

## State Fiscal Year 2023 Print Annual Reviews Quarter 3

Count	Category/Medication
1.	Actinic Keratosis Medications
2.	Anticonvulsants
3.	Antihypertensive Medications
4.	Benign Prostatic Hyperplasia (BPH) Medications
5.	Benzodiazepines
6.	Hereditary Angioedema (HAE) Medications
7.	Inhaled Anti-Infective Medications
8.	Myalept® (Metreleptin)
9.	Osteoporosis Medications
10.	Parkinson's Disease Medications
11.	Prenatal Vitamins
12.	Qbrexza® (Glycopyrronium)
13.	Qualaquin® (Quinine Sulfate)
14.	Short-Acting Beta <sub>2</sub> Agonists (SABAs)
15.	Strensiq® (Asfotase Alfa)
16.	Urea Cycle Disorder (UCD) Medications
17.	Xgeva® (Denosumab)
18.	Xuriden® (Uridine Triacetate)

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

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

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# Fiscal Year 2023 Annual Review of Actinic Keratosis Medications

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## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

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### Current Prior Authorization Criteria

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#### **Carac® (Fluorouracil 0.5% Cream) Approval Criteria:**

1. An FDA approved diagnosis of multiple actinic or solar keratoses of the face and anterior scalp in adults; and
2. Carac® must be prescribed by a dermatologist or an advanced care practitioner with a supervising physician who is a dermatologist; and
3. A patient-specific, clinically significant reason why the member cannot use fluorouracil 5% cream, fluorouracil 5% solution, or fluorouracil 2% solution must be provided.

#### **Picato® (Ingenol Mebutate Gel) Approval Criteria:**

1. An FDA approved diagnosis of actinic keratosis (AK); and
2. Member must be 18 years of age or older; and
3. Patient-specific information must be documented on the prior authorization form, including all of the following:
  - a. Number of AK lesion(s) being treated; and
  - b. Size of each lesion being treated; and
  - c. Location of lesion(s) being treated; and
4. Approval quantity and length will be based on patient-specific information provided, in accordance with package labeling and FDA approved dosing regimen.

#### **Solaraze® (Diclofenac 3% Gel) Approval Criteria:**

1. An FDA approved diagnosis of actinic keratosis (AK); and
2. Patient-specific information must be documented on the prior authorization form, including all of the following:
  - a. Number of AK lesion(s) being treated; and
  - b. Size of each lesion being treated; and
  - c. Anticipated duration of treatment; and
3. Approval quantity and length will be based on patient-specific information provided, in accordance package labeling and FDA approved dosing regimen.

#### **Zyclara® (Imiquimod 2.5% and 3.75% Cream) Approval Criteria:**

1. An FDA approved indication for topical treatment of 1 of the following:
  - a. Actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults; or

- b. External genital and perianal warts/condyloma acuminata (EGW) in members 12 years and older; and
- 2. Member must be 12 years of age or older; and
- 3. Requests for a diagnosis of molluscum contagiosum in children 2 to 12 years of age will generally not be approved; and
- 4. A patient-specific, clinically significant reason why the member cannot use generic imiquimod 5% cream in place of Zyclara® (imiquimod 2.5% and 3.75%) must be provided.

### Utilization of Actinic Keratosis Medications: Fiscal Year 2023

#### Comparison of Fiscal Years

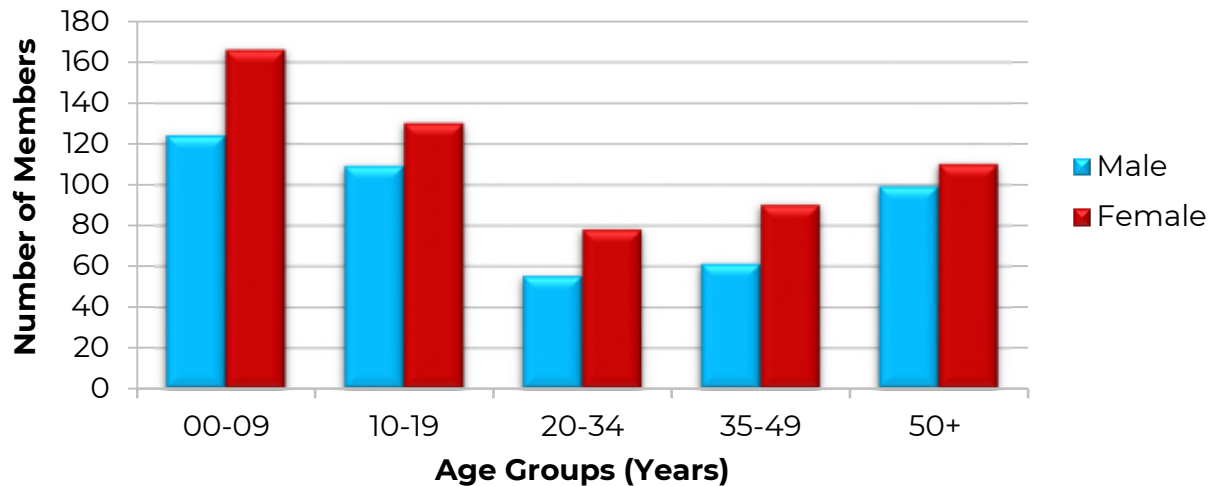
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	947	1,240	\$40,103.07	\$32.34	\$0.92	22,248	43,477
2023	1,022	1,435	\$38,778.45	\$27.02	\$0.72	27,151	53,991
<b>% Change</b>	<b>7.90%</b>	<b>15.70%</b>	<b>-3.30%</b>	<b>-16.50%</b>	<b>-21.70%</b>	<b>22.00%</b>	<b>24.20%</b>
<b>Change</b>	<b>75</b>	<b>195</b>	<b>-\$1,324.62</b>	<b>-\$5.32</b>	<b>-\$0.20</b>	<b>4,903</b>	<b>10,514</b>

Costs do not reflect rebated prices or net costs.

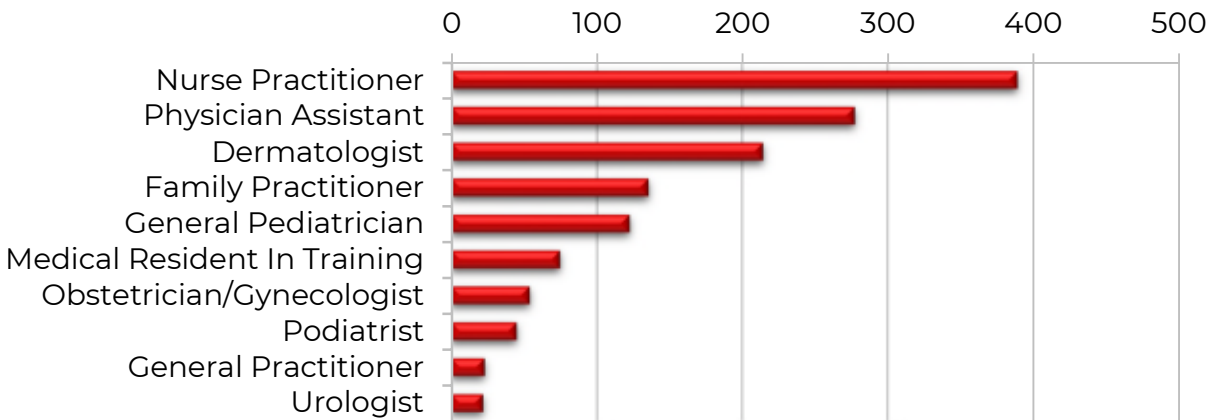
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

#### Demographics of Members Utilizing Actinic Keratosis Medications



## Top Prescriber Specialties of Actinic Keratosis Medications by Number of Claims

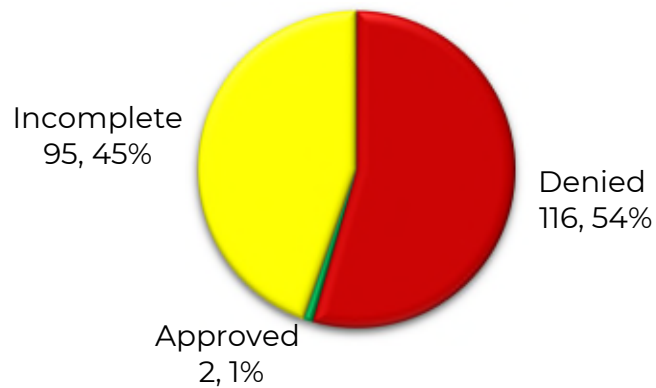


## Prior Authorization of Actinic Keratosis Medications

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There were 213 prior authorization requests submitted for actinic keratosis medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

### Status of Petitions



## Market News and Updates<sup>1</sup>

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### Anticipated Patent Expiration(s):

- Zyclara<sup>®</sup> (imiquimod 2.5% and 3.75% cream): December 2029
- Picato<sup>®</sup> (ingenol mebutate gel): May 2033

## Recommendations

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

## Utilization Details of Actinic Keratosis Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IMIQUIMOD CRE 5%	1,202	839	\$27,840.87	\$23.16	1.43	71.79%
FLUOROURACIL CRE 5%	232	191	\$10,894.07	\$46.96	1.21	28.09%
FLUOROURACIL SOL 2%	1	1	\$43.51	\$43.51	1	0.11%
<b>TOTAL</b>	<b>1,435</b>	<b>1,022*</b>	<b>\$38,778.45</b>	<b>\$27.02</b>	<b>1.4</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

CRE = cream; SOL= solution

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

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<sup>1</sup> 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 02/2024. Last accessed 02/02/2024.

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# Fiscal Year 2023 Annual Review of Anticonvulsants

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## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

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### Current Prior Authorization Criteria

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1. Anticonvulsants are included in the mandatory generic plan.
  - a. All brand-name anticonvulsants (with a generic equivalent) will require prior authorization.
    - i. Brand-name medications (with a generic equivalent) will be approved for all members who are currently stable on these medications and have a seizure diagnosis.
2. Prior authorization will be required for certain non-standard dosage forms of medications when the drug is available in standard dosage forms.
  - a. Members 12 years of age and older must have a documented medical reason demonstrating the need for non-standard dosage forms.
  - b. Criteria for approval of extended-release formulations:
    - i. Previously stabilized on the short-acting formulation; and
    - ii. Dosing is not more than once daily; and
    - iii. A reason why the short-acting formulation is not adequate must be provided; and
    - iv. Dose packs will not be approved if standard dosage forms are available.
3. Quantity limit restrictions will be placed on lower strength tablets and capsules. The highest strengths will continue to have no quantity restrictions unless a maximum dose is specified for a particular medication.

### **Afinitor® (Everolimus) Approval Criteria\* [Tuberous Sclerosis Complex (TSC)-Associated Partial-Onset Seizures Diagnosis]:**

1. An FDA approved diagnosis of TSC-associated partial-onset seizures; and
2. Initial prescription must be written by a neurologist or neuro-oncologist; and
3. Member must have failed therapy with at least 3 anticonvulsants; and
4. Afinitor® must be used as adjunctive treatment; and
5. Member must not be taking any P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, clarithromycin) concurrently with Afinitor®; and

6. Member must not be taking St. John's wort concurrently with Afinitor®; and
7. Prescriber must verify that Afinitor® trough levels and adverse reactions (e.g., non-infectious pneumonitis, stomatitis, hyperglycemia, dyslipidemia, thrombocytopenia, neutropenia, febrile neutropenia) will be monitored, and dosing changes or discontinuations will correspond with recommendations in the drug labeling; and
8. Prescriber must verify that female members will use contraception while receiving Afinitor® therapy and for 8 weeks after the last dose of Afinitor® and that male members with female partners of reproductive potential will use contraception while receiving Afinitor® therapy and for 4 weeks after the last dose of Afinitor®; and
9. The member's recent body surface area (BSA) must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
10. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

\*Utilization data for Afinitor® (everolimus) and approval criteria for indications other than seizure diagnoses can be found in the September 2023 Drug Utilization Review (DUR) Board packet. Afinitor® is reviewed annually with the breast cancer medications.

**Aptiom® (Eslicarbazepine) Approval Criteria:**

1. An FDA approved diagnosis of partial-onset seizures; and
2. Member must not currently be taking oxcarbazepine (concurrent use is contraindicated); and
3. A patient-specific, clinically significant reason why the member cannot use oxcarbazepine must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (200mg and 400mg) and 60 tablets per 30 days on the higher strength tablets (600mg and 800mg).

**Banzel® (Rufinamide) Approval Criteria:**

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); and
2. Initial prescription must be written by a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Authorization of generic rufinamide (in place of brand Banzel®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
5. Members currently stable on Banzel® (rufinamide) and who have a seizure diagnosis will be approved for continuation of therapy.

**Briviact® (Brivaracetam) Approval Criteria:**

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be prescribed by, or in consultation with, a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants; and
4. Members currently stable on Briviact® and who have a seizure diagnosis will be approved for continuation of therapy; and
5. For Briviact® oral solution, an age restriction of 12 years of age and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral tablet formulation; and
6. Approval length for Briviact® intravenous (IV) will be for a maximum of 7 days of therapy. Further approval may be granted if the prescriber documents an ongoing need for Briviact® IV therapy over Briviact® oral formulations.

**Diacomit® (Stiripentol) Approval Criteria:**

1. An FDA approved indication of adjunctive treatment of seizures associated with Dravet syndrome; and
2. Member must be 6 months of age or older and weigh  $\geq 7$ kg; and
3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must have failed or be inadequately controlled with clobazam and valproate; and
5. Member must take clobazam and valproate concomitantly with Diacomit® or a reason why concomitant clobazam and valproate are not appropriate for the member must be provided; and
6. Members currently stable on Diacomit® and who have a seizure diagnosis will be approved for continuation of therapy; 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 package labeling; and
8. For Diacomit® powder for oral suspension, an age restriction of 12 years and younger will apply. Members older than 12 years of age will require a patient-specific, clinically significant reason why the member cannot take the oral capsule formulation; and
9. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

**Elepsia™ XR [Levetiracetam Extended-Release (ER) Tablet] Approval Criteria:**

1. An FDA approved diagnosis of partial-onset seizures; and



2. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use generic formulations of levetiracetam ER must be provided; and
3. A quantity limit of 60 tablets per 30 days will apply.

**Epidiolex® (Cannabidiol Oral Solution) Approval Criteria:**

1. Diagnosis\* of 1 of the following:
  - a. Lennox-Gastaut syndrome (LGS); or
  - b. Dravet syndrome; or
  - c. Tuberous sclerosis complex (TSC)-associated seizures; or
  - d. Intractable epilepsy; and

\*The manufacturer has provided a supplemental rebate to allow Epidiolex® claims to pay at the point of sale if the member has a reported diagnosis of LGS, Dravet syndrome, TSC-associated seizures, or intractable epilepsy within the past 12 months of claims history; however, Epidiolex® will follow the original criteria if the manufacturer chooses not to participate in supplemental rebates.
2. Member must be 1 year of age or older; and
3. Members currently stable on Epidiolex® and who have a seizure diagnosis will be approved for continuation of therapy.

**Eprontia® (Topiramate Oral Solution) Approval Criteria:**

1. An FDA approved indication of 1 of the following:
  - a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
  - b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
  - c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use topiramate tablets and sprinkle capsules must be provided; and
3. An age restriction of 11 years of age and younger will apply. Members older than 11 years of age will require a patient-specific, clinically significant reason why a special formulation product is needed; and
4. A quantity limit of 473mL per 29 days will apply.

**Felbatol® (Felbamate) Approval Criteria:**

1. Initial prescription must be written by a neurologist; and
2. Member must have failed therapy with at least 3 other anticonvulsants.

**Fintepla® (Fenfluramine) Approval Criteria:**

1. An FDA approved diagnosis of 1 of the following:
  - a. Dravet syndrome; or
  - b. Lennox-Gastaut syndrome (LGS); and
2. Member must be 2 years of age or older; and

3. Initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must not be taking monoamine oxidase inhibitors within 14 days of administration of Fintepla®; and
5. Prescriber must verify the member's blood pressure will be monitored; and
6. Member must not be actively suicidal or have uncontrolled depression and prescriber must verify member will be monitored for depression prior to starting Fintepla® therapy and throughout treatment; and
7. For a diagnosis of Dravet syndrome, the member must have failed or be inadequately controlled with at least 2 other anticonvulsants; and
8. For a diagnosis of LGS, the member must have failed or be inadequately controlled with at least 3 other anticonvulsants; and
9. Pharmacy and provider must be certified in the Fintepla® Risk Evaluation and Mitigation Strategy (REMS) program; and
10. Member must be enrolled in the Fintepla® REMS program; and
11. 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
12. Prescriber must verify that dose titration and maximum maintenance dose will be followed according to package labeling based on member weight and concomitant medications; and
13. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
14. A quantity limit of 360mL per 30 days will apply.

**Oxtellar XR® [Oxcarbazepine Extended-Release (ER)] Approval Criteria:**

1. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation must be provided; and
2. A quantity limit of 30 tablets per 30 days will apply on the lower strength tablets (150mg and 300mg).

**Primidone 125mg Tablet Approval Criteria:**

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

**Qudexy® XR [Topiramate Extended-Release (ER)] Approval Criteria:**

1. An FDA approved indication of 1 of the following:
  - a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or
  - b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
  - c. Prophylaxis of migraine headaches; and

2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and
3. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (150mg and 200mg).

**Sabril® (Vigabatrin) Approval Criteria:**

1. An FDA approved diagnosis of refractory complex seizures in adults and pediatric members 2 years of age or older, or infantile spasms in children 1 month to 2 years of age; and
2. Authorization of generic vigabatrin (in place of brand Sabril®) will require a patient-specific, clinically significant reason why the member cannot use the brand formulation (brand formulation is preferred); and
3. Members with refractory complex seizures must have previous trials of at least 3 other anticonvulsants; or
4. Prescription must be written by a neurologist; and
5. Member, prescriber, and pharmacy must all register in the Sabril® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy.

**Spritam® (Levetiracetam Tablet for Oral Suspension) Approval Criteria:**

1. An FDA approved diagnosis of partial-onset seizures, myoclonic seizures, or primary generalized tonic-clonic (PGTC) seizures; and
2. A patient-specific, clinically significant reason why the member cannot use generic formulations of levetiracetam must be provided; and
3. A quantity limit of 60 tablets per 30 days will apply.

**Sympazan® (Clobazam Oral Film) Approval Criteria:**

1. An FDA approved indication of adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in members 2 years of age and older; and
2. Previous failure of at least 2 non-benzodiazepine anticonvulsants; and
3. Previous failure of clonazepam; and
4. A patient-specific, clinically significant reason why the member cannot use clobazam oral tablets or clobazam oral suspension must be provided; and
5. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication.

**Trokendi XR® [Topiramate Extended-Release (ER)] Approval Criteria:**

1. An FDA approved indication of 1 of the following:
  - a. Treatment of partial-onset or primary generalized tonic-clonic (PGTC) seizures; or

- b. Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS); or
  - c. Prophylaxis of migraine headaches; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation, Topamax® (topiramate), must be provided; and
3. Members currently stable on Trokendi XR® (topiramate ER) and who have a seizure diagnosis will be approved for continuation of therapy; and
4. A quantity limit of 30 capsules per 30 days will apply on the lower strength capsules (25mg, 50mg, and 100mg) and 60 capsules per 30 days on the higher strength capsules (200mg).

**Xcopri® (Cenobamate) Approval Criteria:**

1. An FDA approved diagnosis of partial-onset seizures; and
2. Initial prescription must be written by a neurologist; and
3. Member must have failed therapy with at least 3 other anticonvulsants.

**Zonisade® (Zonisamide Oral Suspension) Approval Criteria:**

1. An FDA approved indication of adjunctive treatment of partial-onset seizures; and
2. A patient-specific, clinically significant reason why the member cannot use zonisamide capsules must be provided; and
3. A quantity limit of 900mL per 30 days will apply.

**Ztalmy® (Ganaxolone) Approval Criteria:**

1. An FDA approved diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD); and
  - a. Diagnosis must be confirmed by genetic testing identifying a mutation in the CDKL5 gene that is pathogenic or likely pathogenic; and
2. Member must be 2 years of age or older; and
3. The initial prescription must be written by, or in consultation with, a neurologist; and
4. Member must have failed at least 2 other anticonvulsants; and
5. Members currently stable on Ztalmy® and who have a CDD diagnosis confirmed by genetic testing will be grandfathered; and
6. The member's recent weight (kg), taken within the last 3 weeks, must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling; and
7. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of the medication; and
8. Subsequent approvals will be for the duration of 1 year; and

9. A quantity limit of 1,100mL per 30 days will apply.

**Utilization of Anticonvulsants: Fiscal Year 2023**

The following utilization data includes anticonvulsants used for all diagnoses and does not differentiate between seizure diagnoses and other diagnoses, for which use may be appropriate.

**Comparison of Fiscal Years**

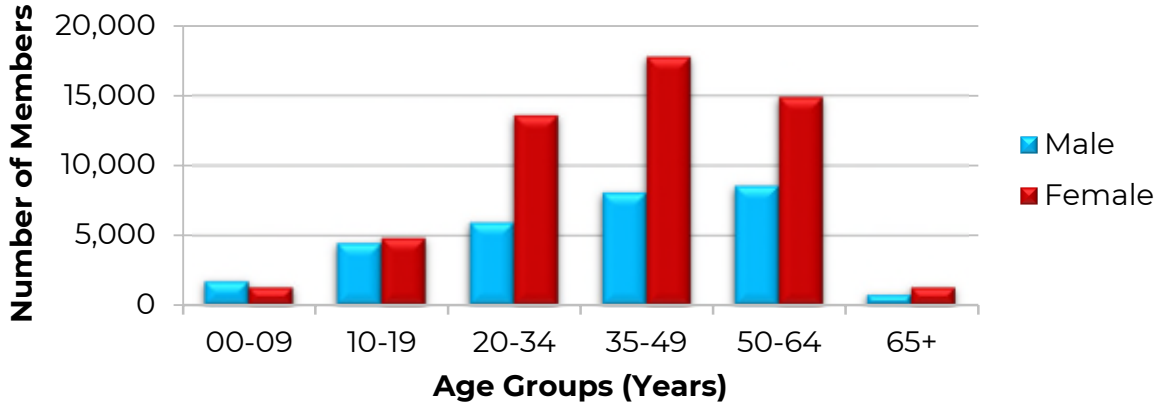
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	68,516	409,614	\$33,620,716.68	\$82.08	\$2.34	42,887,177	14,339,424
2023	82,679	473,870	\$34,525,014.60	\$72.86	\$2.01	49,769,513	17,196,283
% Change	20.7%	15.7%	2.7%	-11.2%	-14.1%	16.0%	19.9%
Change	14,163	64,256	\$904,297.92	-\$9.22	-\$0.33	6,882,336	2,856,859

Costs do not reflect rebated prices or net costs.

