A syndrome (mucopolysaccharidosis type IVA; MPS IVA) confirmed by:
   a. Enzyme assay demonstrating a deficiency of N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity; or
   b. Molecular genetic testing to confirm biallelic pathogenic variants in GALNS; and
2. Vimizim® must be administered by a health care professional prepared to manage anaphylaxis; and
3. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
4. Initial approvals will be for the duration of 12 months. Reauthorization may be granted if the prescriber documents the member is responding well to treatment.

Utilization of Vimizim® (Elosulfase Alfa): Fiscal Year 2022

There was no SoonerCare utilization of Vimizim® (elosulfase alfa) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Prior Authorization of Vimizim® (Elosulfase Alfa)

There were no prior authorization requests submitted for Vimizim® (elosulfase alfa) during fiscal year 2022 (07/01/2021 to 06/30/2022).

Market News and Updates[1]

News:

- **September 2021:** Developing gene therapies for mucopolysaccharidosis type IVA (MPSIVA), or Morquio A disease, is limited by the inability to develop the severe and disabling skeletal and articular pathology of MPSIVA patients in the existing MPSIVA mouse models. In previous studies, treatment of MPSIVA mice with liver-directed adeno-associated virus (AAV)-based gene therapy resulted in increased secretion of N-acetylgalactosamine-6-sulfatase (GALNS) and

normalization of keratan sulfate (KS) levels in plasma, liver, and lungs, but because of the lack of skeletal dysplasia in MPSIVA mouse models, the therapeutic efficacy of this AAV gene therapy approach in the skeletal system could not be assessed. The availability of animal models that reproduce human diseases is crucial for the development of efficacious therapies. In a study using CRISPR/Cas9 technology, the first MPSIVA rat model was generated with all the skeletal and non-skeletal alterations experienced by MPSIVA patients. Treatment of MPSIVA in these rats with AAV vector serotype 9 encoding *Galns* (AAV9-*Galns)* resulted in widespread expression of the therapeutic gene in the bones, cartilage, and peripheral tissues. This led to a long-term (1 year) increase of GALNS activity and whole-body correction of KS levels, thus preventing body size reduction and severe alterations of the bones, teeth, joints, trachea, and heart. This study demonstrates the potential of AAV9-*Galns* gene therapy to correct the disabling MPSIVA pathology, providing strong rationale for future clinical translation to MPSIVA patients.

Recommendations

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

[1] Bertolin J, Sánchez V, Ribera A, et al. Treatment of Skeletal and Non-Skeletal Alterations of Mucopolysaccharidosis Type IVA by AAV-Mediated Gene Therapy. *Nat Commun* 2021; 12:5343.

Fiscal Year 2022 Annual Review of Zinplava™ (Bezlotoxumab)

Oklahoma Health Care Authority
Fiscal Year 2022 Print Report

Current Prior Authorization Criteria

Zinplava™ (Bezlotoxumab) Approval Criteria:

1. An FDA approved diagnosis of *Clostridium difficile* infection (CDI) in members 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence; and
    a. Prescriber must document the member has ≥1 of the following risk factor(s) for high risk of CDI recurrence:
        i. Age 65 years or older; or
        ii. One or more episodes of CDI within the 6 months prior to the episode under treatment; or
        iii. Need for ongoing therapy with concomitant antibiotics during treatment for CDI; or
        iv. Severe underlying medical disorders; or
        v. Immunocompromised; or
        vi. Clinically severe CDI (Zar score ≥2); and
2. Current or planned antibacterial drug for CDI must be provided on the prior authorization request to ensure medication is within standard of care; and
3. Prescriber must document that Zinplava™ (bezlotoxumab) will be administered while the member is receiving antibacterial drug treatment of CDI; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

Utilization of Zinplava™ (Bezlotoxumab): Fiscal Year 2022

Fiscal Year 2022 Utilization: Medical Claims (J0565)