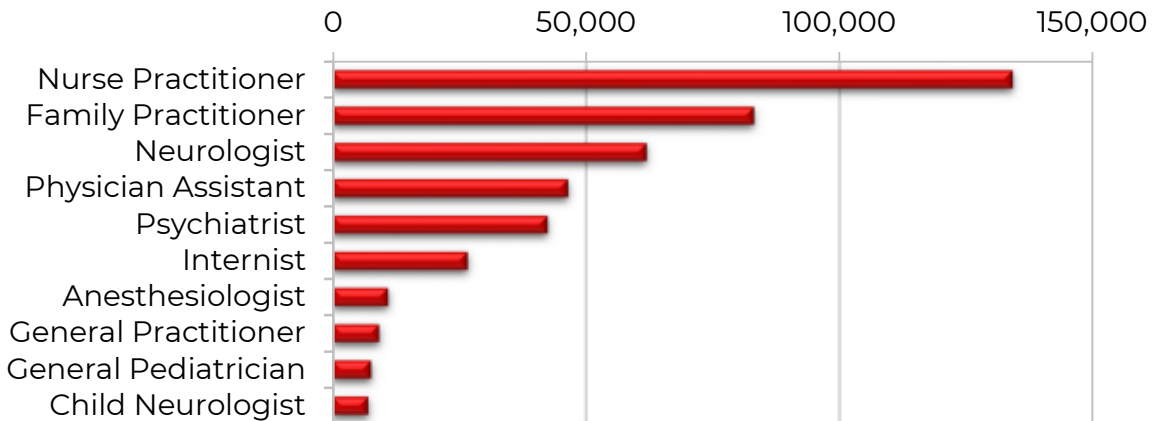
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

**Demographics of Members Utilizing Anticonvulsants**



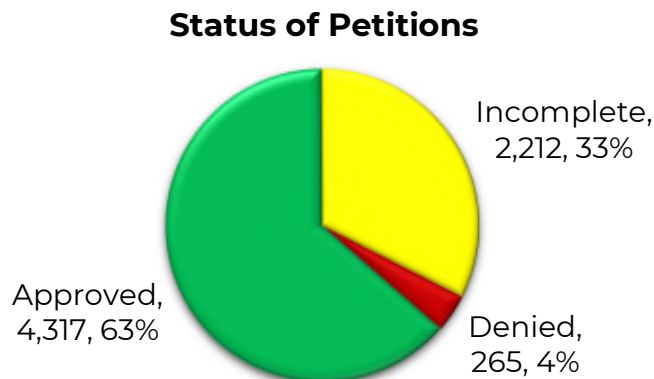
**Top Prescriber Specialties of Anticonvulsants by Number of Claims**



## Prior Authorization of Anticonvulsants

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There were 6,794 prior authorization requests submitted for anticonvulsants fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



## Market News and Updates<sup>1,2,3,4</sup>

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### Anticipated Patent Expiration(s):

- Fycompa<sup>®</sup> (perampanel tablets, oral suspension): July 2026
- Oxtellar XR<sup>®</sup> [oxcarbazepine extended-release (ER) tablets]: April 2027
- Elepsia<sup>™</sup> XR (levetiracetam ER tablets): October 2027
- Nayzilam<sup>®</sup> (midazolam nasal spray): January 2028
- Trokendi XR<sup>®</sup> (topiramate ER capsules): April 2028
- Valtoco<sup>®</sup> (diazepam nasal spray): March 2029
- Diacomit<sup>®</sup> (stiripentol capsules, oral suspension): July 2029\*  
\*Diacomit<sup>®</sup> does not have any unexpired patents; however, it does currently have exclusivity through July 2029.
- Briviact<sup>®</sup> (brivaracetam tablets, oral solution, IV solution): April 2030
- Aptiom<sup>®</sup> (eslicarbazepine tablets): August 2032
- Qudexy<sup>®</sup> XR (topiramate ER capsules): March 2033
- Spritam<sup>®</sup> (levetiracetam tablets for oral suspension): March 2034
- Ztalmy (ganaxolone oral suspension): August 2037
- Zonisade<sup>®</sup> (zonisamide oral suspension): August 2038
- Fintepla<sup>®</sup> (fenfluramine oral solution): December 2038
- Xcopri<sup>®</sup> (cenobamate tablets): June 2039
- Sympazan<sup>®</sup> (clobazam oral films): January 2040
- Epidiolex<sup>®</sup> (cannabidiol oral solution): March 2041

### News:

- **July 2023:** Center for Drug Evaluation and Research (CDER) researchers conducted a study of lamotrigine to compare the generic ER tablets to the brand name ER tablets (Lamictal<sup>®</sup> XR<sup>™</sup>) in healthy subjects. The study evaluated the pharmacokinetics and bioequivalence of generic

and brand lamotrigine ER products and whether it could better support the approval of generic lamotrigine ER products. The findings showed that generic and brand lamotrigine ER tablets are bioequivalent, supporting the use of generic-brand substitution of these products.

- **November 2023:** The U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication warning that the antiseizure medications levetiracetam and clobazam can cause a rare but serious reaction called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Manufacturers of these medications are now required to add new warnings to their *Prescribing Information* and the medication guides to include information about early symptoms and what patients or caregivers should do if they experience the symptoms.

### Pipeline:

- **Libervant™:** Libervant™ is a buccal formulation of diazepam. The FDA accepted a New Drug Application (NDA) for Libervant™ in patients 2 to 5 years of age and set a Prescription Drug User Fee Act (PDUFA) date of April 28, 2024. Libervant™ received tentative approval for the treatment of intermittent, stereotypic episodes of frequent seizure activity in patients 12 years of age and older in August 2022, but Libervant™ is currently under an orphan drug block to market access until January 2027.

### Recommendations

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

### Utilization Details of Anticonvulsants: Fiscal Year 2023

#### Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
<b>GABAPENTIN PRODUCTS</b>						
GABAPENTIN CAP 300MG	63,536	21,256	\$903,460.17	\$14.22	2.99	2.62%
GABAPENTIN TAB 600MG	33,544	7,948	\$666,710.49	\$19.88	4.22	1.93%
GABAPENTIN TAB 800MG	25,269	4,866	\$588,797.09	\$23.30	5.19	1.71%
GABAPENTIN CAP 100MG	22,582	9,915	\$274,043.73	\$12.14	2.28	0.79%
GABAPENTIN CAP 400MG	10,127	2,915	\$152,722.74	\$15.08	3.47	0.44%
GABAPENTIN SOL 250MG/5ML	1,768	342	\$70,242.49	\$39.73	5.17	0.20%
NEURONTIN CAP 300MG	12	1	\$6,698.55	\$558.21	12	0.02%
<b>SUBTOTAL</b>	<b>156,838</b>	<b>47,243</b>	<b>\$2,662,675.26</b>	<b>\$16.98</b>	<b>3.32</b>	<b>7.71%</b>
<b>LAMOTRIGINE PRODUCTS</b>						
LAMOTRIGINE TAB 100MG	17,450	4,660	\$217,344.23	\$12.46	3.74	0.63%
LAMOTRIGINE TAB 25MG	14,523	5,852	\$174,501.09	\$12.02	2.48	0.51%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
LAMOTRIGINE TAB 200MG	10,676	2,228	\$152,420.14	\$14.28	4.79	0.44%
LAMOTRIGINE TAB 150MG	6,768	1,649	\$90,337.90	\$13.35	4.1	0.26%
LAMOTRIGINE CHW 25MG	284	46	\$10,491.01	\$36.94	6.17	0.03%
LAMOTRIGINE TAB 200MG ER	237	51	\$19,904.64	\$83.99	4.65	0.06%
LAMOTRIGINE TAB 300MG ER	195	33	\$31,003.31	\$158.99	5.91	0.09%
LAMOTRIGINE CHW 5MG	164	40	\$6,868.97	\$41.88	4.1	0.02%
LAMOTRIGINE TAB 100MG ER	116	26	\$5,510.22	\$47.50	4.46	0.02%
LAMOTRIGINE TAB 250MG ER	114	27	\$23,744.44	\$208.28	4.22	0.07%
LAMOTRIGINE ODT 25MG	90	15	\$30,172.44	\$335.25	6	0.09%
LAMOTRIGINE ODT 50MG	88	14	\$18,843.13	\$214.13	6.29	0.05%
LAMOTRIGINE TAB 50MG ER	86	24	\$4,673.00	\$54.34	3.58	0.01%
LAMOTRIGINE ODT 100MG	72	11	\$13,158.78	\$182.76	6.55	0.04%
LAMICTAL TAB 200MG	61	10	\$69,780.36	\$1,143.94	6.1	0.20%
LAMICTAL TAB 150MG	36	5	\$73,037.69	\$2,028.82	7.2	0.21%
LAMICTAL TAB 100MG	33	4	\$38,331.16	\$1,161.55	8.25	0.11%
LAMOTRIGINE TAB 200MG	32	6	\$6,102.13	\$190.69	5.33	0.02%
LAMOTRIGINE TAB 25MG ER	17	6	\$637.97	\$37.53	2.83	0.00%
LAMICTAL XR TAB 200MG	15	2	\$33,654.42	\$2,243.63	7.5	0.10%
LAMICTAL ODT 50MG	10	1	\$8,156.44	\$815.64	10	0.02%
LAMICTAL TAB 25MG	10	2	\$9,769.29	\$976.93	5	0.03%
SUBVENITE TAB 200MG	9	6	\$133.43	\$14.83	1.5	0.00%
LAMICTAL CHW 25MG	7	1	\$3,260.36	\$465.77	7	0.01%
SUBVENITE TAB 100MG	7	7	\$73.68	\$10.53	1	0.00%
SUBVENITE TAB 150MG	4	1	\$46.12	\$11.53	4	0.00%
SUBVENITE TAB 25MG	3	3	\$37.85	\$12.62	1	0.00%
LAMICTAL XR TAB 250MG	2	1	\$10,350.66	\$5,175.33	2	0.03%
LAMOTRIGINE STARTER KIT 49	2	2	\$1,284.98	\$642.49	1	0.00%
LAMICTAL ODT KIT	1	1	\$633.01	\$633.01	1	0.00%
SUBVENITE STARTER KIT 35	1	1	\$447.12	\$447.12	1	0.00%
<b>SUBTOTAL</b>	<b>51,113</b>	<b>14,735</b>	<b>\$1,054,709.97</b>	<b>\$20.63</b>	<b>3.47</b>	<b>3.05%</b>
<b>LEVETIRACETAM PRODUCTS</b>						
LEVETIRACETAM TAB 500MG	12,581	3,607	\$213,205.01	\$16.95	3.49	0.62%
LEVETIRACETAM SOL 100MG/ML	12,025	1,817	\$276,343.54	\$22.98	6.62	0.80%
LEVETIRACETAM TAB 1,000MG	7,945	1,788	\$231,937.83	\$29.19	4.44	0.67%
LEVETIRACETAM TAB 750MG	6,175	1,436	\$150,665.86	\$24.40	4.3	0.44%
LEVETIRACETAM TAB 250MG	1,873	496	\$28,326.14	\$15.12	3.78	0.08%
LEVETIRACETAM TAB 500MG ER	820	190	\$20,717.07	\$25.26	4.32	0.06%
LEVETIRACETAM TAB 750MG ER	804	132	\$27,086.12	\$33.69	6.09	0.08%
KEPPRA XR TAB 750MG	56	7	\$68,513.42	\$1,223.45	8	0.20%
KEPPRA XR TAB 500MG	52	7	\$47,848.54	\$920.16	7.43	0.14%
KEPPRA TAB 1,000MG	39	4	\$54,070.78	\$1,386.43	9.75	0.16%
KEPPRA SOL 100MG/ML	25	3	\$19,844.29	\$793.77	8.33	0.06%
KEPPRA TAB 750MG	19	2	\$24,801.37	\$1,305.34	9.5	0.07%



PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
KEPPRA TAB 500MG	18	4	\$15,818.52	\$878.81	4.5	0.05%
KEPPRA TAB 250MG	6	1	\$5,659.41	\$943.24	6	0.02%
ELEPSIA XR TAB 1,000MG	4	2	\$11,691.18	\$2,922.80	2	0.03%
<b>SUBTOTAL</b>	<b>42,442</b>	<b>9,496</b>	<b>\$1,196,529.08</b>	<b>\$28.19</b>	<b>4.47</b>	<b>3.48%</b>
<b>CLONAZEPAM PRODUCTS</b>						
CLONAZEPAM TAB 1MG	17,575	3,353	\$198,912.10	\$11.32	5.24	0.58%
CLONAZEPAM TAB 0.5MG	16,321	4,169	\$168,906.81	\$10.35	3.91	0.49%
CLONAZEPAM TAB 2MG	4,303	803	\$46,974.71	\$10.92	5.36	0.14%
CLONAZEPAM ODT 0.25MG	1,404	511	\$53,077.29	\$37.80	2.75	0.15%
CLONAZEPAM ODT 0.125MG	830	346	\$28,238.18	\$34.02	2.4	0.08%
CLONAZEPAM ODT 0.5MG	736	276	\$26,503.26	\$36.01	2.67	0.08%
CLONAZEPAM ODT 1MG	373	142	\$11,875.80	\$31.84	2.63	0.03%
CLONAZEPAM ODT 2MG	56	21	\$2,099.78	\$37.50	2.67	0.01%
<b>SUBTOTAL</b>	<b>41,598</b>	<b>9,621</b>	<b>\$536,587.93</b>	<b>\$12.90</b>	<b>4.32</b>	<b>1.56%</b>
<b>TOPIRAMATE PRODUCTS</b>						
TOPIRAMATE TAB 50MG	13,765	4,757	\$161,129.80	\$11.71	2.89	0.47%
TOPIRAMATE TAB 25MG	13,448	5,888	\$157,098.78	\$11.68	2.28	0.46%
TOPIRAMATE TAB 100MG	8,891	2,404	\$124,942.52	\$14.05	3.7	0.36%
TOPIRAMATE TAB 200MG	2,856	598	\$49,150.09	\$17.21	4.78	0.14%
TOPIRAMATE CAP 25MG	389	78	\$41,908.46	\$107.73	4.99	0.12%
TOPIRAMATE CAP 15MG	245	69	\$11,063.37	\$45.16	3.55	0.03%
EPRONTIA SOL 25MG/ML	92	21	\$24,700.97	\$268.49	4.38	0.07%
TROKENDI XR CAP 100MG	66	13	\$114,873.33	\$1,740.51	5.08	0.33%
TROKENDI XR CAP 200MG	60	19	\$132,741.72	\$2,212.36	3.16	0.38%
TOPIRAMATE CAP SPR 100MG ER	51	15	\$28,216.88	\$553.27	3.4	0.08%
TOPIRAMATE CAP SPR 200MG ER	43	10	\$38,511.06	\$895.61	4.3	0.11%
TROKENDI XR CAP 50MG	31	8	\$15,090.78	\$486.80	3.88	0.04%
TOPIRAMATE CAP SPR 150MG ER	29	7	\$20,134.60	\$694.30	4.14	0.06%
TOPIRAMATE CAP SPR 50MG ER	26	8	\$7,157.31	\$275.28	3.25	0.02%
TOPAMAX TAB 100MG	20	3	\$47,723.26	\$2,386.16	6.67	0.14%
TOPAMAX TAB 200MG	19	3	\$39,484.39	\$2,078.13	6.33	0.11%
TOPIRAMATE CAP 100MG ER	12	6	\$10,507.12	\$875.59	2	0.03%
TOPIRAMATE CAP 200MG ER	10	6	\$14,073.01	\$1,407.30	1.67	0.04%
TROKENDI XR CAP 25MG	9	2	\$4,485.30	\$498.37	4.5	0.01%
TOPAMAX TAB 50MG	6	1	\$1,214.25	\$202.38	6	0.00%
TOPAMAX SPR CAP 25MG	4	1	\$53,187.44	\$13,296.86	4	0.15%
TOPIRAMATE CAP SPR 25MG ER	3	2	\$470.76	\$156.92	1.5	0.00%
TOPIRAMATE CAP 50MG ER	3	3	\$1,884.61	\$628.20	1	0.01%
QUDEXY XR CAP 100MG/24HR	2	1	\$1,402.90	\$701.45	2	0.00%
QUDEXY XR CAP 25MG/24HR	1	1	\$276.33	\$276.33	1	0.00%
TOPIRAMATE CAP 25MG ER	1	1	\$963.57	\$963.57	1	0.00%
<b>SUBTOTAL</b>	<b>40,082</b>	<b>13,925</b>	<b>\$1,102,392.61</b>	<b>\$27.50</b>	<b>2.88</b>	<b>3.16%</b>
<b>DIVALPROEX, VALPROATE, AND VALPROIC ACID PRODUCTS</b>						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
DIVALPROEX TAB 500MG DR	9,652	2,197	\$193,292.32	\$20.03	4.39	0.56%
DIVALPROEX TAB 500MG ER	7,680	1,765	\$175,470.09	\$22.85	4.35	0.51%
DIVALPROEX TAB 250MG DR	6,556	1,778	\$93,851.12	\$14.32	3.69	0.27%
DIVALPROEX TAB 250MG ER	3,568	888	\$68,450.61	\$19.18	4.02	0.20%
VALPROIC ACID SOL 250MG/5ML	2,267	334	\$43,871.97	\$19.35	6.79	0.13%
DIVALPROEX TAB 125MG DR	1,937	552	\$28,004.01	\$14.46	3.51	0.08%
DIVALPROEX CAP 125MG	1,661	266	\$94,645.58	\$56.98	6.24	0.27%
VALPROIC ACD CAP 250MG	808	207	\$26,211.96	\$32.44	3.9	0.08%
DEPAKOTE SPR CAP 125MG	78	10	\$31,934.61	\$409.42	7.8	0.09%
DEPAKOTE TAB 500MG DR	39	4	\$25,898.81	\$664.07	9.75	0.08%
DEPAKOTE ER TAB 500MG	30	4	\$25,656.85	\$855.23	7.5	0.07%
DEPAKOTE ER TAB 250MG	18	3	\$3,084.42	\$171.36	6	0.01%
DEPAKOTE TAB 250MG DR	17	2	\$3,489.89	\$205.29	8.5	0.01%
DEPAKOTE TAB 125MG DR	1	1	\$0.00	\$0.00	1	0.00%
VALPROATE INJ 100MG/ML	1	1	\$34.33	\$34.33	1	0.00%
<b>SUBTOTAL</b>	<b>34,313</b>	<b>8,012</b>	<b>\$813,896.57</b>	<b>\$23.72</b>	<b>4.28</b>	<b>2.36%</b>
<b>OXCARBAZEPINE PRODUCTS</b>						
OXCARBAZEPINE TAB 300MG	11,176	2,702	\$241,601.20	\$21.62	4.14	0.70%
OXCARBAZEPINE TAB 600MG	8,956	1,498	\$339,595.36	\$37.92	5.98	0.98%
OXCARBAZEPINE TAB 150MG	7,449	2,137	\$142,878.65	\$19.18	3.49	0.41%
OXCARBAZEPINE SUS 300MG/5ML	3,631	538	\$450,561.42	\$124.09	6.75	1.31%
OXTELLAR XR TAB 600MG	134	26	\$198,743.93	\$1,483.16	5.15	0.58%
OXTELLAR XR TAB 300MG	57	7	\$18,908.44	\$331.73	8.14	0.05%
OXTELLAR XR TAB 150MG	10	2	\$2,496.92	\$249.69	5	0.01%
TRILEPTAL TAB 600MG	6	1	\$1,791.76	\$1,965.29	6	0.03%
TRILEPTAL TAB 300MG	2	1	\$1,763.04	\$881.52	2	0.01%
<b>SUBTOTAL</b>	<b>31,421</b>	<b>6,912</b>	<b>\$1,408,340.72</b>	<b>\$44.82</b>	<b>4.55</b>	<b>4.08%</b>
<b>PREGABALIN PRODUCTS</b>						
PREGABALIN CAP 150MG	7,255	1,567	\$109,393.88	\$15.08	4.63	0.32%
PREGABALIN CAP 75MG	6,459	2,218	\$92,083.10	\$14.26	2.91	0.27%
PREGABALIN CAP 100MG	5,782	1,609	\$81,791.79	\$14.15	3.59	0.24%
PREGABALIN CAP 50MG	4,071	1,633	\$57,765.39	\$14.19	2.49	0.17%
PREGABALIN CAP 200MG	3,081	573	\$46,032.04	\$14.94	5.38	0.13%
PREGABALIN CAP 300MG	1,851	303	\$29,026.79	\$15.68	6.11	0.08%
PREGABALIN CAP 25MG	1,137	608	\$15,151.20	\$13.33	1.87	0.04%
PREGABALIN CAP 225MG	401	85	\$5,935.50	\$14.80	4.72	0.02%
LYRICA CAP 200MG	98	16	\$58,543.94	\$597.39	6.13	0.17%
LYRICA CAP 150MG	52	13	\$37,012.95	\$711.79	4	0.11%
LYRICA CAP 300MG	43	7	\$15,859.81	\$368.83	6.14	0.05%
LYRICA CAP 75MG	40	10	\$20,263.98	\$506.60	4	0.06%
PREGABALIN SOL 20MG/ML	38	11	\$1,575.28	\$41.45	3.45	0.00%
LYRICA CAP 100MG	37	8	\$13,878.88	\$375.10	4.63	0.04%
LYRICA CAP 50MG	25	6	\$16,014.40	\$640.58	4.17	0.05%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
LYRICA CAP 25MG	18	6	\$4,131.46	\$229.53	3	0.01%
LYRICA CAP 225MG	2	2	\$2,155.07	\$1,077.54	1	0.01%
<b>SUBTOTAL</b>	<b>30,390</b>	<b>8,675</b>	<b>\$606,615.46</b>	<b>\$19.96</b>	<b>3.5</b>	<b>1.77%</b>
<b>LACOSAMIDE PRODUCTS</b>						
LACOSAMIDE TAB 200MG	2,277	361	\$84,454.04	\$37.09	6.31	0.24%
LACOSAMIDE TAB 100MG	1,855	450	\$53,279.57	\$28.72	4.12	0.15%
LACOSAMIDE SOL 10MG/ML	1,334	224	\$122,846.47	\$92.09	5.96	0.36%
LACOSAMIDE TAB 150MG	1,065	222	\$32,038.97	\$30.08	4.8	0.09%
LACOSAMIDE TAB 50MG	1,012	269	\$21,111.96	\$20.86	3.76	0.06%
VIMPAT SOL 10MG/ML	673	126	\$823,380.80	\$1,223.45	5.34	2.38%
VIMPAT TAB 200MG	453	99	\$563,468.43	\$1,243.86	4.58	1.63%
VIMPAT TAB 100MG	297	75	\$317,414.34	\$1,068.74	3.96	0.92%
VIMPAT TAB 150MG	162	50	\$161,998.31	\$999.99	3.24	0.47%
VIMPAT TAB 50MG	111	40	\$81,703.62	\$736.07	2.78	0.24%
<b>SUBTOTAL</b>	<b>9,239</b>	<b>1,916</b>	<b>\$2,261,696.51</b>	<b>\$244.80</b>	<b>4.82</b>	<b>6.54%</b>
<b>CARBAMAZEPINE PRODUCTS</b>						
CARBAMAZEPINE TAB 200MG	2,935	697	\$81,979.37	\$27.93	4.21	0.24%
CARBAMAZEPINE TAB 400MG ER	512	96	\$63,368.38	\$123.77	5.33	0.18%
CARBAMAZEPINE CHW 100MG	381	84	\$17,519.87	\$45.98	4.54	0.05%
CARBAMAZEPINE TAB 200MG ER	329	103	\$24,466.78	\$74.37	3.19	0.07%
CARBAMAZEPINE CAP 300MG ER	310	61	\$34,723.44	\$112.01	5.08	0.10%
CARBAMAZEPINE TAB 100MG ER	279	94	\$12,369.53	\$44.34	2.97	0.04%
CARBAMAZEPINE CAP 200MG ER	235	64	\$29,268.32	\$124.55	3.67	0.08%
CARBAMAZEPINE SUS 100MG/5ML	199	26	\$14,248.08	\$71.60	7.65	0.04%
EPITOL TAB 200MG	175	74	\$4,710.07	\$26.91	2.36	0.01%
TRILEPTAL SUS 300MG/5ML	173	56	\$114,008.77	\$659.01	3.09	0.33%
CARBAMAZEPINE CAP 100MG ER	127	51	\$9,259.02	\$72.91	2.49	0.03%
TEGRETOL-XR TAB 400MG	36	6	\$16,125.36	\$447.93	6	0.05%
TEGRETOL TAB 200MG	36	7	\$21,415.66	\$594.88	5.14	0.06%
TEGRETOL-XR TAB 200MG	33	4	\$15,355.33	\$465.31	8.25	0.04%
CARBATROL CAP 200MG	23	3	\$4,170.32	\$181.32	7.67	0.01%
TEGRETOL SUS 100MG/5ML	21	4	\$10,848.38	\$516.59	5.25	0.03%
CARBATROL CAP 300MG	12	1	\$2,539.07	\$211.59	12	0.01%
TEGRETOL-XR TAB 100MG	5	2	\$624.68	\$124.94	2.5	0.00%
<b>SUBTOTAL</b>	<b>5,821</b>	<b>1,433</b>	<b>\$477,000.43</b>	<b>\$81.94</b>	<b>4.06</b>	<b>1.37%</b>
<b>CLOBAZAM PRODUCTS</b>						
CLOBAZAM SUS 2.5MG/ML	2,188	269	\$197,863.65	\$90.43	8.13	0.57%
CLOBAZAM TAB 10MG	1,749	238	\$51,931.06	\$29.69	7.35	0.15%
CLOBAZAM TAB 20MG	1,164	162	\$54,784.75	\$47.07	7.19	0.16%
ONFI TAB 20MG	60	8	\$288,605.59	\$4,810.09	7.5	0.84%
ONFI TAB 10MG	20	2	\$21,458.23	\$1,072.91	10	0.06%
ONFI SUS 2.5MG/ML	16	3	\$83,639.10	\$5,227.44	5.33	0.24%
SYMPAZAN MIS 10MG	12	1	\$22,471.32	\$1,872.61	12	0.07%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
SYMPAZAN MIS 5MG	9	2	\$4,279.29	\$475.48	4.5	0.01%
<b>SUBTOTAL</b>	<b>5,218</b>	<b>685</b>	<b>\$725,032.99</b>	<b>\$138.95</b>	<b>7.62</b>	<b>2.10%</b>
<b>ZONISAMIDE PRODUCTS</b>						
ZONISAMIDE CAP 100MG	3,800	618	\$83,888.05	\$22.08	6.15	0.24%
ZONISAMIDE CAP 50MG	792	159	\$12,044.41	\$15.21	4.98	0.03%
ZONISAMIDE CAP 25MG	426	103	\$6,491.26	\$15.24	4.14	0.02%
ZONISADE SUS 100MG/5ML	21	9	\$9,183.33	\$437.30	2.33	0.03%
ZONEGRAN CAP 100MG	1	1	\$14,957.50	\$14,957.50	1	0.04%
<b>SUBTOTAL</b>	<b>5,040</b>	<b>890</b>	<b>\$126,564.55</b>	<b>\$25.11</b>	<b>5.66</b>	<b>0.36%</b>
<b>PHENYTOIN AND FOSPHENYTOIN PRODUCTS</b>						
PHENYTOIN EX CAP 100MG	2,457	494	\$68,434.57	\$27.85	4.97	0.20%
DILANTIN CAP 100MG	176	29	\$44,025.01	\$250.14	6.07	0.13%
PHENYTOIN SUS 125MG/5ML	144	19	\$4,718.67	\$32.77	7.58	0.01%
PHENYTOIN CHW 50MG	137	30	\$5,655.15	\$41.28	4.57	0.02%
PHENYTOIN EX CAP 300MG	132	30	\$10,010.32	\$75.84	4.4	0.03%
PHENYTOIN EX CAP 200MG	75	24	\$8,062.35	\$107.50	3.13	0.02%
DILANTIN CAP 30MG	66	12	\$13,614.20	\$206.28	5.5	0.04%
DILANTIN CHW 50MG	16	3	\$2,734.01	\$170.88	5.33	0.01%
DILANTIN-125 SUS 125MG/5ML	8	1	\$2,301.00	\$287.63	8	0.01%
PHENYTEK CAP 300MG	7	6	\$520.37	\$74.34	1.17	0.00%
PHENYTEK CAP 200MG	4	2	\$461.30	\$115.33	2	0.00%
FOSPHENYTOIN INJ 100MG/2ML	2	1	\$200.42	\$100.21	2	0.00%
<b>SUBTOTAL</b>	<b>3,224</b>	<b>651</b>	<b>\$160,737.37</b>	<b>\$49.86</b>	<b>4.95</b>	<b>0.47%</b>
<b>DIAZEPAM PRODUCTS</b>						
VALTOCO SPR 10MG	924	597	\$869,385.59	\$940.89	1.55	2.52%
DIAZEPAM GEL 10MG	788	564	\$283,540.11	\$359.82	1.4	0.82%
VALTOCO SPR 15MG	336	218	\$334,234.73	\$994.75	1.54	0.97%
VALTOCO SPR 5MG	185	111	\$152,823.65	\$826.07	1.67	0.44%
DIAZEPAM GEL 20MG	180	92	\$92,307.53	\$512.82	1.96	0.27%
VALTOCO SPR 20MG	160	98	\$143,802.59	\$898.77	1.63	0.42%
DIASTAT ACDL GEL 12.5-20MG	26	16	\$9,714.17	\$373.62	1.63	0.03%
DIAZEPAM GEL 2.5MG	21	21	\$6,233.90	\$296.85	1	0.02%
DIASTAT ACDL GEL 5-10MG	14	14	\$6,536.00	\$466.86	1	0.02%
DIASTAT PED GEL 2.5MG	1	1	\$476.27	\$476.27	1	0.00%
<b>SUBTOTAL</b>	<b>2,635</b>	<b>1,732</b>	<b>\$1,899,054.54</b>	<b>\$720.70</b>	<b>1.52</b>	<b>5.51%</b>
<b>CANNABIDIOL PRODUCTS</b>						
EPIDIOLEX SOL 100MG/ML	2,003	241	\$5,205,977.80	\$2,599.09	8.31	15.08%
<b>SUBTOTAL</b>	<b>2,003</b>	<b>241</b>	<b>\$5,205,977.80</b>	<b>\$2,599.09</b>	<b>8.31</b>	<b>15.08</b>
<b>PHENOBARBITAL PRODUCTS</b>						
PHENOBARBITAL SOL 20MG/5ML	444	101	\$14,619.65	\$32.93	4.4	0.04%
PHENOBARBITAL TAB 64.8MG	432	52	\$11,550.07	\$26.74	8.31	0.03%
PHENOBARBITAL TAB 32.4MG	335	52	\$8,495.51	\$25.36	6.44	0.02%
PHENOBARBITAL ELX 20MG/5ML	174	59	\$6,460.10	\$37.13	2.95	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
PHENOBARBITAL TAB 97.2MG	147	20	\$3,765.44	\$25.62	7.35	0.01%
PHENOBARBITAL TAB 30MG	143	30	\$3,474.86	\$24.30	4.77	0.01%
PHENOBARBITAL TAB 60MG	90	17	\$2,213.11	\$24.59	5.29	0.01%
PHENOBARBITAL TAB 100MG	73	11	\$1,918.12	\$26.28	6.64	0.01%
PHENOBARBITAL TAB 16.2MG	71	8	\$1,543.24	\$21.74	8.88	0.00%
PHENOBARBITAL TAB 15MG	14	3	\$270.79	\$19.34	4.67	0.00%
<b>SUBTOTAL</b>	<b>1,923</b>	<b>353</b>	<b>\$54,310.89</b>	<b>\$28.24</b>	<b>5.45</b>	<b>0.15%</b>
<b>ETHOSUXIMIDE PRODUCTS</b>						
ETHOSUXIMIDE CAP 250MG	1,033	155	\$46,842.39	\$45.35	6.66	0.14%
ETHOSUXIMIDE SOL 250MG/5ML	672	110	\$22,553.13	\$33.56	6.11	0.07%
ZARONTIN CAP 250MG	1	1	\$398.03	\$398.03	1	0.00%
<b>SUBTOTAL</b>	<b>1,706</b>	<b>266</b>	<b>\$69,793.55</b>	<b>\$40.91</b>	<b>6.41</b>	<b>0.21%</b>
<b>BRIVARACETAM PRODUCTS</b>						
BRIVIACT TAB 100MG	703	109	\$949,198.10	\$1,350.21	6.45	2.75%
BRIVIACT TAB 50MG	377	65	\$513,733.69	\$1,362.69	5.8	1.49%
BRIVIACT SOL 10MG/ML	203	24	\$313,893.88	\$1,546.28	8.46	0.91%
BRIVIACT TAB 75MG	105	18	\$191,060.88	\$1,819.63	5.83	0.55%
BRIVIACT TAB 25MG	36	9	\$38,612.82	\$1,072.58	4	0.11%
<b>SUBTOTAL</b>	<b>1,424</b>	<b>225</b>	<b>\$2,006,499.37</b>	<b>\$1,409.06</b>	<b>6.33</b>	<b>5.81%</b>
<b>PRIMIDONE PRODUCTS</b>						
PRIMIDONE TAB 50MG	1,118	276	\$21,997.21	\$19.68	4.05	0.06%
PRIMIDONE TAB 250MG	218	39	\$4,980.48	\$22.85	5.59	0.01%
MYSOLINE TAB 250MG	19	2	\$109,497.19	\$5,763.01	9.5	0.32%
<b>SUBTOTAL</b>	<b>1,355</b>	<b>317</b>	<b>\$136,474.88</b>	<b>\$100.72</b>	<b>4.27</b>	<b>0.39%</b>
<b>CENOBAMATE PRODUCTS</b>						
XCOPRI TAB 150MG	365	62	\$484,045.36	\$1,326.15	5.89	1.40%
XCOPRI TAB 100MG	328	77	\$314,139.04	\$957.74	4.26	0.91%
XCOPRI TAB 200MG	291	53	\$324,800.64	\$1,116.15	5.49	0.94%
XCOPRI TAB 50MG	195	53	\$195,205.98	\$1,001.06	3.68	0.57%
XCOPRI PAK 100-150MG	49	11	\$54,005.69	\$1,102.16	4.45	0.16%
XCOPRI PAK 150-200MG	38	3	\$82,994.26	\$2,184.06	12.67	0.24%
XCOPRI PAK 12.5-25MG	36	35	\$3,778.80	\$104.97	1.03	0.01%
XCOPRI PAK 50-100MG	32	29	\$33,964.14	\$1,061.38	1.1	0.10%
XCOPRI PAK 150-200MG	11	11	\$12,199.90	\$1,109.08	1	0.04%
<b>SUBTOTAL</b>	<b>1,345</b>	<b>334</b>	<b>\$1,505,133.81</b>	<b>\$1,119.06</b>	<b>4.03</b>	<b>4.37%</b>
<b>ACETAZOLAMIDE PRODUCTS</b>						
ACETAZOLAMIDE TAB 250MG	620	205	\$16,207.40	\$26.14	3.02	0.05%
ACETAZOLAMIDE CAP 500MG ER	560	167	\$18,191.74	\$32.49	3.35	0.05%
ACETAZOLAMIDE TAB 125MG	110	41	\$2,068.02	\$18.80	2.68	0.01%
<b>SUBTOTAL</b>	<b>1,290</b>	<b>413</b>	<b>\$36,467.16</b>	<b>\$28.27</b>	<b>3.12</b>	<b>0.11%</b>
<b>PERAMPANEL PRODUCTS</b>						
FYCOMPA SUS 0.5MG/ML	271	42	\$372,294.45	\$1,373.78	6.45	1.08%
FYCOMPA TAB 4MG	196	50	\$193,663.36	\$988.08	3.92	0.56%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
FYCOMPA TAB 8MG	130	25	\$129,361.24	\$995.09	5.2	0.37%
FYCOMPA TAB 6MG	125	30	\$133,120.61	\$1,064.96	4.17	0.39%
FYCOMPA TAB 12MG	103	14	\$110,082.03	\$1,068.76	7.36	0.32%
FYCOMPA TAB 2MG	103	37	\$46,739.29	\$453.78	2.78	0.14%
FYCOMPA TAB 10MG	100	13	\$112,578.15	\$1,125.78	7.69	0.33%
<b>SUBTOTAL</b>	<b>1,028</b>	<b>211</b>	<b>\$1,097,839.13</b>	<b>\$1,067.94</b>	<b>4.87</b>	<b>3.19%</b>
<b>MIDAZOLAM PRODUCTS</b>						
NAYZILAM SPR 5MG	738	414	\$719,954.05	\$975.55	1.78	2.09%
<b>SUBTOTAL</b>	<b>738</b>	<b>414</b>	<b>\$719,954.05</b>	<b>\$975.55</b>	<b>1.78</b>	<b>2.09%</b>
<b>RUFINAMIDE PRODUCTS</b>						
RUFINAMIDE SUS 40MG/ML	216	26	\$163,612.44	\$757.47	8.31	0.47%
RUFINAMIDE TAB 400MG	168	22	\$114,806.80	\$683.37	7.64	0.33%
BANZEL TAB 400MG	120	15	\$508,322.53	\$4,236.02	8	1.47%
BANZEL SUS 40MG/ML	51	8	\$209,989.97	\$4,117.45	6.38	0.61%
RUFINAMIDE TAB 200MG	38	6	\$16,965.49	\$446.46	6.33	0.05%
BANZEL TAB 200MG	18	3	\$14,381.53	\$798.97	6	0.04%
<b>SUBTOTAL</b>	<b>611</b>	<b>80</b>	<b>\$1,028,078.76</b>	<b>\$1,682.62</b>	<b>7.64</b>	<b>2.97%</b>
<b>FELBAMATE PRODUCTS</b>						
FELBAMATE TAB 600MG	170	17	\$24,039.66	\$141.41	10	0.07%
FELBAMATE SUS 600MG/5ML	88	9	\$23,448.65	\$266.46	9.78	0.07%
FELBAMATE TAB 400MG	51	7	\$5,474.64	\$107.35	7.29	0.02%
FELBATOL TAB 400MG	9	2	\$12,341.00	\$1,371.22	4.5	0.04%
FELBATOL SUS 600MG/5ML	3	2	\$2,864.95	\$954.98	1.5	0.01%
<b>SUBTOTAL</b>	<b>321</b>	<b>37</b>	<b>\$68,168.90</b>	<b>\$212.36</b>	<b>8.68</b>	<b>0.21%</b>
<b>VIGABATRIN PRODUCTS</b>						
SABRIL POW 500MG	190	23	\$4,758,939.11	\$25,047.0	8.26	13.78%
VIGABATRIN PAK 500MG	17	4	\$20,183.15	\$1,187.24	4.25	0.06%
SABRIL TAB 500MG	13	2	\$368,018.78	\$28,309.14	6.5	1.07%
VIGABATRIN TAB 500MG	7	1	\$52,836.41	\$7,548.06	7	0.15%
VIGADRONE POW 500MG	4	1	\$25,699.14	\$6,424.79	4	0.07%
<b>SUBTOTAL</b>	<b>231</b>	<b>31</b>	<b>\$5,225,676.59</b>	<b>\$22,621.98</b>	<b>7.45</b>	<b>15.13%</b>
<b>ESLICARBAZEPINE PRODUCTS</b>						
APTIOM TAB 600MG	92	12	\$171,927.47	\$1,868.78	7.67	0.50%
APTIOM TAB 800MG	71	16	\$127,657.89	\$1,798.00	4.44	0.37%
APTIOM TAB 400MG	23	6	\$27,888.00	\$1,212.52	3.83	0.08%
APTIOM TAB 200MG	6	3	\$11,360.00	\$1,893.33	2	0.03%
<b>SUBTOTAL</b>	<b>192</b>	<b>37</b>	<b>\$338,833.36</b>	<b>\$1,764.76</b>	<b>5.19</b>	<b>0.98%</b>
<b>FENFLURAMINE PRODUCTS</b>						
FINTEPLA SOL 2.2MG/ML	170	25	\$1,715,606.47	\$10,091.80	6.8	4.97%
<b>SUBTOTAL</b>	<b>170</b>	<b>25</b>	<b>\$1,715,606.47</b>	<b>\$10,091.80</b>	<b>6.8</b>	<b>4.97%</b>
<b>TIAGABINE PRODUCTS</b>						
TIAGABINE TAB 4MG	71	18	\$13,191.09	\$185.79	3.94	0.04%
TIAGABINE TAB 2MG	18	6	\$4,447.25	\$247.07	3	0.01%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
TIAGABINE TAB 12MG	15	3	\$4,196.05	\$279.74	5	0.01%
TIAGABINE TAB 16MG	7	2	\$2,988.18	\$426.88	3.5	0.01%
<b>SUBTOTAL</b>	<b>111</b>	<b>29</b>	<b>\$24,822.57</b>	<b>\$223.63</b>	<b>3.83</b>	<b>0.07%</b>
<b>METHSUXIMIDE PRODUCTS</b>						
CELONTIN CAP 300MG	26	3	\$9,489.91	\$365.00	8.67	0.03%
METHSUXIMIDE CAP 300MG	1	1	\$254.42	\$254.42	1	0.00%
<b>SUBTOTAL</b>	<b>27</b>	<b>4</b>	<b>\$9,744.33</b>	<b>\$360.90</b>	<b>6.75</b>	<b>0.03%</b>
<b>STIRIPENTOL PRODUCTS</b>						
DIACOMIT CAP 250MG	11	1	\$72,794.01	\$6,617.64	11	0.21%
<b>SUBTOTAL</b>	<b>11</b>	<b>1</b>	<b>\$72,794.01</b>	<b>\$6,617.64</b>	<b>11</b>	<b>0.21%</b>
<b>GANAXOLONE PRODUCTS</b>						
ZTALMY SUS 50MG/ML	10	2	\$177,004.98	\$17,700.50	5	0.51%
<b>SUBTOTAL</b>	<b>10</b>	<b>2</b>	<b>\$177,004.98</b>	<b>\$17,700.5</b>	<b>5</b>	<b>0.51%</b>
<b>TOTAL</b>	<b>473,870</b>	<b>82,679*</b>	<b>\$34,525,014.60</b>	<b>\$72.86</b>	<b>5.73</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

ACDL = AcuDial; CAP = capsule; CHW = chewable; DR = delayed-release; ELX = elixir; ER = extended-release; EX = extended; HR = hour; INJ = injection; MIS = film; ODT = orally disintegrating tablet; PAK = pack; PED = pediatric; POW = powder; SOL = solution; SPR = spray or sprinkle; SUS = suspension; TAB = tablet; XR = extended-release

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

<sup>1</sup> 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 03/2024. Last accessed 03/13/2024.

<sup>2</sup> U.S. FDA. FDA Shows Generic Lamotrigine Extended-Release Tablets are Bioequivalent to Innovator Drug in Fully Replicated Crossover Bioequivalence Study. Available online at: <https://www.fda.gov/drugs/regulatory-science-action/fda-shows-generic-lamotrigine-extended-release-tablets-are-bioequivalent-innovator-drug-fully>. Issued 07/25/2023. Last accessed 03/13/2024.

<sup>3</sup> U.S. FDA. FDA Warns of Rare But Serious Drug Reaction to the Antiseizure Medicines Levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and Clobazam (Onfi, Sympazan). Available online at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-rare-serious-drug-reaction-antiseizure-medicines-levetiracetam-keppra-keppra-xr-elepsia-xr>. Issued 11/28/2023. Last accessed 03/13/2024.

<sup>4</sup> Aquestive Therapeutics. Aquestive Therapeutics Receives FDA Acceptance Of New Drug Application (NDA) For Libervant™ (Diazepam) Buccal Film In Pediatric Patients And Assignment Of Prescription Drug User Fee Act (PDUFA) Date. Available online at: <https://investors.aquestive.com/news-releases/news-release-details/aquestive-therapeutics-receives-fda-acceptance-new-drug>. Issued 09/11/2023. Last accessed 03/13/2024.



# Fiscal Year 2023 Annual Review of Antihypertensive Medications

## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

### Current Prior Authorization Criteria

There are 6 major subcategories of antihypertensive medications divided by drug class currently included in the antihypertensive medications Product Based Prior Authorization (PBPA) category:

1. Angiotensin I Converting Enzyme Inhibitors (ACEIs)
2. ACEI/Hydrochlorothiazide (HCTZ) Combination Products
3. Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products
4. Calcium Channel Blockers (CCBs)
5. ACEI/CCB Combination Products
6. Direct Renin Inhibitors (DRIs) and DRI Combination Products

Angiotensin I Converting Enzyme Inhibitors (ACEIs)		
Tier-1	Tier-2	Special PA
benazepril (Lotensin®)	captopril (Capoten®)	enalapril oral solution (Epaned®)
enalapril (Vasotec®)		lisinopril oral solution (Qbrelis®)
enalaprilat (Vasotec® IV)		
fosinopril (Monopril®)		
lisinopril (Prinivil®, Zestril®)		
moexipril (Univasc®)		
perindopril (Aceon®)		
quinapril (Accupril®)		
ramipril (Altace®)		
trandolapril (Mavik®)		
ACEI/Hydrochlorothiazide (HCTZ) Combination Products		
Tier-1	Tier-2	Special PA
benazepril/HCTZ (Lotensin® HCT)	captopril/HCTZ (Capozide®)	fosinopril/HCTZ (Monopril-HCT®)
enalapril/HCTZ (Vasoretic®)		
lisinopril/HCTZ (Prinzide®, Zestoretic®)		
moexipril/HCTZ (Uniretic®)		
quinapril/HCTZ (Accuretic®)		



<b>Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products</b>		
<b>Tier-1</b>	<b>Tier-2</b>	<b>Special PA</b>
candesartan (Atacand®)+	candesartan 32mg (Atacand®)	azilsartan (Edarbi®)
irbesartan (Avapro®)	olmesartan/amlodipine/HCTZ (Tribenzor®)	azilsartan/chlorthalidone (Edarbyclor®)
irbesartan/HCTZ (Avalide®)	telmisartan/HCTZ (Micardis® HCT)	candesartan/HCTZ (Atacand® HCT)
losartan (Cozaar®)		eprosartan (Teveten®)
losartan/HCTZ (Hyzaar®)		eprosartan/HCTZ (Teveten® HCT)
olmesartan (Benicar®)		telmisartan/amlodipine (Twynsta®)
olmesartan/amlodipine (Azor®)		
olmesartan/HCTZ (Benicar HCT®)		
telmisartan (Micardis®)		
valsartan (Diovan®)		
valsartan/amlodipine (Exforge®)		
valsartan/amlodipine/HCTZ (Exforge® HCT)		
valsartan/HCTZ (Diovan HCT®)		
<b>Calcium Channel Blockers (CCBs)</b>		
<b>Tier-1</b>	<b>Tier-2</b>	<b>Special PA</b>
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine oral solution (Norliqva®)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	amlodipine oral suspension (Katerzia®)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	amlodipine/celecoxib (Consensi®)
diltiazem CD (Cardizem® CD)*	isradipine (Dynacirc®, Dynacirc CR®)	diltiazem CD 360mg (Cardizem® CD)
diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene®)	levamlodipine (Conjupri®)
diltiazem XR (Dilacor® XR)	nicardipine (Cardene® SR)	
felodipine (Plendil®)	nisoldipine (Sular®)	
nifedipine (Adalat®, Procardia®)	verapamil (Covera-HS®)	
nifedipine ER (Adalat® CC)	verapamil ER (Verelan®, Verelan® PM)	
nifedipine XL (Nifedical XL®, Procardia XL®)		
nimodipine (Nimotop®)		

verapamil (Calan <sup>®</sup> , Isoptin <sup>®</sup> )		
verapamil SR (Calan <sup>®</sup> SR, Isoptin <sup>®</sup> SR)		
ACEI/CCB Combination Products		
Tier-1	Tier-2	Special PA
Tier-1 ACEI + Tier-1 CCB	trandolapril/verapamil (Tarka <sup>®</sup> )	perindopril/amlodipine (Prestalia <sup>®</sup> )
benazepril/amlodipine (Lotrel <sup>®</sup> )		

\*All strengths other than 32mg.