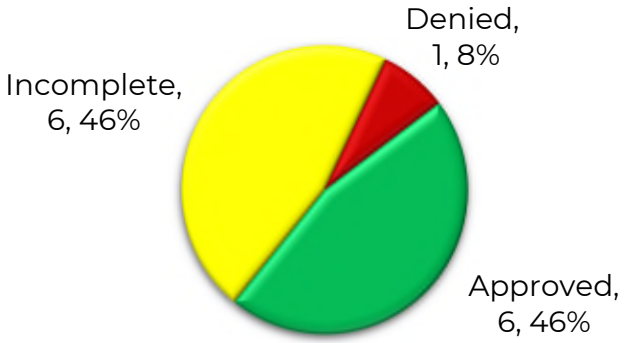
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2022	4	4	$13,918.50	$3,479.63	1

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
Please note: There was no SoonerCare utilization of Zinplava™ (bezlotoxumab) during fiscal year 2021 (07/01/2020 to 06/30/2021) to allow for a fiscal year comparison.

Prior Authorization of Zinplava™ (Bezlotoxumab)

There were 13 prior authorization requests submitted for Zinplava™ (bezlotoxumab) during fiscal year 2022. The following chart shows the status of the submitted petitions for fiscal year 2022.

Status of Petitions



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

Pipeline:

- **CP101:** In November 2021, Finch Therapeutics announced positive topline results from PRISM-EXT, an open-label extension of the company's PRISM3 Phase 2 placebo-controlled study evaluating CP101 for the prevention of recurrent *Clostridium difficile* (*C. diff*) infection (rCDI). CP101 is an investigational drug designed to deliver complete microbiome communities in orally administered, enteric release capsules. PRISM-EXT was a 24-week study that evaluated the safety and efficacy of CP101 for the prevention of rCDI in 132 participants who either rolled over from PRISM3 after experiencing a CDI recurrence (N=50) or directly enrolled after experiencing a CDI recurrence without previously participating in PRISM3 (N=82). In the PRISM-EXT study, there were no treatment-related serious adverse events reported and CP101 exhibited an overall safety profile consistent with the profile observed in PRISM3. The primary efficacy endpoint was sustained clinical cure (defined as absence of CDI recurrence) through 8 weeks post-treatment. Overall, 80.3% of participants who received a single oral administration of CP101 following standard-of-care (SOC) antibiotics in PRISM-EXT achieved sustained clinical cure through week 8. At week 24, 78.8% of participants had sustained clinical cure. The PRISM-EXT results are consistent with and build on the previously reported PRISM3 results, which showed that CP101 provided a statistically significant improvement in the prevention of rCDI compared to placebo through 8 weeks and 24 weeks post-treatment. Finch Therapeutics also announced the start of enrollment in PRISM4 Phase 3 study in

November 2021; however, in February 2022, the company received a clinical hold letter from the U.S. Food and Drug Administration (FDA), requesting additional information about Finch's SARS-CoV-2 donor screening protocols.