\*All strengths other than 360mg.

CD = controlled-delivery; ER, XR, XL = extended-release; LA = long-acting; SR = sustained-release

### Antihypertensive Medications Tier-2 Approval Criteria:

(or Tier-3 approval criteria when no Tier-2 medications exist)

1. A documented inadequate response to 2 Tier-1 medications (trials must include medication(s) from all available classes where applicable); or
2. An adverse drug reaction to all Tier-1 classes of medications; or
3. Previous stabilization on the Tier-2 medication; or
4. A unique indication for which the Tier-1 antihypertensive medications lack.

### Antihypertensive Medications Tier-3 Approval Criteria:

1. A documented inadequate response to 2 Tier-1 medications and documented inadequate response to all available Tier-2 medication(s); or
2. An adverse drug reaction to all Tier-1 and Tier-2 classes of medications; or
3. Previous stabilization on the Tier-3 medication; or
4. A unique indication which the lower tiered antihypertensive medications lack.

### Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:

#### 1. Angiotensin I Converting Enzyme Inhibitors (ACEIs):

##### a. Epaned<sup>®</sup> (Enalapril Solution) Approval Criteria:

- i. An age restriction of 7 years or older will apply with the following criteria:

1. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation in place of the oral solution formulation, even when the tablets are crushed, must be provided.

##### b. Qbrelis<sup>®</sup> (Lisinopril Oral Solution) Approval Criteria:

- i. A patient-specific, clinically significant reason why the member cannot use lisinopril oral tablets in place of the oral

solution formulation, even when the tablets are crushed, must be provided.

**2. ACEI/Hydrochlorothiazide (HCTZ) Combination Products:**

**a. Monopril-HCT® (Fosinopril/HCTZ) Approval Criteria:**

- i. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided.

**3. Calcium Channel Blockers (CCBs):**

**a. Cardizem® CD (Diltiazem CD 360mg Capsules) Approval Criteria:**

- i. A patient-specific, clinically significant reason why the member cannot use (2) 180mg Cardizem® CD (diltiazem CD) capsules must be provided.

**b. Conjugri® (Levamlodipine Tablets) Approval Criteria:**

- i. A patient-specific, clinically significant reason why the member cannot use amlodipine oral tablets, which are available without prior authorization, must be provided.

**c. Consensi® (Amlodipine/Celecoxib Tablets) Approval Criteria:**

- i. A patient-specific, clinically significant reason why the member cannot use the individual components separately, which are available without prior authorization, must be provided; and
- ii. A quantity limit of 30 tablets per 30 days will apply.

**d. Katerzia® (Amlodipine Oral Suspension) and Norliqva® (Amlodipine Oral Solution) Approval Criteria:**

- i. An FDA approved diagnosis of 1 of the following:
  1. Hypertension in adults and pediatric members 6 years of age and older; or
  2. Coronary artery disease; or
  3. Chronic stable angina; or
  4. Vasospastic angina; and
- ii. A patient specific, clinically significant reason why the member cannot use amlodipine oral tablets, even when the tablets are crushed, must be provided; and
- iii. A quantity limit of 300mL per 30 days will apply.

**4. ACEI/CCB Combination Products:**

**a. Prestalia® (Perindopril/Amlodipine) Approval Criteria:**

- i. An FDA approved diagnosis; and
- ii. Documented trials of inadequate response to 2 Tier-1 angiotensin I converting enzyme inhibitors (ACEIs) in combination with amlodipine; and
- iii. A patient-specific, clinically significant reason why the member cannot use the individual components separately must be provided; and
- iv. A quantity limit of 30 tablets per 30 days will apply.

The following restrictions also apply for each individual product based on U.S. Food and Drug Administration (FDA) approval information, special formulations, or individualized Drug Utilization Review (DUR) Board recommended criteria:

**CaroSpir® (Spironolactone Oral Suspension) Approval Criteria:**

1. An FDA approved indication; and
2. A patient-specific, clinically significant reason why the member cannot use spironolactone oral tablets must be provided.

**Hemangeol® (Propranolol Hydrochloride Oral Solution) Approval Criteria:**

1. An FDA approved indication for the treatment of proliferating infantile hemangioma requiring systemic therapy.

**Kapsargo™ Sprinkle [Metoprolol Succinate Extended-Release (ER) Capsules] Approval Criteria:**

1. A patient-specific, clinically significant reason why the member cannot use metoprolol succinate ER tablets, which are available without prior authorization, must be provided.

**Nymalize® (Nimodipine Oral Solution) Approval Criteria:**

1. A patient-specific, clinically significant reason why the member cannot use nimodipine liquid-filled capsules, which are available without prior authorization and can be opened for administration of the liquid contents via oral syringe for members unable to swallow the capsules whole, must be provided.

**Sotylize® (Sotalol Oral Solution) Approval Criteria:**

1. An FDA approved diagnosis of life-threatening ventricular arrhythmias or for the maintenance of normal sinus rhythm in members with highly symptomatic atrial fibrillation/flutter; and
2. A patient-specific, clinically significant reason why the member cannot use sotalol oral tablets in place of the oral solution formulation must be provided; and
3. A quantity limit of 64mL per day or 1,920mL per 30 days will apply.

**Tekturna® (Aliskiren Oral Pellets and Tablets) and Tekturna HCT® (Aliskiren/Hydrochlorothiazide) Approval Criteria:**

1. An FDA approved diagnosis; and
2. Member must be 6 years of age or older; and
3. A recent trial, within the previous 6 months and at least 4 weeks in duration, of an angiotensin I converting enzyme inhibitor (ACEI) [or an angiotensin II receptor blocker (ARB) if previous trial of an ACEI] and a diuretic, used concomitantly at recommended doses, that did not yield adequate blood pressure control; and
4. May be used in either monotherapy or combination therapy; and

5. For Tekturna® oral pellets, a patient-specific, clinically significant reason why the member cannot use Tekturna® oral tablets must be provided.

**Vecamyl® (Mecamylamine) Approval Criteria:**

1. An FDA approved diagnosis of moderately-severe-to-severe essential hypertension or uncomplicated malignant hypertension; and
2. Use of at least 6 classes of medications, in the past 12 months, that did not yield adequate blood pressure control. Treatment must have included combination therapy with a diuretic and therapy with at least a 4-drug regimen. Medications can be from, but not limited to, the following classes: angiotensin I converting enzyme inhibitors (ACEIs), angiotensin II receptor blockers (ARBs), calcium channel blockers (CCBs), direct renin inhibitors (DRIs), beta blockers, alpha blockers, alpha agonists, or diuretics; and
3. Prescriber must verify member does not have any of the following contraindications:
  - a. Coronary insufficiency; or
  - b. Recent myocardial infarction; or
  - c. Rising or elevated blood urea nitrogen (BUN), or known renal insufficiency; or
  - d. Uremia; or
  - e. Glaucoma; or
  - f. Organic pyloric stenosis; or
  - g. Currently receiving sulfonamides or antibiotics; or
  - h. Known sensitivity to Vecamyl® (mecamylamine).

**Utilization of Antihypertensive Medications: Fiscal Year 2023**

**Comparison of Fiscal Years**

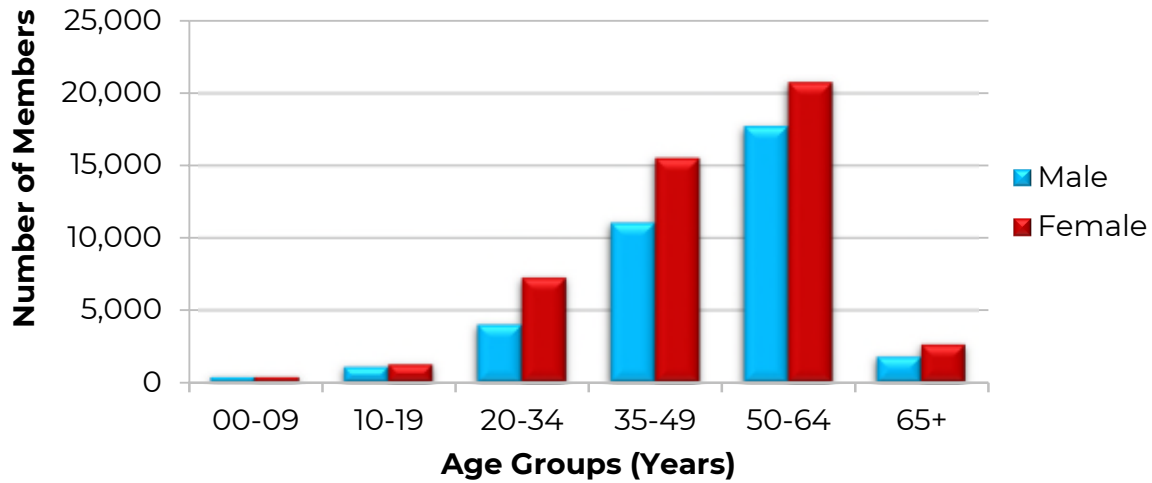
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
<b>2022</b>	65,955	276,045	\$4,290,193.81	\$15.54	\$0.27	18,504,082	15,788,882
<b>2023</b>	83,544	357,508	\$5,186,923.14	\$14.51	\$0.24	24,870,578	21,490,954
<b>% Change</b>	<b>26.70%</b>	<b>29.50%</b>	<b>20.90%</b>	<b>-6.60%</b>	<b>-11.10%</b>	<b>34.40%</b>	<b>36.10%</b>
<b>Change</b>	<b>17,589</b>	<b>81,463</b>	<b>\$896,729.33</b>	<b>-\$1.03</b>	<b>-\$0.03</b>	<b>6,366,496</b>	<b>5,702,072</b>

Costs do not reflect rebated prices or net costs.

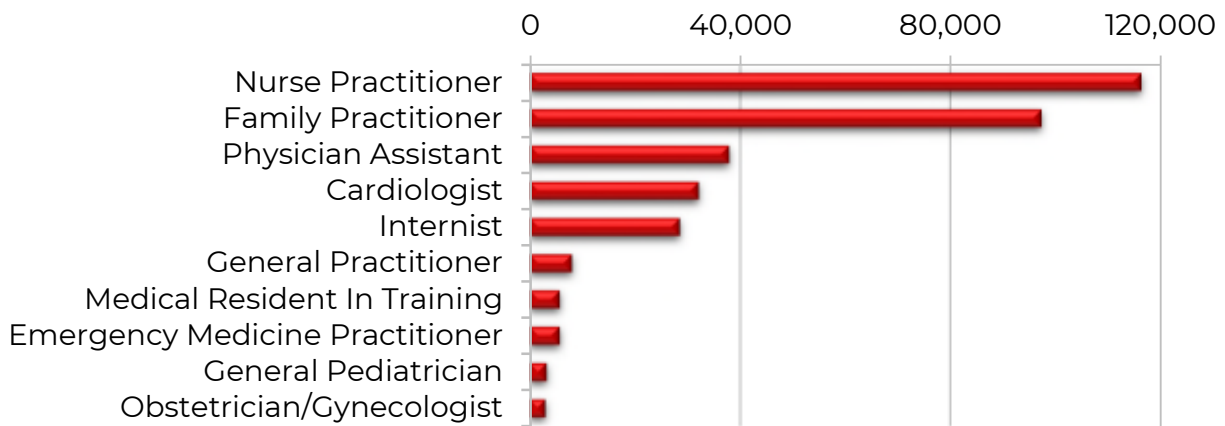
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

### Demographics of Members Utilizing Antihypertensive Medications

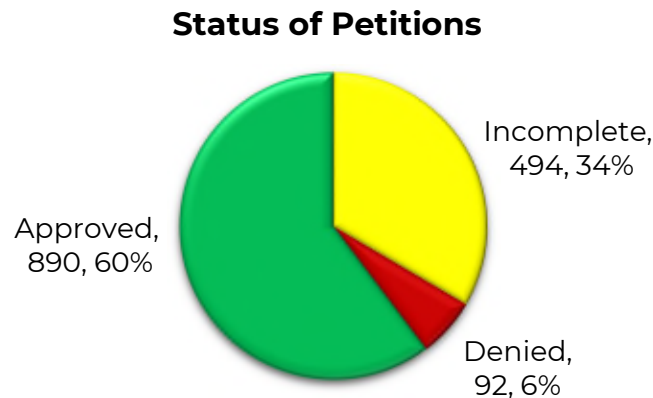


### Top Prescriber Specialties of Antihypertensive Medications by Number of Claims



### Prior Authorization of Antihypertensive Medications

There were 1,476 prior authorization requests submitted for antihypertensive medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



## Market News and Updates<sup>1</sup>

### Anticipated Patent Expiration(s):

- Tekturna<sup>®</sup> (aliskiren tablet): August 2026
- Edarbi<sup>®</sup> (azilsartan tablet): March 2028
- Hemangeol<sup>®</sup> (propranolol hydrochloride oral solution): October 2028
- Prestalia<sup>®</sup> (perindopril/amlodipine tablet): October 2029
- Edarbyclor<sup>®</sup> (azilsartan/chlorthalidone tablet): July 2031
- Kapspargo Sprinkle<sup>™</sup> [metoprolol succinate extended-release (ER) capsule]: July 2035
- Sotylize<sup>®</sup> (sotalol oral solution): August 2035
- Qbrelis<sup>®</sup> (lisinopril oral solution): November 2035
- Epaned<sup>®</sup> (enalapril oral solution): March 2036
- CaroSpir<sup>®</sup> (spironolactone oral suspension): October 2036
- Nymalize<sup>®</sup> (nimodipine oral solution): April 2038
- Katerzia<sup>®</sup> (amlodipine oral suspension): April 2039
- Norliqva<sup>®</sup> (amlodipine oral solution): February 2041

### Recommendations

The College of Pharmacy does not recommend any changes to the antihypertensive medications Product Based Prior Authorization (PBPA) category or prior authorization criteria at this time.

### Utilization Details of Antihypertensive Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
<b>ANGIOTENSIN I CONVERTING ENZYME INHIBITORS (ACEIs)</b>						
<b>TIER-1 UTILIZATION</b>						
LISINOPRIL TAB 20MG	30,395	11,350	\$297,776.63	\$9.80	2.68	5.74%
LISINOPRIL TAB 10MG	29,585	11,734	\$276,482.74	\$9.35	2.52	5.33%
LISINOPRIL TAB 40MG	16,320	5,569	\$202,415.14	\$12.40	2.93	3.90%
LISINOPRIL TAB 5MG	12,065	4,694	\$109,857.47	\$9.11	2.57	2.12%
LISINOPRIL TAB 2.5MG	5,307	2,019	\$49,083.97	\$9.25	2.63	0.95%
LISINOPRIL TAB 30MG	2,217	823	\$23,478.98	\$10.59	2.69	0.45%
ENALAPRIL TAB 20MG	883	263	\$17,179.69	\$19.46	3.36	0.33%
ENALAPRIL TAB 5MG	654	173	\$10,821.68	\$16.55	3.78	0.21%
ENALAPRIL TAB 2.5MG	609	138	\$9,567.32	\$15.71	4.41	0.18%
ENALAPRIL TAB 10MG	587	187	\$9,636.90	\$16.42	3.14	0.19%
BENAZEPRIL TAB 20MG	457	149	\$5,285.12	\$11.56	3.07	0.10%
BENAZEPRIL TAB 40MG	389	123	\$4,999.40	\$12.85	3.16	0.10%
RAMIPRIL CAP 10MG	251	86	\$3,095.66	\$12.33	2.92	0.06%
BENAZEPRIL TAB 10MG	224	72	\$3,055.59	\$13.64	3.11	0.06%
RAMIPRIL CAP 5MG	144	52	\$1,527.57	\$10.61	2.77	0.03%
RAMIPRIL CAP 2.5MG	76	29	\$825.45	\$10.86	2.62	0.02%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
BENAZEPRIL TAB 5MG	76	23	\$935.08	\$12.30	3.3	0.02%
RAMIPRIL CAP 1.25MG	73	26	\$1,067.73	\$14.63	2.81	0.02%
QUINAPRIL TAB 40MG	49	17	\$740.15	\$15.11	2.88	0.01%
FOSINOPRIL TAB 20MG	43	13	\$892.09	\$20.75	3.31	0.02%
QUINAPRIL TAB 20MG	38	14	\$572.09	\$15.06	2.71	0.01%
FOSINOPRIL TAB 40MG	29	8	\$572.54	\$19.74	3.63	0.01%
FOSINOPRIL TAB 10MG	24	8	\$492.41	\$20.52	3	0.01%
QUINAPRIL TAB 10MG	17	8	\$243.95	\$14.35	2.13	0.00%
MOEXIPRIL TAB 15MG	6	1	\$370.76	\$61.79	6	0.01%
TRANDOLAPRIL TAB 4MG	6	2	\$150.55	\$25.09	3	0.00%
TRANDOLAPRIL TAB 2MG	5	3	\$75.96	\$15.19	1.67	0.00%
QUINAPRIL TAB 5MG	3	1	\$52.33	\$17.44	3	0.00%
PERINDOPRIL TAB 4MG	2	1	\$110.34	\$55.17	2	0.00%
PERINDOPRIL TAB 8MG	1	1	\$24.67	\$24.67	1	0.00%
<b>TIER-1 SUBTOTAL</b>	<b>100,535</b>	<b>37,587</b>	<b>\$1,031,389.96</b>	<b>\$10.26</b>	<b>2.67</b>	<b>19.88%</b>
<b>TIER-2 UTILIZATION</b>						
CAPTOPRIL TAB 50MG	71	11	\$3,073.78	\$43.29	6.45	0.06%
CAPTOPRIL TAB 25MG	45	6	\$1,155.31	\$25.67	7.5	0.02%
CAPTOPRIL TAB 12.5MG	10	2	\$244.43	\$24.44	5	0.00%
CAPTOPRIL TAB 100MG	5	1	\$457.05	\$91.41	5	0.01%
<b>TIER-2 SUBTOTAL</b>	<b>131</b>	<b>20</b>	<b>\$4,930.57</b>	<b>\$37.64</b>	<b>6.55</b>	<b>0.10%</b>
<b>SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION</b>						
ENALAPRIL SOL 1MG/ML	1,038	215	\$179,292.28	\$172.73	4.83	3.46%
EPANED SOL 1MG/ML	299	72	\$113,509.58	\$379.63	4.15	2.19%
QBRELIS SOL 1MG/ML	147	24	\$63,593.24	\$432.61	6.13	1.23%
<b>SPECIAL PA SUBTOTAL</b>	<b>1,484</b>	<b>311</b>	<b>\$356,395.10</b>	<b>\$240.16</b>	<b>4.77</b>	<b>6.87%</b>
<b>ACEI TOTAL</b>	<b>102,150</b>	<b>37,918</b>	<b>\$1,392,715.63</b>	<b>\$13.63</b>	<b>2.69</b>	<b>26.85%</b>
<b>CALCIUM CHANNEL BLOCKERS (CCBs)</b>						
<b>TIER-1 UTILIZATION</b>						
AMLODIPINE TAB 10MG	34,081	12,020	\$339,297.05	\$9.96	2.84	6.54%
AMLODIPINE TAB 5MG	27,814	10,835	\$270,643.05	\$9.73	2.57	5.22%
AMLODIPINE TAB 2.5MG	4,107	1,652	\$40,948.77	\$9.97	2.49	0.79%
NIFEDIPINE TAB 30MG ER	2,134	1,136	\$34,774.99	\$16.30	1.88	0.67%
NIFEDIPINE TAB 60MG ER	1,188	511	\$22,362.54	\$18.82	2.32	0.43%
DILTIAZEM CAP 120MG ER	1,074	443	\$19,178.19	\$17.86	2.42	0.37%
DILTIAZEM CAP 240MG ER	945	307	\$21,167.27	\$22.40	3.08	0.41%
NIFEDIPINE TAB 30MG ER	922	438	\$15,702.82	\$17.03	2.11	0.30%
DILTIAZEM CAP 180MG ER	844	310	\$18,243.84	\$21.62	2.72	0.35%
NIFEDIPINE TAB 60MG ER	659	276	\$13,117.41	\$19.91	2.39	0.25%
NIFEDIPINE TAB 90MG ER	483	195	\$12,627.12	\$26.14	2.48	0.24%
VERAPAMIL TAB 240MG ER	481	138	\$9,102.86	\$18.92	3.49	0.18%
VERAPAMIL TAB 120MG ER	437	159	\$8,506.77	\$19.47	2.75	0.16%
NIFEDIPINE CAP 10MG	407	269	\$11,867.20	\$29.16	1.51	0.23%



PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
VERAPAMIL TAB 180MG ER	341	111	\$6,883.91	\$20.19	3.07	0.13%
NIFEDIPINE TAB 90MG ER	325	134	\$8,762.76	\$26.96	2.43	0.17%
DILTIAZEM TAB 30MG	310	121	\$5,056.59	\$16.31	2.56	0.10%
DILTIAZEM TAB 60MG	287	98	\$6,119.49	\$21.32	2.93	0.12%
DILTIAZEM TAB 120MG	264	85	\$6,258.60	\$23.71	3.11	0.12%
VERAPAMIL TAB 80MG	204	77	\$2,905.37	\$14.24	2.65	0.06%
VERAPAMIL TAB 120MG	188	55	\$3,159.05	\$16.80	3.42	0.06%
DILTIAZEM CAP 300MG ER	171	49	\$4,493.78	\$26.28	3.49	0.09%
VERAPAMIL TAB 40MG	148	74	\$3,197.26	\$21.60	2	0.06%
CARTIA XT CAP 120/24HR	144	69	\$2,579.53	\$17.91	2.09	0.05%
DILT-XR CAP 240MG	135	45	\$6,962.88	\$51.58	3	0.13%
DILTIAZEM CAP 360MG ER	129	37	\$4,550.07	\$35.27	3.49	0.09%
DILT-XR CAP 120MG	110	55	\$2,723.55	\$24.76	2	0.05%
DILTIAZEM CAP 120MG/24HR	100	39	\$2,268.25	\$22.68	2.56	0.04%
DILTIAZEM TAB 90MG	99	28	\$2,790.97	\$28.19	3.54	0.05%
NIFEDIPINE CAP 20MG	88	54	\$5,733.40	\$65.15	1.63	0.11%
DILT-XR CAP 180MG	65	32	\$2,746.61	\$42.26	2.03	0.05%
DILTIAZEM CAP 240MG ER	59	18	\$2,411.76	\$40.88	3.28	0.05%
DILTIAZEM CAP 180MG ER	53	23	\$2,310.58	\$43.60	2.3	0.04%
DILTIAZEM CAP 240MG/24HR	49	21	\$1,966.45	\$40.13	2.33	0.04%
DILTIAZEM CAP 180MG/24HG	47	28	\$1,344.10	\$28.60	1.68	0.03%
FELODIPINE TAB 5MG ER	42	13	\$717.85	\$17.09	3.23	0.01%
FELODIPINE TAB 10MG ER	30	14	\$593.52	\$19.78	2.14	0.01%
DILTIAZEM CAP 300MG ER	28	9	\$1,367.63	\$48.84	3.11	0.03%
NIMODIPINE CAP 30MG	23	20	\$3,994.80	\$173.69	1.15	0.08%
TIADYLT CAP 120MG/24HR	22	5	\$439.51	\$19.98	4.4	0.01%
CARTIA XT CAP 240/24HR	18	9	\$331.69	\$18.43	2	0.01%
FELODIPINE TAB 2.5MG ER	16	7	\$268.21	\$16.76	2.29	0.01%
CARTIA XT CAP 180/24HR	15	13	\$406.98	\$27.13	1.15	0.01%
DILTIAZEM CAP 420MG/24HR	12	4	\$965.75	\$80.48	3	0.02%
TIADYLT CAP 240MG/24HR	12	3	\$474.14	\$39.51	4	0.01%
TIADYLT CAP 360MG/24HR	11	3	\$351.30	\$31.94	3.67	0.01%
TIADYLT CAP 180MG/24HR	5	4	\$140.09	\$28.02	1.25	0.00%
CALAN SR TAB 240MG	4	1	\$958.21	\$239.55	4	0.02%
TIADYLT CAP 420MG/24	3	1	\$198.22	\$66.07	3	0.00%
CARTIA XT CAP 300MG/24HR	1	1	\$36.90	\$36.90	1	0.00%
TAZTIA XT CAP 120MG/24HR	1	1	\$14.22	\$14.22	1	0.00%
<b>TIER-1 SUBTOTAL</b>	<b>79,135</b>	<b>30,050</b>	<b>\$934,023.86</b>	<b>\$11.80</b>	<b>2.63</b>	<b>18.01%</b>
<b>TIER-2 UTILIZATION</b>						
DILTIAZEM CAP 120MG ER	70	16	\$12,998.07	\$185.69	4.38	0.25%
VERAPAMIL CAP 180MG SR	57	19	\$4,555.51	\$79.92	3	0.09%
VERAPAMIL CAP 240MG SR	47	19	\$4,398.70	\$93.59	2.47	0.08%
DILTIAZEM CAP 120MG ER	44	20	\$1,524.72	\$34.65	2.2	0.03%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
VERAPAMIL CAP 120MG SR	43	11	\$2,501.55	\$58.18	3.91	0.05%
DILTIAZEM ER TAB 180MG	41	7	\$3,761.57	\$91.75	5.86	0.07%
VERAPAMIL CAP 360MG SR	37	13	\$11,880.05	\$321.08	2.85	0.23%
DILTIAZEM CAP 90MG ER	31	7	\$3,293.80	\$106.25	4.43	0.06%
DILTIAZEM ER TAB 240MG	29	11	\$3,706.29	\$127.80	2.64	0.07%
AMLOD/ATORVA TAB 10/40MG	28	10	\$3,529.10	\$126.04	2.8	0.07%
DILTIAZEM CAP 60MG ER	25	7	\$3,322.53	\$132.90	3.57	0.06%
AMLOD/ATORVA TAB 10/10MG	24	7	\$1,942.72	\$80.95	3.43	0.04%
DILTIAZEM ER TAB 360MG	19	7	\$4,298.41	\$226.23	2.71	0.08%
VERAPAMIL CAP 100MG ER	16	4	\$4,570.29	\$285.64	4	0.09%
AMLOD/ATORVA TAB 10/80MG	15	4	\$2,994.56	\$199.64	3.75	0.06%
ISRADIPINE CAP 2.5MG	13	5	\$850.25	\$65.40	2.6	0.02%
VERAPAMIL CAP 300MG ER	12	4	\$8,144.88	\$678.74	3	0.16%
AMLOD/ATORVA TAB 5/40MG	11	3	\$1,332.92	\$121.17	3.67	0.03%
MATZIM LA TAB 180MG/24HR	11	5	\$1,316.65	\$119.70	2.2	0.03%
AMLOD/ATORVA TAB 5/20MG	9	1	\$758.68	\$84.30	9	0.01%
AMLOD/ATORVA TAB 5/10MG	7	3	\$890.86	\$127.27	2.33	0.02%
CARDIZEM LA TAB 120MG	7	2	\$1,174.36	\$167.77	3.5	0.02%
AMLOD/ATORVA TAB 10/20MG	5	3	\$454.08	\$90.82	1.67	0.01%
DILTIAZEM ER TAB 420MG	5	2	\$1,313.13	\$262.63	2.5	0.03%
MATZIM LA TAB 240MG/24HR	5	3	\$728.27	\$145.65	1.67	0.01%
NICARDIPINE CAP 20MG	5	3	\$2,973.15	\$594.63	1.67	0.06%
VERAPAMIL CAP 120MG ER	5	4	\$549.62	\$109.92	1.25	0.01%
MATZIM LA TAB 360MG/24HR	4	1	\$1,124.11	\$281.03	4	0.02%
AMLOD/ATORVA TAB 2.5/10MG	3	1	\$315.60	\$105.20	3	0.01%
VERAPAMIL CAP 180MG ER	3	3	\$198.04	\$66.01	1	0.00%
VERAPAMIL CAP 240MG ER	3	3	\$233.07	\$77.69	1	0.00%
AMLOD/ATORVA TAB 2.5/20MG	1	1	\$243.41	\$243.41	1	0.00%
DILTIAZEM ER TAB 300MG	1	1	\$233.11	\$233.11	1	0.00%
VERAPAMIL CAP 200MG ER	1	1	\$403.71	\$403.71	1	0.01%
<b>TIER-2 SUBTOTAL</b>	<b>637</b>	<b>211</b>	<b>\$92,515.77</b>	<b>\$145.24</b>	<b>3.02</b>	<b>1.78%</b>
<b>SPECIAL PA UTILIZATION</b>						
KATERZIA SUS 1MG/ML	220	46	\$87,091.94	\$395.87	4.78	1.68%
NORLIQVA SOL 1MG/ML	44	12	\$18,611.30	\$422.98	3.67	0.36%
DILTIAZEM CAP 360MG CD	25	9	\$1,006.13	\$40.25	2.78	0.02%
<b>SPECIAL PA SUBTOTAL</b>	<b>289</b>	<b>67</b>	<b>\$106,709.37</b>	<b>\$369.24</b>	<b>4.31</b>	<b>2.06%</b>
<b>CCB TOTAL</b>	<b>80,061</b>	<b>30,328</b>	<b>\$1,133,249.00</b>	<b>\$14.15</b>	<b>2.64</b>	<b>21.85%</b>
<b>METOPROLOL PRODUCTS</b>						
<b>NO PA REQUIRED</b>						
METOPROLOL SUC TAB 25MG ER	16,485	6,238	\$215,884.08	\$13.10	2.64	4.16%
METOPROLOL TAR TAB 25MG	14,849	5,300	\$145,367.28	\$9.79	2.8	2.80%
METOPROLOL SUC TAB 50MG ER	12,615	4,599	\$180,428.07	\$14.30	2.74	3.48%
METOPROLOL TAR TAB 50MG	10,110	3,318	\$101,638.47	\$10.05	3.05	1.96%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
METOPROLOL SUC TAB 100MG ER	6,401	2,168	\$104,421.91	\$16.31	2.95	2.01%
METOPROLOL TAR TAB 100MG	3,502	1,121	\$36,309.50	\$10.37	3.12	0.70%
METOPROLOL SUC TAB 200MG ER	1,043	325	\$23,983.56	\$22.99	3.21	0.46%
METOPROLOL TAR TAB 75MG	266	116	\$7,104.35	\$26.71	2.29	0.14%
METOPROLOL TAR TAB 37.5MG	54	18	\$840.74	\$15.57	3	0.02%
<b>NO PA SUBTOTAL</b>	<b>65,325</b>	<b>23,203</b>	<b>\$815,977.96</b>	<b>\$12.49</b>	<b>2.82</b>	<b>15.73%</b>
<b>SPECIAL PA UTILIZATION</b>						
KAPSPARGO CAP 50MG	10	1	\$632.12	\$63.21	10	0.01%
KAPSPARGO CAP 25MG	10	1	\$586.66	\$58.67	10	0.01%
<b>SPECIAL PA SUBTOTAL</b>	<b>20</b>	<b>2</b>	<b>\$1,218.78</b>	<b>\$60.94</b>	<b>10</b>	<b>0.02%</b>
<b>METOPROLOL TOTAL</b>	<b>65,345</b>	<b>23,205</b>	<b>\$817,196.74</b>	<b>\$12.51</b>	<b>2.82</b>	<b>15.75%</b>
<b>ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs) AND ARB COMBINATION PRODUCTS</b>						
<b>TIER-1 UTILIZATION</b>						
LOSARTAN POT TAB 50MG	15,816	6,087	\$197,469.21	\$12.49	2.6	3.81%
LOSARTAN POT TAB 100MG	12,816	4,447	\$176,551.20	\$13.78	2.88	3.40%
LOSARTAN POT TAB 25MG	11,177	4,551	\$127,853.34	\$11.44	2.46	2.46%
LOSAR/HCTZ TAB 100/25MG	3,075	1,143	\$55,552.77	\$18.07	2.69	1.07%
LOSAR/HCTZ TAB 50/12.5MG	2,804	1,121	\$37,638.53	\$13.42	2.5	0.73%
LOSAR/HCTZ TAB 100/12.5MG	1,869	671	\$32,329.29	\$17.30	2.79	0.62%
OLMESARTAN TAB 40MG	1,305	417	\$20,787.89	\$15.93	3.13	0.40%
OLMESARTAN TAB 20MG	1,219	477	\$17,817.66	\$14.62	2.56	0.34%
VALSARTAN TAB 160MG	1,210	444	\$27,076.02	\$22.38	2.73	0.52%
VALSARTAN TAB 80MG	1,094	397	\$21,950.01	\$20.06	2.76	0.42%
VALSARTAN TAB 320MG	703	237	\$17,485.88	\$24.87	2.97	0.34%
VALSARTAN TAB 40MG	618	230	\$11,474.11	\$18.57	2.69	0.22%
TELMISARTAN TAB 40MG	475	167	\$12,557.11	\$26.44	2.84	0.24%
IRBESARTAN TAB 300MG	455	141	\$9,830.98	\$21.61	3.23	0.19%
IRBESARTAN TAB 150MG	422	147	\$7,780.16	\$18.44	2.87	0.15%
VALSAR/HCTZ TAB 160/12.5MG	420	129	\$8,083.88	\$19.25	3.26	0.16%
TELMISARTAN TAB 80MG	410	130	\$10,012.88	\$24.42	3.15	0.19%
OLMESAR/HCTZ TAB 40/25MG	389	137	\$10,024.25	\$25.77	2.84	0.19%
VALSAR/HCTZ TAB 320/25MG	357	129	\$10,151.82	\$28.44	2.77	0.20%
CANDESARTAN TAB 8MG	335	117	\$14,774.89	\$44.10	2.86	0.28%
CANDESARTAN TAB 16MG	328	111	\$14,570.94	\$44.42	2.95	0.28%
AMLOD/VALSAR TAB 5/160MG	279	98	\$9,647.85	\$34.58	2.85	0.19%
OLMESAR/HCTZ TAB 20/12.5MG	268	101	\$5,609.53	\$20.93	2.65	0.11%
VALSAR/HCTZ TAB 160/25MG	248	105	\$6,142.70	\$24.77	2.36	0.12%
OLMESARTAN TAB 5MG	232	97	\$3,152.24	\$13.59	2.39	0.06%
TELMISARTAN TAB 20MG	227	86	\$5,025.69	\$22.14	2.64	0.10%
AMLOD/VALSAR TAB 10/320MG	216	69	\$9,424.58	\$43.63	3.13	0.18%
IRBESARTAN TAB 75MG	210	53	\$3,974.57	\$18.93	3.96	0.08%
CANDESARTAN TAB 4MG	187	80	\$9,298.80	\$49.73	2.34	0.18%
OLMESAR/HCTZ TAB 40/12.5MG	184	63	\$4,379.26	\$23.80	2.92	0.08%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
VALSAR/HCTZ TAB 80/12.5MG	182	57	\$3,785.85	\$20.80	3.19	0.07%
AMLOD/VALSAR TAB 10/160MG	172	59	\$7,005.06	\$40.73	2.92	0.14%
IRBESAR/HCTZ TAB 150/12.5MG	117	32	\$2,389.68	\$20.42	3.66	0.05%
AMLOD/OLMESAR TAB 5/20MG	106	37	\$2,563.18	\$24.18	2.86	0.05%
VALSAR/HCTZ TAB 320/12.5MG	106	45	\$3,160.02	\$29.81	2.36	0.06%
IRBESAR/HCTZ TAB 300/12.5MG	102	41	\$2,388.33	\$23.42	2.49	0.05%
AMLOD/OLMESAR TAB 10/40MG	99	37	\$2,714.12	\$27.42	2.68	0.05%
AMLOD/OLMESAR TAB 10/20MG	68	33	\$1,912.89	\$28.13	2.06	0.04%
AMLOD/VALSAR TAB 5/320MG	53	21	\$1,927.65	\$36.37	2.52	0.04%
AMLOD/OLMESAR TAB 5/40MG	25	7	\$625.07	\$25.00	3.57	0.01%
AMLOD/VAL/HCTZ TAB 10/320/25MG	24	9	\$1,311.36	\$54.64	2.67	0.03%
AMLOD/VAL/HCTZ TAB 5/160/12.5MG	20	7	\$663.66	\$33.18	2.86	0.01%
AMLOD/VAL/HCTZ TAB 10/160/12.5MG	17	4	\$1,815.97	\$106.82	4.25	0.04%
MICARDIS TAB 80MG	4	1	\$1,677.10	\$419.28	4	0.03%
BENICAR TAB 20MG	4	1	\$3,009.00	\$752.25	4	0.06%
AMLOD/VAL/HCTZ TAB 10/160/25MG	2	1	\$92.90	\$46.45	2	0.00%
EXFORGE HCT TAB 10/320/25MG	2	1	\$401.78	\$200.89	2	0.01%
AMLOD/VAL/HCTZ TAB 10/160/12.5MG	1	1	\$44.17	\$44.17	1	0.00%
EXFORGE HCT TAB 10/160/12.5MG	1	1	\$309.05	\$309.05	1	0.01%
<b>TIER-1 SUBTOTAL</b>	<b>60,453</b>	<b>22,577</b>	<b>\$936,224.88</b>	<b>\$15.49</b>	<b>2.68</b>	<b>18.05%</b>
<b>TIER-2 UTILIZATION</b>						
CANDESARTAN TAB 32MG	54	19	\$4,225.92	\$78.26	2.84	0.08%
TELMISAR/HCTZ TAB 40/12.5MG	50	12	\$2,486.07	\$49.72	4.17	0.05%
TELMISAR/HCTZ TAB 80/12.5MG	38	13	\$2,551.69	\$67.15	2.92	0.05%
OLMESAR/AMLOD/HCTZ TAB 40/10/25MG	26	7	\$2,121.59	\$81.60	3.71	0.04%
OLMESAR/AMLOD/HCTZ TAB 20/5/12.5MG	7	4	\$414.52	\$59.22	1.75	0.01%
TELMISAR/HCTZ TAB 80/25MG	6	4	\$403.60	\$67.27	1.5	0.01%
OLMESAR/AMLOD/HCTZ TAB 40/5/12.5MG	5	1	\$174.55	\$34.91	5	0.00%
OLMESAR/AMLOD/HCTZ TAB 40/10/12.5MG	4	2	\$316.53	\$79.13	2	0.01%
OLMESAR/AMLOD/HCTZ TAB 40/5/25MG	1	1	\$132.00	\$132.00	1	0.00%
<b>TIER-2 SUBTOTAL</b>	<b>191</b>	<b>63</b>	<b>\$12,826.47</b>	<b>\$67.15</b>	<b>3.03</b>	<b>0.25%</b>
<b>SPECIAL PA UTILIZATION</b>						
EDARBYCLOR TAB 40/25MG	22	5	\$7,318.21	\$332.65	4.4	0.14%
EDARBYCLOR TAB 40/12.5MG	21	3	\$7,474.01	\$355.91	7	0.14%
CANDESAR/HCTZ TAB 32/25MG	7	3	\$979.00	\$139.86	2.33	0.02%
TELMISAR/AMLOD TAB 80/5MG	6	1	\$1,291.40	\$215.23	6	0.02%
CANDESAR/HCTZ TAB 16/12.5MG	5	2	\$249.60	\$49.92	2.5	0.00%
<b>SPECIAL PA SUBTOTAL</b>	<b>61</b>	<b>14</b>	<b>\$17,312.22</b>	<b>\$283.81</b>	<b>4.36</b>	<b>0.33%</b>
<b>ARB TOTAL</b>	<b>60,705</b>	<b>22,654</b>	<b>966,364</b>	<b>\$15.92</b>	<b>2.68</b>	<b>18.63%</b>
<b>SPIRONOLACTONE PRODUCTS</b>						
<b>NO PA REQUIRED</b>						
SPIRONOLACTONE TAB 25MG	12,261	4,311	\$145,209.03	\$11.84	2.84	2.80%
SPIRONOLACTONE TAB 50MG	7,255	2,599	\$110,959.33	\$15.29	2.79	2.14%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
SPIRONOLACTONE TAB 100MG	5,031	1,642	\$97,188.99	\$19.32	3.06	1.87%
SPIRONOLACTONE POW	14	2	\$315.65	\$22.55	7	0.01%
<b>NO PA SUBTOTAL</b>	<b>24,561</b>	<b>8,554</b>	<b>\$353,673.00</b>	<b>\$14.40</b>	<b>2.87</b>	<b>6.82%</b>
<b>SPECIAL PA UTILIZATION</b>						
CAROSPIR SUS 25MG/5ML	200	54	\$78,174.06	\$390.87	3.7	1.51%
<b>SPECIAL PA SUBTOTAL</b>	<b>200</b>	<b>54</b>	<b>\$78,174.06</b>	<b>\$390.87</b>	<b>3.7</b>	<b>1.51%</b>
<b>SPIRONOLACTONE TOTAL</b>	<b>24,761</b>	<b>8,608</b>	<b>\$431,847.06</b>	<b>\$17.44</b>	<b>2.88</b>	<b>8.33%</b>
<b>ACEI/HYDROCHLOROTHIAZIDE (HCTZ) COMBINATION PRODUCTS</b>						
<b>TIER-1 UTILIZATION</b>						
LISINOP/HCTZ TAB 20/12.5MG	7,837	2,844	\$97,366.99	\$12.42	2.76	1.88%
LISINOP/HCTZ TAB 20/25MG	7,122	2,494	\$73,916.33	\$10.38	2.86	1.43%
LISINOP/HCTZ TAB 10/12.5MG	4,725	1,771	\$50,031.83	\$10.59	2.67	0.96%
ENALAP/HCTZ TAB 10/25MG	137	40	\$2,614.75	\$19.09	3.43	0.05%
BENAZEP/HCTZ TAB 20/12.5MG	79	22	\$3,093.15	\$39.15	3.59	0.06%
BENAZEP/HCTZ TAB 10/12.5MG	58	24	\$2,013.85	\$34.72	2.42	0.04%
ENALAP/HCTZ TAB 5/12.5MG	37	14	\$684.60	\$18.50	2.64	0.01%
BENAZEP/HCTZ TAB 20/25MG	36	14	\$1,553.16	\$43.14	2.57	0.03%
BENAZEP/HCTZ TAB 5/6.25MG	12	5	\$914.10	\$76.18	2.4	0.02%
QUINAPRIL/HCTZ TAB 20/12.5MG	4	2	\$135.24	\$33.81	2	0.00%
<b>TIER-1 SUBTOTAL</b>	<b>20,047</b>	<b>7,230</b>	<b>\$232,324.00</b>	<b>\$11.59</b>	<b>2.77</b>	<b>4.48%</b>
<b>ACEI/HCTZ TOTAL</b>	<b>20,047</b>	<b>7,230</b>	<b>\$232,324.00</b>	<b>\$11.59</b>	<b>2.77</b>	<b>4.48%</b>
<b>ACEI/CCB COMBINATION PRODUCTS</b>						
<b>TIER-1 UTILIZATION</b>						
AMLOD/BENAZEP CAP 10/40MG	452	132	\$8,635.06	\$19.10	3.42	0.17%
AMLOD/BENAZEP CAP 10/20MG	367	128	\$6,610.54	\$18.01	2.87	0.13%
AMLOD/BENAZEP CAP 5/20MG	239	87	\$4,044.48	\$16.92	2.75	0.08%
AMLOD/BENAZEP CAP 5/10MG	190	75	\$2,941.82	\$15.48	2.53	0.06%
AMLOD/BENAZEP CAP 5/40MG	81	30	\$1,446.40	\$17.86	2.7	0.03%
AMLOD/BENAZEP CAP 2.5/10MG	51	17	\$807.85	\$15.84	3	0.02%
<b>TIER-1 SUBTOTAL</b>	<b>1,380</b>	<b>469</b>	<b>\$24,486.15</b>	<b>\$17.74</b>	<b>2.94</b>	<b>0.47%</b>
<b>ACEI/CCB TOTAL</b>	<b>1,380</b>	<b>469</b>	<b>\$24,486.15</b>	<b>\$17.74</b>	<b>2.94</b>	<b>0.47%</b>
<b>MISCELLANEOUS (MISC) COMBINATION PRODUCTS</b>						
<b>NO PA REQUIRED</b>						
ATENOLOL/CHLOR TAB 50/25MG	328	82	\$8,795.29	\$26.81	4	0.17%
BISOPROLOL/HCTZ TAB 10/6.25MG	279	81	\$7,979.15	\$28.60	3.44	0.15%
BISOPROLOL/HCTZ TAB 5/6.25MG	272	93	\$7,794.32	\$28.66	2.92	0.15%
ATENOLOL/CHLOR TAB 100/25MG	137	58	\$5,344.61	\$39.01	2.36	0.10%
BISOPROLOL/HCTZ TAB 2.5/6.25MG	117	37	\$3,141.03	\$26.85	3.16	0.06%
METOPROLOL/HCTZ TAB 50/25MG	96	34	\$6,995.33	\$72.87	2.82	0.13%
METOPROLOL/HCTZ TAB 100/25MG	37	11	\$3,667.12	\$99.11	3.36	0.07%
METOPROLOL/HCTZ TAB 100/50MG	1	1	\$59.32	\$59.32	1	0.00%
<b>NO PA SUBTOTAL</b>	<b>1,267</b>	<b>397</b>	<b>\$43,776.17</b>	<b>\$34.55</b>	<b>3.19</b>	<b>0.84%</b>
<b>MISC TOTAL</b>	<b>1,267</b>	<b>397</b>	<b>\$43,776.17</b>	<b>\$34.55</b>	<b>3.19</b>	<b>0.84%</b>