- **SER-109:** Seres Therapeutics presented data at the 2022 Digestive Disease Week Annual Meeting from its Phase 3 ECOSPOR III study that suggested investigational microbiome-based therapeutic SER-109 prevents rCDI by rapidly establishing a long-lasting colony of beneficial gut microbes, which can produce fatty acids that disrupt the *C. diff* lifecycle. SER-109 is an investigational oral microbiome therapeutic consisting of highly purified Firmicutes spores, which normally live in a healthy microbiome. SER-109 is designed to prevent further recurrences of CDI by modulating the disrupted microbiome to a state that resists *C. diff* colonization and growth. The ECOSPOR III Phase 3 study was a multicenter, randomized, placebo-controlled clinical study that enrolled 182 adults with rCDI, and previously demonstrated that SER-109 prevented rCDI in 88% of recipients at the 8-week primary endpoint, whereas only 60% in the placebo arm remained recurrence-free over the same time period. The safety profile was similar across both groups. A pre-planned exploratory analysis from the ECOSPOR III study showed that approximately 2/3 of CDI recurrences occurred within the first 2 weeks following antibiotic treatment for CDI when the microbiome is further decimated and *C. diff* spores, untouched by antibiotics, are free to germinate into toxin-producing vegetative bacteria. SER-109 introduces diverse bacterial species into the gut in the form of spores, which rapidly germinate and incorporate themselves into the microbiome, showing up in the stool as vegetative bacteria. This process is called engraftment. Within a week of SER-109 treatment, the number of new bacterial species in stool increased and remained significantly higher than the placebo group for the entire 24-week study period. Bacterial diversity rebounded more slowly and to a lesser degree in the placebo group. The pattern of results was the same regardless of which antibiotic participants received, vancomycin or fidaxomicin. Seres expects to finalize a Biologics License Application (BLA) submission for SER-109 with the FDA in 2022, positioning SER-109 to potentially become the first FDA-approved microbiome-based therapeutic for treating rCDI with a potential product launch in the first half of 2023.

Guideline Update:

- In 2021, clinical practice guidelines for CDI were updated by the American College of Gastroenterology (ACG), and the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America (IDSA-SHEA) also published clinical practice

guidelines focusing on the use of fidaxomicin and bezlotoxumab in adults. Recommended treatment is based on the type of episode (primary or recurrent) as well as the number of previous recurrences and/or presence of fulminant infection. The IDSA-SHEA guidelines suggest fidaxomicin as the preferred agent for treating initial CDI, with oral vancomycin considered an acceptable alternative. For a first recurrence, standard or extended-pulsed dosing of fidaxomicin is suggested, with oral vancomycin considered an acceptable alternative. The IDSA-SHEA guidelines suggest the addition of bezlotoxumab to antibiotic therapy in patients who had a CDI recurrence within the previous 6 months. Patients with a first episode of CDI who have additional risk factors (particularly those with multiple risk factors) for recurrence, such as age 65 years or older, immunocompromised status, or severe CDI, may benefit from the addition of bezlotoxumab to antibiotic therapy in settings with available resources for its use.

Recommendations

The College of Pharmacy does not recommend any changes to the current Zinplava™ (bezlotoxumab) prior authorization criteria at this time.

[1] Finch Therapeutics. Finch Therapeutics Announces Positive Topline Results from PRISM-EXT Phase 2 Trial of CP101 for Prevention of Recurrent *C. difficile* Infection. Available online at: https://ir.finchtherapeutics.com/news-releases/news-release-details/finch-therapeutics-announces-positive-topline-results-prism-ext. Issued 11/09/2021. Last accessed 09/01/2022.
[2] Finch Therapeutics. Finch Therapeutics Presents Data from its Positive PRISM3 Trial of CP101 in Recurrent *C. difficile* Infection at Two Leading Medical Conferences. Available online at: https://ir.finchtherapeutics.com/news-releases/news-release-details/finch-therapeutics-presents-data-its-positive-prism3-trial-cp101/. Issued 10/28/2020. Last accessed 09/01/2022.
[3] Finch Therapeutics. Finch Therapeutics Provides an Update on its Phase 3 Trial of CP101 in Recurrent *C. difficile* Infection. Available online at: https://ir.finchtherapeutics.com/news-releases/news-release-details/finch-therapeutics-provides-update-its-phase-3-trial-cp101. Issued 03/01/2022. Last accessed 09/01/2022.
[4] Seres Therapeutics, Inc. Seres Therapeutics Presents Phase III Results of SER-109 for Recurrent *C. Difficile* Infection at the Digestive Disease Week (DDW) Annual Meeting. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20220522005035/en. Issued 05/22/2022. Last accessed 09/01/2022.
[5] Sucher A, Biehle L, Smith A, Tran C. Updated Clinical Practice Guidelines for *C. difficile* Infection in Adults. *US Pharm* 2021; 46(12):HS10-HS16.