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
<b>PROPRANOLOL SOLUTION (SOL) PRODUCTS</b>						
<b>NO PA REQUIRED</b>						
PROPRANOLOL SOL 20MG/5ML	1,061	237	\$25,553.69	\$24.08	4.48	0.49%
PROPRANOLOL SOL 40MG/5ML	37	8	\$1,180.64	\$31.91	4.63	0.02%
<b>NO PA SUBTOTAL</b>	<b>1,098</b>	<b>245</b>	<b>\$26,734.33</b>	<b>\$24.35</b>	<b>4.48</b>	<b>0.52%</b>
<b>SPECIAL PA UTILIZATION</b>						
HEMANGEOL SOL 4.28/ML	82	20	\$59,340.48	\$723.66	4.1	1.14%
<b>SPECIAL PA SUBTOTAL</b>	<b>82</b>	<b>20</b>	<b>\$59,340.48</b>	<b>\$723.66</b>	<b>4.1</b>	<b>1.14%</b>
<b>PROPRANOLOL SOL TOTAL</b>	<b>1,180</b>	<b>265</b>	<b>\$86,074.81</b>	<b>\$72.94</b>	<b>4.45</b>	<b>1.66%</b>
<b>SOTALOL PRODUCTS</b>						
<b>NO PA REQUIRED</b>						
SOTALOL HCL TAB 80MG	301	84	\$4,590.76	\$15.25	3.58	0.09%
SOTALOL HCL TAB 120MG	147	37	\$2,405.37	\$16.36	3.97	0.05%
SOTALOL AF TAB 80MG	44	11	\$629.70	\$14.31	4	0.01%
SOTALOL HCL TAB 160MG	19	8	\$453.39	\$23.86	2.38	0.01%
SOTALOL AF TAB 120MG	13	4	\$190.15	\$14.63	3.25	0.00%
SOTALOL AF TAB 160MG	1	1	\$29.68	\$29.68	1	0.00%
<b>NO PA SUBTOTAL</b>	<b>525</b>	<b>145</b>	<b>\$8,299.05</b>	<b>\$15.81</b>	<b>3.62</b>	<b>0.16%</b>
<b>SPECIAL PA UTILIZATION</b>						
SOTYLIZE SOL 5MG/ML	87	17	\$50,590.96	\$581.51	5.12	0.98%
<b>SPECIAL PA SUBTOTAL</b>	<b>87</b>	<b>17</b>	<b>\$50,590.96</b>	<b>\$581.51</b>	<b>5.12</b>	<b>0.98%</b>
<b>SOTALOL TOTAL</b>	<b>612</b>	<b>162</b>	<b>\$58,890.01</b>	<b>\$96.23</b>	<b>3.78</b>	<b>1.14%</b>
<b>TOTAL</b>	<b>357,508</b>	<b>83,544*</b>	<b>\$5,186,923.14</b>	<b>\$14.51</b>	<b>4.28</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

AMLOD = amlodipine; ATORVA = atorvastatin; BENAZEP = benazepril; CANDESAR = candesartan; CAP = capsule; CD = controlled-delivery; CHLOR = chlorthalidone; ENALEP = enalapril; ER = extended-release; HCL = hydrochloride; HCTZ = hydrochlorothiazide; HR = hour; INJ = injection; IRBESAR = irbesartan; LA = long-acting; LISINOP = lisinopril; LOSAR = losartan; OLMESAR = olmesartan; POT = potassium; SOL = solution; SR = sustained-release; SUC = succinate; SUS = suspension; TAB = tablet; TAR = tartrate; TELMISAR = telmisartan; VAL = valsartan; VALSAR = valsartan; XR = extra-release; XT = extra-time  
Fiscal Year 2023 = 07/01/2022 to 06/30/2023

<sup>1</sup> U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <https://www.accessdata.fda.gov/scripts/cder/ob/>. Last revised 12/2023. Last accessed 12/10/2023.

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# Fiscal Year 2023 Annual Review of Benign Prostatic Hyperplasia (BPH) Medications

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Oklahoma Health Care Authority  
Fiscal Year 2023 Print Report

## Current Prior Authorization Criteria

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Benign Prostatic Hyperplasia (BPH) Medications		
Tier-1	Tier-2	Tier-3
alfuzosin (Uroxatral®)	doxazosin (Cardura XL®)	tadalafil 5mg (Cialis®)
doxazosin (Cardura®)	dutasteride/tamsulosin (Jalyn®)	finasteride 5mg/ tadalafil 5mg (Entadfi®)
dutasteride (Avodart®)	silodosin (Rapaflo®)	
finasteride (Proscar®)		
tamsulosin (Flomax®)		
terazosin (Hytrin®)		

### BPH Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. A 4-week trial of 2 Tier-1 medications from different pharmacological classes within the past 90 days; or
3. Documented adverse effect, drug interaction, or contraindication to all available Tier-1 medications.

### BPH Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH); and
2. A 4-week trial of at least 2 Tier-1 medications from different pharmacological classes; and
3. A 4-week trial of all Tier-2 medications within the past 5 months; or
4. Documented adverse effect, drug interaction, contraindication, or lack of efficacy to all available Tier-1 and Tier-2 medications; and
5. Authorizations for Cialis® (tadalafil) will be granted for the 5mg tablets only.

### Entadfi® (Finasteride 5mg/Tadalafil 5mg) Approval Criteria:

1. An FDA approved diagnosis of benign prostatic hyperplasia (BPH); and
2. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components (finasteride and tadalafil) must be provided; and
4. A quantity limit of 30 capsules per 30 days will apply; and



5. Maximum treatment duration of 26 weeks will apply.

**Utilization of BPH Medications: Fiscal Year 2023**

**Comparison of Fiscal Years**

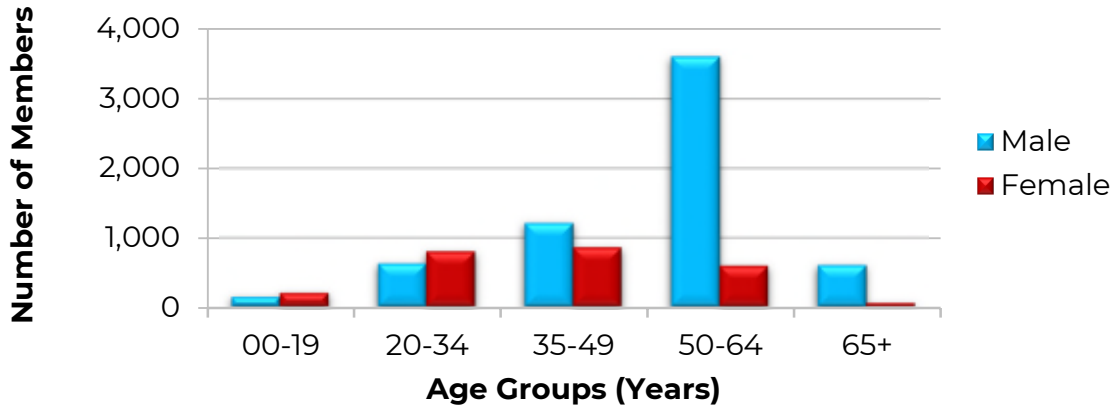
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	6,484	17,890	\$236,624.39	\$13.23	\$0.29	903,181	817,371
2023	8,636	23,738	\$303,263.81	\$12.78	\$0.26	1,275,506	1,146,177
% Change	33.2%	32.7%	28.2%	-3.4%	-10.30%	41.2%	40.2%
Change	2,152	5,848	\$66,639.42	-\$0.45	-\$0.03	372,325	328,806

Costs do not reflect rebated prices or net costs.

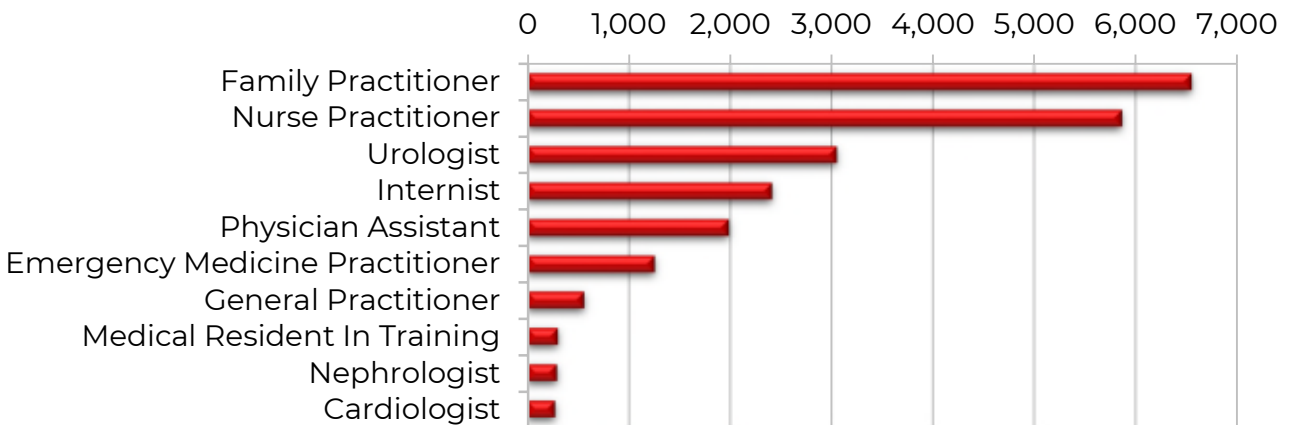
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

**Demographics of Members Utilizing BPH Medications**



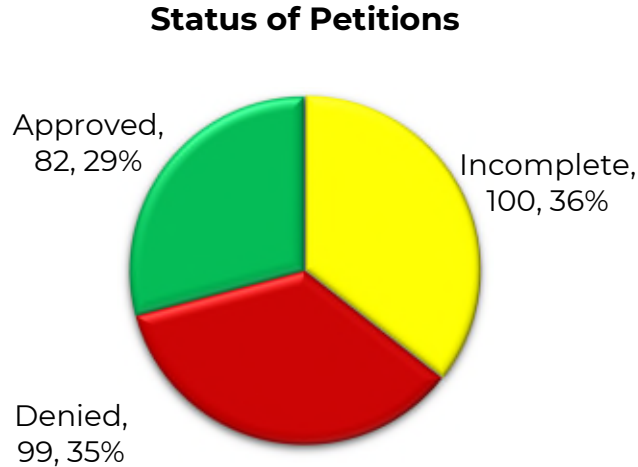
**Top Prescriber Specialties of BPH Medications by Number of Claims**





## Prior Authorization of BPH Medications

There were 281 prior authorization requests submitted for BPH medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



## Recommendations

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

## Utilization Details of BPH Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
<b>TIER-1 UTILIZATION</b>						
TAMSULOSIN CAP 0.4MG	17,900	7,471	\$218,127.49	\$12.19	2.4	71.93%
FINASTERIDE TAB 5MG	2,062	658	\$26,593.66	\$12.90	3.13	8.77%
DOXAZOSIN TAB 4MG	934	244	\$12,717.00	\$13.62	3.83	4.19%
DOXAZOSIN TAB 2MG	646	225	\$8,534.98	\$13.21	2.87	2.81%
DOXAZOSIN TAB 1MG	333	122	\$3,985.64	\$11.97	2.73	1.31%
ALFUZOSIN ER TAB 10MG	326	125	\$4,931.19	\$15.13	2.61	1.63%
DOXAZOSIN TAB 8MG	295	91	\$4,184.10	\$14.18	3.24	1.38%
TERAZOSIN CAP 1MG	294	125	\$4,667.26	\$15.88	2.35	1.54%
TERAZOSIN CAP 2MG	271	87	\$5,142.06	\$18.97	3.11	1.7%
DUTASTERIDE CAP 0.5MG	250	75	\$4,781.30	\$19.13	3.33	1.58%
TERAZOSIN CAP 5MG	173	49	\$3,286.54	\$19.00	3.53	1.08%
TERAZOSIN CAP 10MG	116	31	\$2,318.41	\$19.99	3.74	0.76%
<b>SUBTOTAL</b>	<b>23,600</b>	<b>9,303</b>	<b>\$299,269.63</b>	<b>\$12.68</b>	<b>2.54</b>	<b>98.68%</b>
<b>TIER-2 UTILIZATION</b>						
SILODOSIN CAP 8MG	65	13	\$1,784.49	\$27.45	5	0.59%
SILODOSIN CAP 4MG	11	5	\$416.82	\$37.89	2.2	0.14%
DUTAST/TAMSU CAP 0.5/0.4MG	4	2	\$573.91	\$143.48	2	0.19%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DOXAZOSIN ER TAB 4MG	1	1	\$192.78	\$192.78	1	0.06%
<b>SUBTOTAL</b>	<b>81</b>	<b>21</b>	<b>\$2,968.00</b>	<b>\$36.64</b>	<b>3.86</b>	<b>0.98%</b>
<b>TIER-3 UTILIZATION</b>						
TADALAFIL TAB 5MG	57	13	\$1,026.18	\$18.00	9.5	0.34%
<b>SUBTOTAL</b>	<b>57</b>	<b>13</b>	<b>\$1,026.18</b>	<b>\$18.00</b>	<b>9.5</b>	<b>0.34%</b>
<b>TOTAL</b>	<b>23,738</b>	<b>8,636</b>	<b>\$303,263.81</b>	<b>\$12.78</b>	<b>2.75</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

CAP = capsule; DUTAST/TAMSU = dutasteride/tamsulosin; ER = extended-release; TAB = tablet

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

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# Fiscal Year 2023 Annual Review of Benzodiazepine Medications

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Oklahoma Health Care Authority  
Fiscal Year 2023 Print Report

## Current Prior Authorization Criteria

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### **Benzodiazepine Medications Approval Criteria for Members 19 Years of Age and Older:**

1. Currently there is no prior authorization required; however, quantity limits are set at a maximum of 3 units per day for most products (except alprazolam 2mg, which is set at 2 units per day); and
2. Approval for dosing >3 times daily requires a chronic physical diagnosis; for these diagnoses, the maximum allowed dosing would be 4 times daily (no anxiolytic benzodiazepine therapy >3 times daily dosing if member also concurrently taking an insomnia medication); and
  - a. Member may receive >3 units per day if the following criteria exist:
    - i. The number of units per day is >3, but is less than the maximum daily dose for the product (or for a total daily dosing of 3 times daily); or
    - ii. The member has a chronic diagnosis and a clinical reason for excessive units has been provided; and
3. Current members will be given 2 months to taper dosing to no more than 3 doses daily.

### **Benzodiazepine Medications Approval Criteria for Members Younger than 19 Years of Age:**

1. Member must have a chronic behavioral health-related diagnosis or a chronic physical diagnosis; and
2. Approval criteria for a chronic behavior health-related diagnosis:
  - a. No concurrent stimulant ADHD medications; and
  - b. Maximum dosing of 3 times daily will apply; or
3. Approval criteria for a chronic physical diagnosis:
  - a. Maximum dosing of 3 times daily will apply if a hypnotic medication is being used concurrently; or
  - b. Maximum dosing of 4 times daily will apply if no hypnotic medication is being used concurrently; and
4. Exceptions can be granted for administration prior to procedures; and
5. Members 12 years of age or younger will have the same criteria as above, and the prescription must be originally written by a psychiatrist or neurologist.

**Loreev XR® [Lorazepam Extended-Release (ER) Capsule] Approval Criteria:**

1. An FDA approved diagnosis for the treatment of anxiety disorders; and
2. Member must be 18 years of age or older; and
3. Member must be receiving stable, evenly divided, 3 times daily dosing of lorazepam tablets; and
4. A patient-specific, clinically significant reason (beyond convenience) why the member cannot use the immediate-release formulation must be provided; and
5. A quantity limit of 30 capsules per 30 days will apply.

**Niravam® (Alprazolam Orally Disintegrating Tablet) Approval Criteria:**

1. An FDA approved diagnosis; and
2. A diagnosis indicating that the member has a condition that prevents him/her from swallowing tablets; and
3. The physician’s signature is required for approval; and
4. Dosing regimens that involve splitting of tablets will not be covered.

**Utilization of Benzodiazepine Medications: Fiscal Year 2023**

**Comparison of Fiscal Years**

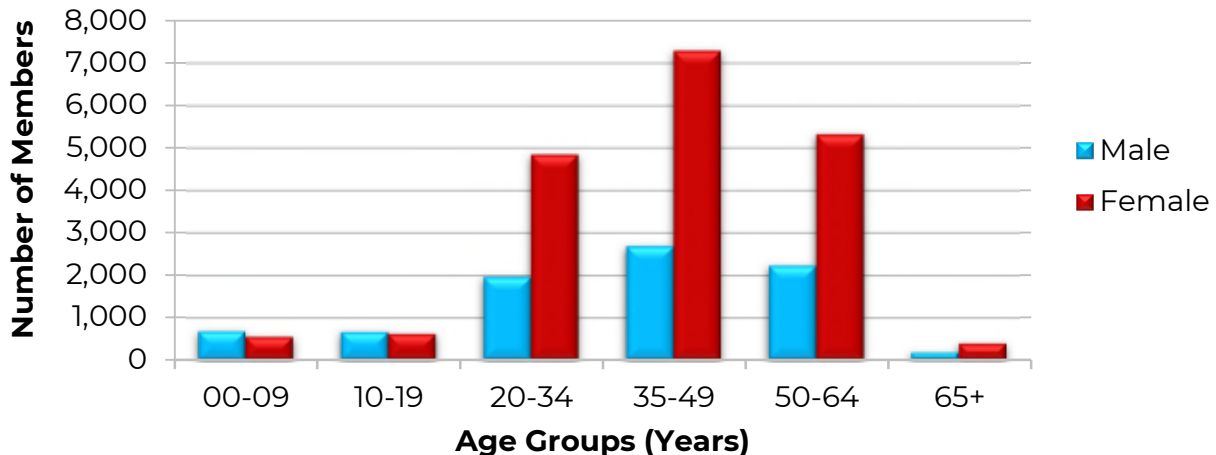
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	23,324	110,368	\$3,030,090.33	\$27.45	\$1.04	6,240,361	2,900,220
2023	27,388	128,902	\$3,384,128.91	\$26.25	\$1.00	7,184,500	3,389,338
<b>% Change</b>	<b>17.40%</b>	<b>16.80%</b>	<b>11.70%</b>	<b>-4.40%</b>	<b>-3.80%</b>	<b>15.10%</b>	<b>16.90%</b>
<b>Change</b>	<b>4,064</b>	<b>18,534</b>	<b>\$354,038.58</b>	<b>-\$1.20</b>	<b>-\$0.04</b>	<b>944,139</b>	<b>489,118</b>

Costs do not reflect rebated prices or net costs.

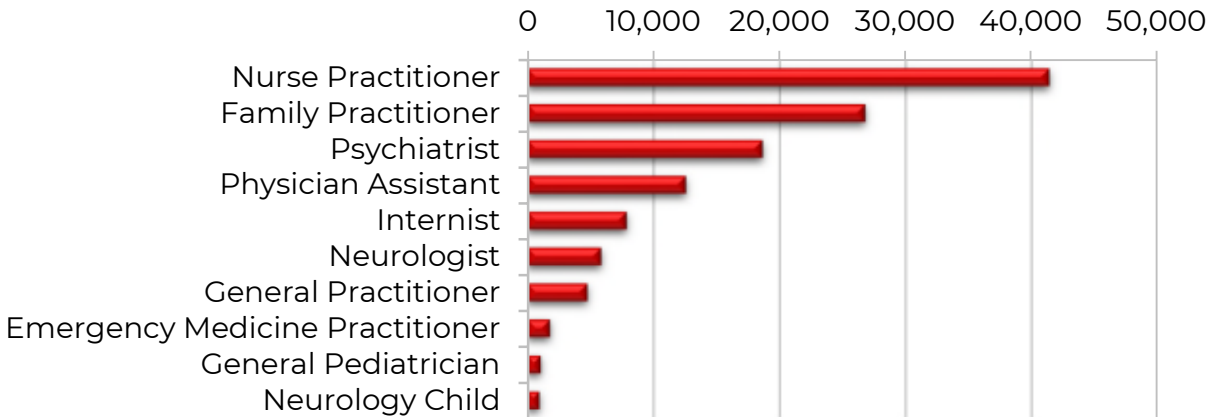
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

**Demographics of Members Utilizing Benzodiazepine Medications**



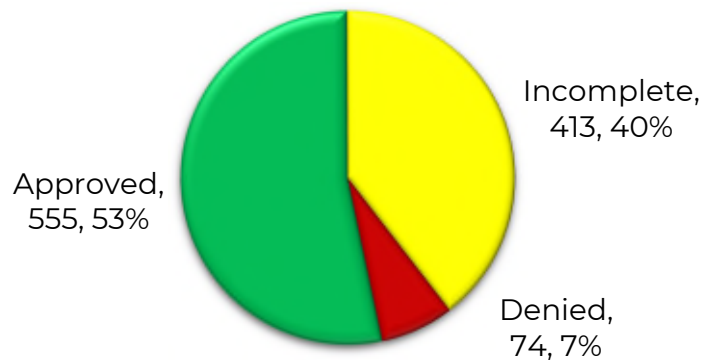
## Top Prescriber Specialties of Benzodiazepine Medications by Number of Claims



## Prior Authorization of Benzodiazepine Medications

There were 1,042 prior authorization requests submitted for benzodiazepine medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

### Status of Petitions



## Market News and Updates<sup>1</sup>

### Anticipated Patent Expiration(s):

- Valtoco® (diazepam nasal spray): March 2029
- Loreev XR® (lorazepam extended-release capsule): January 2034

## Recommendations

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

## Utilization Details of Benzodiazepine Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
<b>ALPRAZOLAM PRODUCTS</b>						
ALPRAZOLAM TAB 1MG	26,245	4,174	\$284,500.67	\$10.84	6.29	8.41%
ALPRAZOLAM TAB 0.5MG	14,898	3,673	\$153,194.37	\$10.28	4.06	4.53%
ALPRAZOLAM TAB 2MG	7,587	1,064	\$92,226.34	\$12.16	7.13	2.73%
ALPRAZOLAM TAB 0.25MG	4,320	1,508	\$43,332.09	\$10.03	2.86	1.28%
ALPRAZOLAM TAB 2MG ER	426	105	\$7,333.70	\$17.22	4.06	0.22%
ALPRAZOLAM TAB 1MG ER	331	111	\$4,741.32	\$14.32	2.98	0.14%
ALPRAZOLAM TAB 0.5MG ER	111	39	\$1,567.64	\$14.12	2.85	0.05%
ALPRAZOLAM TAB 3MG ER	101	21	\$1,709.65	\$16.93	4.81	0.05%
ALPRAZOLAM ODT 0.5MG	3	1	\$84.72	\$28.24	3	0.00%
ALPRAZOLAM CON 1MG/ML	1	1	\$13.35	\$13.35	1	0.00%
<b>SUBTOTAL</b>	<b>54,023</b>	<b>10,697</b>	<b>\$588,703.85</b>	<b>\$10.90</b>	<b>5.05</b>	<b>17.40%</b>
<b>CLONAZEPAM PRODUCTS</b>						
CLONAZEPAM TAB 1MG	17,575	3,353	\$198,912.10	\$11.32	5.24	5.88%
CLONAZEPAM TAB 0.5MG	16,321	4,169	\$168,906.81	\$10.35	3.91	4.99%
CLONAZEPAM TAB 2MG	4,303	803	\$46,974.71	\$10.92	5.36	1.39%
CLONAZEPAM ODT 0.25MG	1,404	511	\$53,077.29	\$37.80	2.75	1.57%
CLONAZEPAM ODT 0.125MG	830	346	\$28,238.18	\$34.02	2.4	0.83%
CLONAZEPAM ODT 0.5MG	736	276	\$26,503.26	\$36.01	2.67	0.78%
CLONAZEPAM ODT 1MG	373	142	\$11,875.80	\$31.84	2.63	0.35%
CLONAZEPAM ODT 2MG	56	21	\$2,099.78	\$37.50	2.67	0.06%
<b>SUBTOTAL</b>	<b>41,598</b>	<b>9,621</b>	<b>\$536,587.93</b>	<b>\$12.90</b>	<b>4.32</b>	<b>15.86%</b>
<b>DIAZEPAM PRODUCTS</b>						
DIAZEPAM TAB 5MG	7,178	2,792	\$69,145.97	\$9.63	2.57	2.04%
DIAZEPAM TAB 10MG	6,396	2,139	\$62,914.23	\$9.84	2.99	1.86%
DIAZEPAM TAB 2MG	1,791	748	\$17,770.66	\$9.92	2.39	0.53%
VALTOCO SPR 10MG	924	597	\$869,385.59	\$940.89	1.55	25.69%
DIAZEPAM GEL 10MG	788	564	\$283,540.11	\$359.82	1.4	8.38%
VALTOCO SPR 15MG	336	218	\$334,234.73	\$994.75	1.54	9.88%
DIAZEPAM SOL 5MG/5ML	281	50	\$10,133.26	\$36.06	5.62	0.30%
VALTOCO SPR 5MG	185	111	\$152,823.65	\$826.07	1.67	4.52%
DIAZEPAM GEL 20MG	180	92	\$92,307.53	\$512.82	1.96	2.73%
VALTOCO SPR 20MG	160	98	\$143,802.59	\$898.77	1.63	4.25%
DIASTAT ACDL GEL 12.5-20MG	26	16	\$9,714.17	\$373.62	1.63	0.29%
DIAZEPAM CON 5MG/ML	25	5	\$936.47	\$37.46	5	0.03%
DIAZEPAM GEL 2.5MG	21	21	\$6,233.90	\$296.85	1	0.18%
DIAZEPAM POW	15	12	\$164.25	\$10.95	1.25	0.00%
DIASTAT ACDL GEL 5-10MG	14	14	\$6,536.00	\$466.86	1	0.19%
DIASTAT PED GEL 2.5MG GEL	1	1	\$476.27	\$476.27	1	0.01%
<b>SUBTOTAL</b>	<b>18,321</b>	<b>7,478</b>	<b>\$2,060,119.38</b>	<b>\$112.45</b>	<b>2.45</b>	<b>60.88%</b>
<b>LORAZEPAM PRODUCTS</b>						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
LORAZEPAM TAB 1MG	6,596	2,154	\$73,993.46	\$11.22	3.06	2.19%
LORAZEPAM TAB 0.5MG	4,924	1,766	\$51,760.36	\$10.51	2.79	1.53%
LORAZEPAM TAB 2MG	1,898	563	\$24,958.12	\$13.15	3.37	0.74%
LORAZEPAM CON 2MG/ML	102	54	\$2,701.35	\$26.48	1.89	0.08%
LORAZEPAM POW	53	19	\$818.06	\$15.44	2.79	0.02%
LORAZEPAM INJ 2MG/ML	14	3	\$495.50	\$35.39	4.67	0.01%
LORAZEPAM INJ 4MG/ML	1	1	\$17.06	\$17.06	1	0.00%
<b>SUBTOTAL</b>	<b>13,588</b>	<b>4,560</b>	<b>\$154,743.91</b>	<b>\$11.39</b>	<b>2.98</b>	<b>4.57%</b>
<b>CHLORDIAZEPOXIDE PRODUCTS</b>						
CHLORDIAZEP CAP 25MG	604	433	\$6,816.51	\$11.29	1.39	0.20%
CHLORDIAZEP CAP 10MG	211	132	\$2,812.29	\$13.33	1.6	0.08%
CHLORDIAZEP CAP 5MG	123	81	\$1,912.95	\$15.55	1.52	0.06%
<b>SUBTOTAL</b>	<b>938</b>	<b>646</b>	<b>\$11,541.75</b>	<b>\$12.30</b>	<b>1.45</b>	<b>0.34%</b>
<b>CLORAZEPATE PRODUCTS</b>						
CLORAZ DIPOT TAB 7.5MG	147	25	\$10,609.23	\$72.17	5.88	0.31%
CLORAZ DIPOT TAB 3.75MG	116	18	\$7,526.65	\$64.88	6.44	0.22%
CLORAZ DIPOT TAB 15MG	75	12	\$9,530.92	\$127.08	6.25	0.28%
<b>SUBTOTAL</b>	<b>338</b>	<b>55</b>	<b>\$27,666.80</b>	<b>\$81.85</b>	<b>6.15</b>	<b>0.82%</b>
<b>OXAZEPAM PRODUCTS</b>						
OXAZEPAM CAP 10MG	35	9	\$1,338.87	\$38.25	3.89	0.04%
OXAZEPAM CAP 30MG	32	4	\$1,806.06	\$56.44	8	0.05%
OXAZEPAM CAP 15MG	29	3	\$1,620.36	\$55.87	9.67	0.05%
<b>SUBTOTAL</b>	<b>96</b>	<b>16</b>	<b>\$4,765.29</b>	<b>\$49.64</b>	<b>6</b>	<b>0.14%</b>
<b>TOTAL</b>	<b>128,902</b>	<b>27,388*</b>	<b>\$3,384,128.91</b>	<b>\$26.25</b>	<b>4.71</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

ACDL = AcuDial; CAP = capsule; CHLORDIAZEP = chlordiazepoxide; CLORAZ DIPOT = clorazepate dipotassium; CON = concentrate; ER = extended-release; INJ = injection; ODT = orally disintegrating tablet; PED = pediatric; POW = powder; SOL = solution; SPR = spray; TAB = tablet

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

<sup>1</sup> 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 03/2024. Last accessed 03/16/2024.

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# Fiscal Year 2023 Annual Review of Hereditary Angioedema (HAE) Medications

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Oklahoma Health Care Authority  
Fiscal Year 2023 Print Report

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## Current Prior Authorization Criteria

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### **Cinryze® (C1 Esterase Inhibitor), Haegarda® (C1 Esterase Inhibitor), Orladeyo® (Berotralstat), and Takhzyro® (Lanadelumab-flyo) Approval Criteria:**

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for prophylaxis of HAE; and
3. Member must not currently be taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; and
4. Based on HAE attack frequency, attack severity, comorbid conditions, and member's access to emergent treatment, the prescriber has determined long-term prophylaxis is appropriate for the member; or
5. Approval consideration will be given if the member has a recent hospitalization for a severe episode of angioedema; and
6. Authorization of Cinryze® or Haegarda® will also require a patient-specific, clinically significant reason why the member cannot use Orladeyo®; and
7. Authorization of Takhzyro® (lanadelumab-flyo) will also require a patient-specific, clinically significant reason why the member cannot use Cinryze®, Haegarda®, or Orladeyo®; and
8. Cinryze® Dosing:
  - a. The recommended dose of Cinryze® is 1,000 units intravenously (IV) every 3 to 4 days, approximately 2 times per week, to be infused at a rate of 1mL/min; and
  - b. Initial doses should be administered in an outpatient setting by a health care provider; members can be taught by their health care provider to self-administer Cinryze® IV; and
  - c. A quantity limit of 8,000 units per month will apply (i.e., 2 treatments per week or 8 treatments per 28 days); or
9. Haegarda® Dosing:
  - a. The recommended dose of Haegarda® is 60 IU/kg subcutaneously (sub-Q) twice weekly; and
  - b. 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
  - c. A quantity limit of 2 treatments per week or 8 treatments per 28 days will apply; or



10. Orladeyo<sup>®</sup> Dosing:
  - a. The recommended dose of Orladeyo<sup>®</sup> is 150mg by mouth once daily; and
  - b. A quantity limit of 28 capsules per 28 days will apply; or
11. Takhzyro<sup>®</sup> Dosing:
  - a. For members 12 years of age or older: The recommended dose of Takhzyro<sup>®</sup> is 300mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
  - b. For members 6-11 years of age: The recommended dose of Takhzyro<sup>®</sup> is 150mg sub-Q every 2 weeks (every 4 weeks may be considered in some members); and
  - c. For members 2 to 5 years of age: The recommended dose of Takhzyro<sup>®</sup> is 150mg sub-Q every 4 weeks; and
  - d. Prescriber must verify member or caregiver has been trained by a health professional on proper storage and sub-Q administration of Takhzyro<sup>®</sup>; and
  - e. A quantity limit of (2) vials per 28 days will apply.

**Beriner<sup>®</sup> (C1 Esterase Inhibitor), Firazy<sup>®</sup> (Icatibant), Kalbitor<sup>®</sup> (Ecallantide), and Ruconest<sup>®</sup> (C1 Esterase Inhibitor) Approval Criteria:**

1. An FDA approved diagnosis of hereditary angioedema (HAE); and
2. Requested medication must be used for the treatment of acute attacks of HAE; and
3. For authorization consideration of Firazy<sup>®</sup> (icatibant) or Kalbitor<sup>®</sup> (ecallantide), a patient-specific, clinically significant reason why the member cannot use Beriner<sup>®</sup> (C1 esterase inhibitor) must be provided; or
4. For authorization consideration of Ruconest<sup>®</sup> (C1 esterase inhibitor), a patient-specific, clinically significant reason why the member cannot use Beriner<sup>®</sup> (C1 esterase inhibitor), Firazy<sup>®</sup> (icatibant), or Kalbitor<sup>®</sup> (ecallantide) must be provided.

**Utilization of HAE Medications: Fiscal Year 2023**

**Comparison of Fiscal Years: Pharmacy Claims**

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	4	7	\$244,829.52	\$34,975.65	\$2,074.83	54	118
2023	3	9	\$89,768.48	\$9,974.28	\$356.22	88	252
% Change	-25.0%	28.6%	-63.3%	-71.5%	-82.8%	63.0%	113.6%
Change	-1	2	-\$155,061.04	-\$25,001.37	-\$1,718.61	34	134

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

Please note: Most paid pharmacy claims during fiscal year 2023 were claims for which SoonerCare was not the primary payer; therefore, the reimbursed amount included in the above data is not a true reflection of the medication cost.

## Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	*Total Claims	Total Cost	Cost/Claim	Total Units
2022	1	1	\$5,733.00	\$5,733.00	100
2023	0	0	\$0.00	\$0.00	0
% Change	-100.00%	-100.00%	-100.00%	-100.00%	-100.00%
Change	-1	-1	-\$5,733.00	-\$5,733.00	-100

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

\*Total number of unduplicated claims.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

### Demographics of Members Utilizing HAE Medications

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

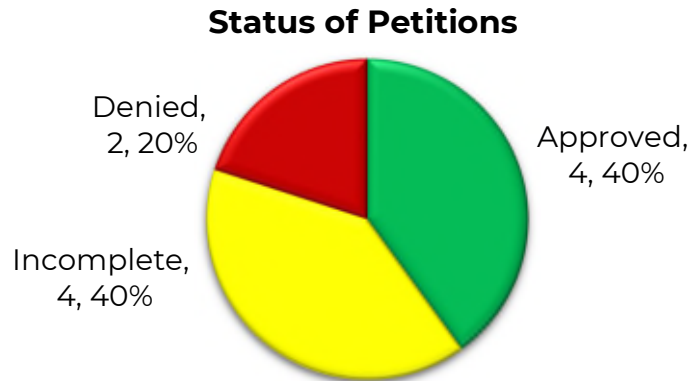
### Top Prescriber Specialties of HAE Medications by Number of Claims

- There were 9 pharmacy claims for HAE medications during fiscal year 2023, all of which were prescribed by allergists.

### Prior Authorization of HAE Medications

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There were 10 prior authorization requests submitted for HAE medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



### Market News and Updates<sup>1,2</sup>

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#### Anticipated Patent Expiration(s):

- Orladeyo® (berotralstat): November 2039

#### Pipeline:

- Donidalorsen:** Formerly known as IONIS-PKK-L<sub>RX</sub>, donidalorsen is an investigational ligand-conjugated antisense (LICA) medicine designed

to target the prekallikrein (PKK) pathway. PKK plays an important role in the activation of inflammatory mediators associated with acute attacks of HAE. Donidalorsen is currently in a Phase 3, multi-center, double-blind, randomized, placebo-controlled study in up to 84 participants primarily measuring confirmed HAE attacks per month.

## Recommendations

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

## Utilization Details of HAE Medications: Fiscal Year 2023

### Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
TAKHZYRO INJ 300MG/2ML*	5	1	\$159.76	\$31.95	5	0.18%
ORLADEYO CAP 150 MG	2	1	\$80,693.98	\$40,346.99	2	89.89%
ICATIBANT INJ 30MG/3ML	2	1	\$8,914.74	\$4,457.37	2	9.93%
<b>TOTAL</b>	<b>9</b>	<b>3*</b>	<b>\$89,768.48</b>	<b>\$9,974.28</b>	<b>3</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

\*Claims for Takhzyro® during fiscal year 2023 consist of claims for 1 member for which SoonerCare was not the primary payer; therefore, the reimbursed amount is not a true reflection of the cost of the medication for SoonerCare.

CAP = capsule; INJ = injection

<sup>1</sup> 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 01/2024. Last accessed 01/18/2024.

<sup>2</sup> Ionis Pharmaceuticals. Innovation: Pipeline - Antisense Pipeline. Available online at: <https://www.ionispharma.com/ionis-technology/antisense-pipeline/>. Last accessed 01/18/2024.

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# Fiscal Year 2023 Annual Review of Inhaled Anti-Infective Medications

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## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

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### Current Prior Authorization Criteria

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#### **Arikayce® (Amikacin Liposome Inhalation Suspension) Approval Criteria:**

1. An FDA approved indication for the treatment of *Mycobacterium avium* complex (MAC) lung disease in adults who have limited or no alternative treatment options; and
2. Member must have had a minimum of 6 consecutive months of a multidrug background regimen therapy used compliantly and not achieved negative sputum cultures within the last 12 months. Dates of previous treatments and regimens must be listed on the prior authorization request; and
  - a. If claims for a multidrug background regimen are not in the member's claim history, the pharmacy profile should be submitted or detailed information regarding dates and doses should be included along with the signature from the prescriber; and
3. Member must continue a multidrug background regimen therapy while on Arikayce®, unless contraindicated, or provide reasoning why continuation of a multidrug background regimen is not appropriate for the member; and
4. A patient-specific, clinically significant reason why the member requires an inhaled aminoglycoside in place of an intravenous or intramuscular aminoglycoside (e.g., amikacin, streptomycin) must be provided; and
5. Arikayce® will not be approved for members with non-refractory MAC lung disease; and
6. Arikayce® must be prescribed by, or in consultation with, a pulmonary disease or infectious disease specialist (or an advanced care practitioner with a supervising physician who is a pulmonary disease or infectious disease specialist); and
7. Initial approvals will be for the duration of 6 months after which time the prescriber must document the member is responding to treatment for continued approval; and
8. A quantity limit of 28 vials per 28 days will apply.

**Cayston® (Aztreonam), Pulmozyme® (Dornase Alfa), and Inhaled Tobramycin Products (Bethkis®, Kitabis® Pak, Tobi®, and Tobi® Podhaler®) Approval Criteria:**

1. Use of inhaled tobramycin products, Pulmozyme® (dornase alfa), and Cayston® (aztreonam) is reserved for members who have a diagnosis of cystic fibrosis (CF).
  - a. Kitabis® Pak and generic tobramycin 300mg/5mL nebulized solution are the preferred inhaled tobramycin products. Authorization of Bethkis® or Tobi® Podhaler® requires a patient-specific, clinically significant reason why the preferred inhaled tobramycin products (Kitabis® Pak and generic tobramycin 300mg/5mL nebulized solution) are not appropriate for the member.
  - b. Preferred inhaled tobramycin products (Kitabis® Pak and generic tobramycin 300mg/5mL nebulized solution), dornase alfa, and aztreonam inhalation will not require a prior authorization and claims will pay at the point of sale if member has a reported diagnosis of CF within the past 12 months of claims history.
  - c. If the member does not have a reported diagnosis, a manual prior authorization will be required for coverage consideration.
2. Use of inhaled tobramycin products and Cayston® (aztreonam) is restricted to 28 days of therapy every 56 days to ensure cycles of 28 days on therapy followed by 28 days off therapy.
  - a. Use outside of this recommended regimen may be considered for coverage via a manual prior authorization submission with a patient-specific, clinically significant reason why the member needs treatment outside of the FDA approved dosing regimen.
  - b. Pharmacies should process the prescription claim with a 56-day supply.

**Utilization of Inhaled Anti-Infective Medications: Fiscal Year 2023**

**Comparison of Fiscal Years**

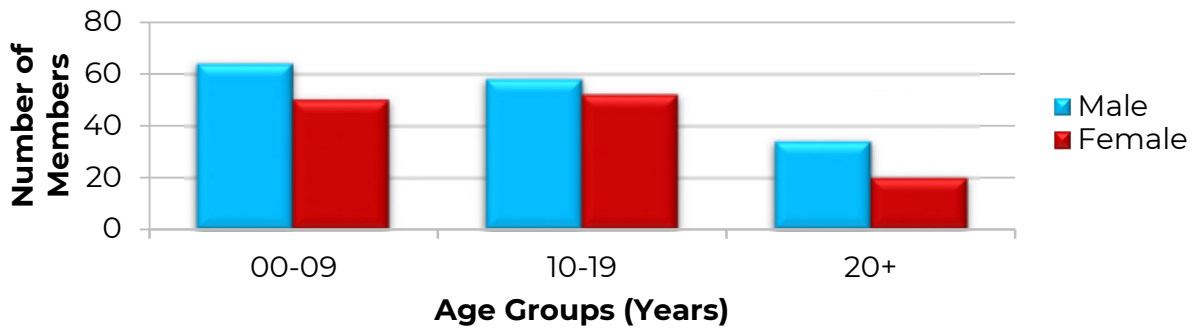
<b>Fiscal Year</b>	<b>*Total Members</b>	<b>Total Claims</b>	<b>Total Cost</b>	<b>Cost/Claim</b>	<b>Cost/Day</b>	<b>Total Units</b>	<b>Total Days</b>
<b>2022</b>	271	1,756	\$6,133,392.21	\$3,492.82	\$88.78	241,005	69,086
<b>2023</b>	278	1,942	\$7,656,803.80	\$3,942.74	\$103.76	254,949	73,792
<b>% Change</b>	<b>2.60%</b>	<b>10.60%</b>	<b>24.80%</b>	<b>12.90%</b>	<b>16.90%</b>	<b>5.80%</b>	<b>6.80%</b>
<b>Change</b>	<b>7</b>	<b>186</b>	<b>\$1,523,411.59</b>	<b>\$449.92</b>	<b>\$14.98</b>	<b>13,944</b>	<b>4,706</b>

Costs do not reflect rebated prices or net costs.

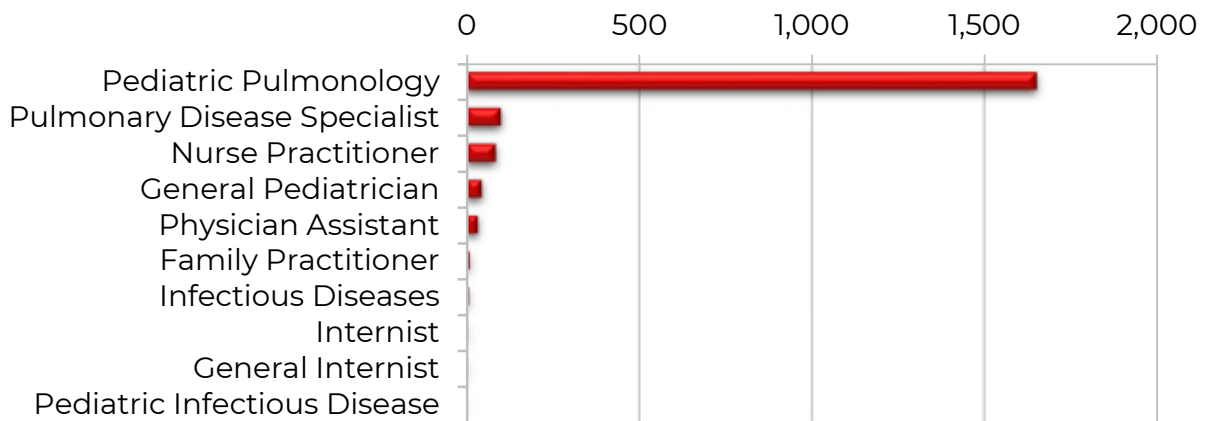
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

## Demographics of Members Utilizing Inhaled Anti-Infective Medications



## Top Prescriber Specialties of Inhaled Anti-Infective Medications by Number of Claims



## Prior Authorization of Inhaled Anti-Infective Medications

There were 367 prior authorization requests submitted for inhaled anti-infective medications during fiscal year 2023. Computer edits are in place to detect a cystic fibrosis (CF) diagnosis in a member's recent diagnosis claims history and generate automated prior authorizations where possible for preferred inhaled tobramycin products, dornase alfa, and aztreonam. The following chart shows the status of the submitted petitions for fiscal year 2023.

### Status of Petitions



## Market News and Updates<sup>1</sup>

### Anticipated Patent Expiration(s):

- Tobii® Podhaler® (tobramycin inhalation powder): November 2030
- Arikayce® (amikacin liposome inhalation suspension): May 2035

### Recommendations

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

### Utilization Details of Inhaled Anti-Infective Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
<b>DORNASE ALFA PRODUCTS</b>						
PULMOZYME SOL 1MG/ML	1,394	186	\$5,620,948.91	\$4,032.24	7.49	73.41%
<b>SUBTOTAL</b>	<b>1,394</b>	<b>186*</b>	<b>\$5,620,948.91</b>	<b>\$4,032.24</b>	<b>7.49</b>	<b>73.41%</b>
<b>TOBRAMYCIN NEBULIZED PRODUCTS</b>						
TOBRAMYCIN NEB 300MG/5ML	397	124	\$588,459.20	\$1,482.26	3.2	7.69%
TOBRAMYCIN NEB 300MG/4ML	35	15	\$165,999.88	\$4,742.85	2.33	2.17%
KITABIS PAK NEB 300MG/5ML	5	2	\$22,557.05	\$4,511.41	2.5	0.29%
<b>SUBTOTAL</b>	<b>437</b>	<b>138*</b>	<b>\$777,016.13</b>	<b>\$1,778.07</b>	<b>3.17</b>	<b>10.15%</b>
<b>AZTREONAM PRODUCTS</b>						
CAYSTON INH 75MG	60	16	\$637,495.82	\$10,624.93	3.75	8.33%
<b>SUBTOTAL</b>	<b>60</b>	<b>16*</b>	<b>\$637,495.82</b>	<b>\$10,624.93</b>	<b>3.75</b>	<b>8.33%</b>
<b>TOBRAMYCIN POWDER PRODUCTS</b>						
TOBI PODHALR CAP 28MG	29	9	\$318,362.56	\$10,978.02	3.22	4.16%
<b>SUBTOTAL</b>	<b>29</b>	<b>9*</b>	<b>\$318,362.56</b>	<b>\$10,978.02</b>	<b>3.22</b>	<b>4.16%</b>
<b>AMIKACIN PRODUCTS</b>						
ARIKAYCE SUS 590MG/8.4ML	22	4	\$302,980.38	\$13,771.84	5.5	3.96%
<b>SUBTOTAL</b>	<b>22</b>	<b>4*</b>	<b>\$302,980.38</b>	<b>\$13,771.84</b>	<b>5.5</b>	<b>3.96%</b>
<b>TOTAL</b>	<b>1,942</b>	<b>278*</b>	<b>\$7,656,803.80</b>	<b>\$3,942.74</b>	<b>6.99</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

CAP = capsule; INH = inhalation; NEB = nebulized; PAK = pack; SOL = solution; SUS = suspension

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

<sup>1</sup> 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 03/2024. Last Accessed 03/15/2024.

# Fiscal Year 2023 Annual Review of Myalept® (Metreleptin)

## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

### Current Prior Authorization Criteria

#### Myalept® (Metreleptin) Approval Criteria:

1. An FDA approved diagnosis of leptin deficiency in members with congenital or acquired generalized lipodystrophy; and
2. Approvals will not be granted for the following diagnoses:
  - a. Metabolic disease without current evidence of generalized lipodystrophy; or
  - b. Human immunodeficiency virus (HIV)-related lipodystrophy; or
  - c. General obesity not associated with congenital leptin deficiency; and
3. Myalept® must be prescribed by an endocrinologist; and
4. Prescriber must agree to test for neutralizing antibodies in members who experience severe infections or if they suspect Myalept® is no longer effective; and
  - a. Baseline hemoglobin A1c (HbA1c), fasting glucose, and fasting triglycerides must be included on prior authorization request; and
  - b. Subsequent approvals will require recent lab values (HbA1c, fasting glucose, and fasting triglycerides) to ensure neutralizing antibodies have not developed; and
5. Prescriber and pharmacy must be enrolled in the Myalept® Risk Evaluation and Mitigation Strategies (REMS) program; and
6. Approvals will be for the duration of 3 months to evaluate compliance and ensure the prescriber is assessing continued efficacy; and
7. A quantity limit of 1 vial per day will apply.

### Utilization of Myalept® (Metreleptin): Fiscal Year 2023

#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	1	13	\$703,067.03	\$54,082.08	\$1,802.74	130	390
2023	1	12	\$684,313.32	\$57,026.11	\$1,900.87	120	360
<b>% Change</b>	<b>0.0%</b>	<b>-7.7%</b>	<b>-2.7%</b>	<b>5.4%</b>	<b>5.4%</b>	<b>-7.7%</b>	<b>-7.7%</b>
<b>Change</b>	<b>0</b>	<b>-1</b>	<b>-\$18,753.71</b>	<b>\$2,944.03</b>	<b>\$98.13</b>	<b>-10</b>	<b>-30</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023



### Demographics of Members Utilizing Myalept® (Metreleptin)

- Due to the limited number of members utilizing Myalept® (metreleptin), detailed demographic information could not be provided.

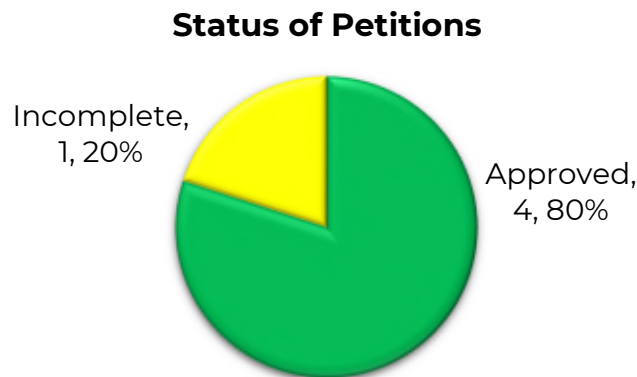
### Top Prescriber Specialties of Myalept® (Metreleptin) by Number of Claims

- The only prescriber specialty listed on paid claims for Myalept® (metreleptin) during fiscal year 2023 was pediatric endocrinologist.

### Prior Authorization of Myalept® (Metreleptin)

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There were 5 prior authorization requests submitted for Myalept® (metreleptin) for 1 unique member during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



### Recommendations

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

### Utilization Details of Myalept® (Metreleptin): Fiscal Year 2023

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PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
MYALEPT INJ 11.3MG	12	1	\$684,313.32	\$56,026.11	12	100%
<b>TOTAL</b>	<b>12</b>	<b>1*</b>	<b>\$684,313.32</b>	<b>\$56,026.11</b>	<b>12</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

INJ = injection

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

# Fiscal Year 2023 Annual Review of Osteoporosis Medications

## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

### Current Prior Authorization Criteria

Osteoporosis Medications*		
Tier-1	Tier-2	Special PA <sup>‡</sup>
alendronate tabs (Fosamax <sup>®</sup> )	alendronate + vitamin D tabs (Fosamax <sup>®</sup> + D)	abaloparatide inj (Tymlos <sup>®</sup> )
calcium + vitamin D <sup>†</sup>	risedronate tabs (Actonel <sup>®</sup> )	alendronate effervescent tabs (Binosto <sup>®</sup> )
ibandronate tabs (Boniva <sup>®</sup> )		alendronate soln (Fosamax <sup>®</sup> )
zoledronic acid inj (Reclast <sup>®</sup> )		alendronate 40mg tabs (Fosamax <sup>®</sup> )
		denosumab inj (Prolia <sup>®</sup> )
		ibandronate inj (Boniva <sup>®</sup> IV)
		risedronate 30mg tabs (Actonel <sup>®</sup> )
		risedronate DR tabs (Atelvia <sup>®</sup> )
		romosozumab-aqqg (Evenity <sup>®</sup> )
		teriparatide inj (Forteo <sup>®</sup> )
		teriparatide inj (Bonsity <sup>®</sup> )

\*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).

<sup>†</sup>OTC calcium + vitamin D must be used at recommended doses in conjunction with Tier-1 bisphosphonates for trial to be accepted unless member has a recent laboratory result showing adequate vitamin D or member is unable to tolerate calcium. OTC calcium + vitamin D are only covered for members with osteoporosis who are being treated with a bisphosphonate.

<sup>‡</sup>Unique criteria applies to medications in the Special PA Tier.

DR = delayed-release; inj = injection; PA = prior authorization; soln = solution; tabs = tablets

### Osteoporosis Medications Tier-2 Approval Criteria:

1. A trial of at least 1 Tier-1 bisphosphonate medication, compliantly used for at least 6 months concomitantly with calcium and vitamin D, that failed to prevent fracture or improve bone mineral density (BMD) scores; or
2. Hypersensitivity to or intolerable adverse effect(s) with all Tier-1 bisphosphonate medications; and
3. Quantity limits apply based on FDA approved maximum doses.

**Actonel® (Risedronate 30mg Tablets), Atelvia® [Risedronate Delayed-Release (DR) Tablets], and Binosto® (Alendronate Effervescent Tablets) Approval Criteria:**

1. A patient-specific, clinically significant reason why the member cannot use all other available Tier-1 and Tier-2 bisphosphonate medications must be provided; or
2. Members with a diagnosis of Paget's disease in claims history will not require prior authorization.

**Boniva® [Ibandronate Intravenous (IV) Solution] and Prolia® (Denosumab) Approval Criteria:**

1. A minimum of a 12-month trial with a Tier-1 or Tier-2 bisphosphonate medication plus adequate calcium and vitamin D; or
2. Contraindication to or intolerable adverse effects with Tier-1 and Tier-2 bisphosphonate medications.

**Evenity® (Romosozumab-aqqg) Approval Criteria:**

1. An FDA approved diagnosis of osteoporosis in postmenopausal women at high-risk for fracture; and
2. Member meets 1 of the following:
  - a. History of osteoporotic fracture; or
  - b. Multiple risk factors for fracture (e.g., T-score  $\leq -2.5$  at the total hip or femoral neck, smoking, corticosteroid use, rheumatoid arthritis); or
  - c. Failure of or intolerance to other available osteoporosis therapies; and
3. Prescriber must verify member has not had a myocardial infarction or stroke within the preceding year; and
4. Prescriber must verify calcium levels will be monitored and pre-existing hypocalcemia will be corrected prior to starting therapy; and
5. Prescriber must verify that the member will take adequate calcium and vitamin D supplements during treatment with Evenity® to reduce the risk of hypocalcemia; and
6. Evenity® must be administered by a health care provider; and
7. Approval will be limited to a total duration of 1 year of therapy.

**Forteo® (Teriparatide) and Teriparatide Approval Criteria:**

1. Diagnosis of 1 of the following:
  - a. Treatment of postmenopausal women with osteoporosis at high risk for fracture; or
  - b. To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; or
  - c. Treatment of men and women with osteoporosis associated with sustained systemic corticosteroid therapy at high risk for fracture; or

- d. Treatment of non-healing fracture (this indication only pertains to Forteo®); and
2. A minimum 12-month trial with a bisphosphonate plus adequate calcium and vitamin D or a patient-specific, clinically significant reason why the member cannot use a bisphosphonate must be provided; and
3. Use of teriparatide will require a patient-specific, clinically significant reason why the member cannot use Forteo® (teriparatide); and
4. The diagnosis of non-healing fracture may be approved for 6 months; and
5. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the patient's lifetime; and
6. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy.

**Fosamax® (Alendronate Oral Solution) Approval Criteria:**

1. An FDA approved diagnosis of osteoporosis or Paget's disease; and
2. A patient-specific, clinically significant reason why the member cannot use the oral tablet formulation must be provided.

**Fosamax® (Alendronate 40mg Tablets) Approval Criteria:**

1. A patient-specific, clinically significant reason why the member cannot use all other available Tier-1 and Tier-2 bisphosphonate medications including a 35mg alendronate tablet in combination with a 5mg alendronate tablet to achieve a 40mg dose must be provided; or
2. Members with a diagnosis of Paget's disease in claims history will not require prior authorization.

**Tymlos® (Abaloparatide) Approval Criteria:**

1. Diagnosis of postmenopausal osteoporosis confirmed by the following:
  - a. History of vertebral fracture(s) or low trauma or fragility fracture(s) (e.g., prior fracture from minor trauma such as falling from standing height or less) within the past 5 years; or
  - b. A bone mineral density (BMD) test (T-score at or below -2.5) within the last month in the spine, femoral neck, total hip, or 33% radius; or
  - c. A T-score between -1.0 and -2.5 in the spine, femoral neck, total hip, or 33% radius, with a FRAX® 10-year probability for major osteoporotic fracture  $\geq 20\%$  or the 10-year probability of hip fracture  $\geq 3\%$ ; and
2. One of the following [if a 12-month bisphosphonate trial is inappropriate for the member, the member must have a trial of Prolia® or a selective estrogen receptor modulator (SERM) or a patient-specific, clinically significant reason why Prolia® or a SERM is not appropriate must be provided]:
  - a. A minimum 12-month trial with a bisphosphonate medication plus adequate calcium and vitamin D; or

- b. A 12-month trial of Prolia® (denosumab), unless contraindicated, intolerant, or allergic, that did not yield adequate results; or
- c. A 12-month trial of a SERM, unless contraindicated, intolerant, or allergic, that did not yield adequate results; and
- 3. A patient-specific, clinically significant reason why the member cannot use Forteo® (teriparatide) must be provided; and
- 4. Treatment duration including other parathyroid hormone analogs has not exceeded a total of 24 months during the member's lifetime; and
- 5. Approval will be for a maximum of 2 years of parathyroid hormone analog therapy; and
- 6. A quantity limit of 1 pen per 30 days will apply.

## Utilization of Osteoporosis Medications: Fiscal Year 2023

### Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
<b>2022</b>	772	2,409	\$298,028.10	\$123.71	\$2.12	23,683	140,787
<b>2023</b>	1,020	3,112	\$404,109.33	\$129.86	\$2.20	30,996	183,767
<b>% Change</b>	<b>32.1%</b>	<b>29.2%</b>	<b>35.6%</b>	<b>5.0%</b>	<b>3.8%</b>	<b>30.9%</b>	<b>30.5%</b>
<b>Change</b>	<b>248</b>	<b>703</b>	<b>\$106,081.23</b>	<b>\$6.15</b>	<b>\$0.08</b>	<b>7,313</b>	<b>42,980</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

### Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	*Total Claims	Total Cost	Cost/Claim	Claims/Member
<b>2022</b>	185	388	\$91,950.96	\$236.99	2.1
<b>2023</b>	243	533	\$145,388.76	\$272.77	2.19
<b>% Change</b>	<b>31.35%</b>	<b>37.37%</b>	<b>58.12%</b>	<b>15.10%</b>	<b>4.29%</b>
<b>Change</b>	<b>58</b>	<b>145</b>	<b>\$53,437.80</b>	<b>\$35.78</b>	<b>0.09</b>

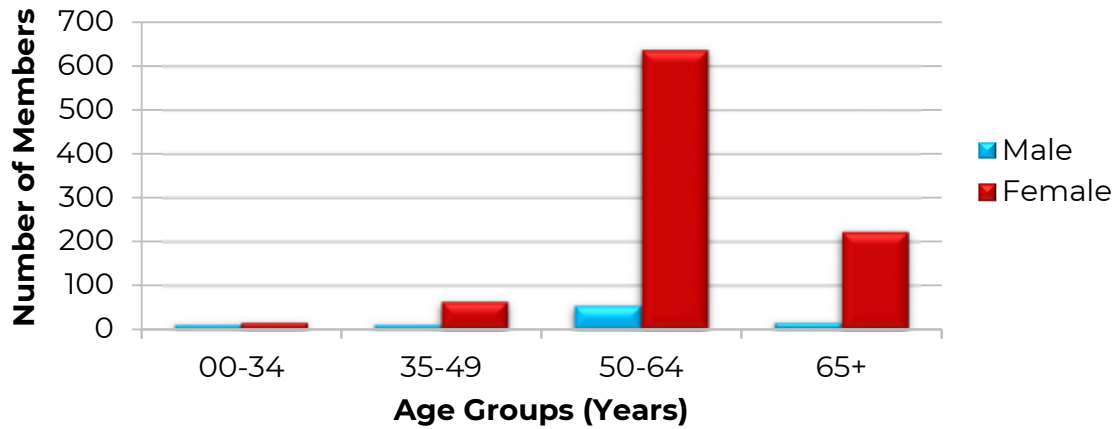
Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

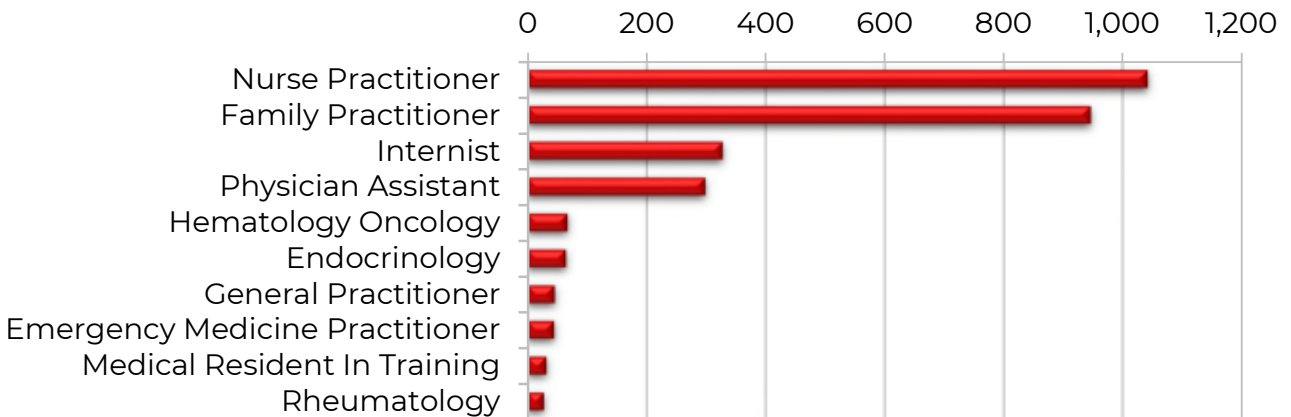
\*Total number of unduplicated claims.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

### Demographics of Members Utilizing Osteoporosis Medications: Pharmacy Claims



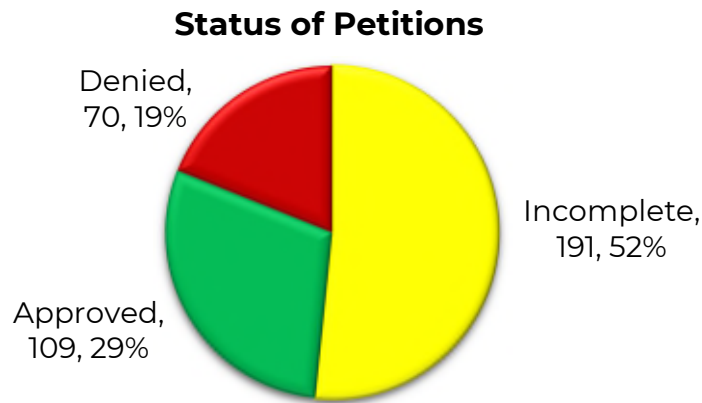
### Top Prescriber Specialties of Osteoporosis Medications by Number of Claims: Pharmacy Claims



### Prior Authorization of Osteoporosis Medications

There were 370 prior authorization requests submitted for osteoporosis medications during fiscal year 2023. Computer edits are in place to detect lower tiered medications in a member’s recent claims history and generate automated prior authorizations where possible. Please note: The status of petitions below includes prior authorization requests for Prolia® (denosumab) only when submitted as a pharmacy claim. When billed as a medical claim, Prolia® (denosumab) and Xgeva® (denosumab) are billed using the same procedure code. The status of petitions for all denosumab products submitted as a medical claim is included in the Fiscal Year 2023 Annual Review of Xgeva® (Denosumab), which is included in the State Fiscal Year 2023 Quarter 3 Print Annual Reviews Drug Utilization Review (DUR) Board

Packet. The following chart shows the status of the submitted petitions for fiscal year 2023.



### Market News and Updates<sup>1,2</sup>

#### Anticipated Patent Expiration(s):

- Forteo® (teriparatide injection): March 2025
- Atelvia® (risedronate sodium DR tablet): January 2028
- Binosto® (alendronate effervescent tablet): December 2031
- Tymlos® (abaloparatide injection): January 2040

#### News:

- **January 2024:** The U.S. Food and Drug Administration (FDA) announced the addition of a *Boxed Warning* for Prolia® (denosumab) warning of an increased risk of severe hypocalcemia in patients with advanced chronic kidney disease (CKD), including those on dialysis. The investigation found that patients with advanced CKD developed severe hypocalcemia 2 to 10 weeks after each Prolia® injection, with the greatest risk during weeks 2 through 5.

### Recommendations

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

### Utilization Details of Osteoporosis Medications: Fiscal Year 2023

#### Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
<b>TIER-1 PRODUCTS</b>						
<b>ALENDRONATE PRODUCTS</b>						
ALENDRONATE TAB 70MG	2,502	810	\$28,719.09	\$11.48	3.09	7.11%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
ALENDRONATE TAB 35MG	141	50	\$1,635.64	\$11.60	2.82	0.40%
ALENDRONATE TAB 10MG	81	30	\$1,172.25	\$14.47	2.7	0.29%
<b>SUBTOTAL</b>	<b>2,724</b>	<b>890</b>	<b>\$31,526.98</b>	<b>\$11.57</b>	<b>3.06</b>	<b>7.8%</b>
<b>IBANDRONATE PRODUCTS</b>						
IBANDRONATE TAB 150MG	199	80	\$3,851.99	\$19.36	2.49	0.95%
<b>SUBTOTAL</b>	<b>199</b>	<b>80</b>	<b>\$3,851.99</b>	<b>\$19.36</b>	<b>2.49</b>	<b>0.95%</b>
<b>ZOLEDRONIC ACID PRODUCTS</b>						
ZOLEDRONIC INJ 4MG/5ML	4	2	\$192.55	\$48.14	2	0.05%
ZOLEDRONIC INJ 5MG/100ML	1	1	\$48.40	\$48.40	1	0.01%
<b>SUBTOTAL</b>	<b>5</b>	<b>3</b>	<b>\$240.95</b>	<b>\$48.19</b>	<b>1.67</b>	<b>0.06%</b>
<b>TIER-1 SUBTOTAL</b>	<b>2,928</b>	<b>973</b>	<b>\$35,619.92</b>	<b>\$12.17</b>	<b>3.01</b>	<b>8.81%</b>
<b>TIER-2 PRODUCTS</b>						
<b>RISEDRONATE PRODUCTS</b>						
RISEDRONATE TAB 35MG	12	2	\$244.40	\$20.37	6	0.06%
RISEDRONATE TAB 5MG	11	1	\$719.51	\$65.41	11	0.18%
<b>TIER-2 SUBTOTAL</b>	<b>23</b>	<b>3</b>	<b>\$963.91</b>	<b>\$85.78</b>	<b>17</b>	<b>0.24%</b>
<b>SPECIAL PA PRODUCTS</b>						
<b>TERIPARATIDE PRODUCTS</b>						
FORTEO INJ 600MCG/2.4ML	74	15	\$262,494.62	\$3,547.22	4.93	64.96%
<b>SUBTOTAL</b>	<b>74</b>	<b>15</b>	<b>\$262,494.62</b>	<b>\$3,547.22</b>	<b>4.93</b>	<b>64.96%</b>
<b>DENOSUMAB PRODUCTS</b>						
PROLIA INJ 60MG/ML	72	49	\$98,805.52	\$1,372.30	1.47	24.45%
<b>SUBTOTAL</b>	<b>72</b>	<b>49</b>	<b>\$98,805.52</b>	<b>\$1,372.30</b>	<b>1.47</b>	<b>24.45%</b>
<b>ALENDRONATE PRODUCTS</b>						
ALENDRONATE SOL 70MG/75ML	14	2	\$3,981.46	\$284.39	7	0.99%
<b>SUBTOTAL</b>	<b>14</b>	<b>2</b>	<b>\$3,981.46</b>	<b>\$284.39</b>	<b>7</b>	<b>0.99%</b>
<b>ROMOSUZUMAB PRODUCTS</b>						
EVENITY INJ 105MG	1	1	\$2,243.90	\$2,243.90	1	0.56%
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$2,243.90</b>	<b>\$2,243.90</b>	<b>1</b>	<b>0.56%</b>
<b>SPECIAL PA SUBTOTAL</b>	<b>147</b>	<b>65</b>	<b>\$363,544.04</b>	<b>\$2,473.09</b>	<b>2.26</b>	<b>89.96%</b>
<b>TOTAL</b>	<b>3,112</b>	<b>1,020*</b>	<b>\$404,109.33</b>	<b>\$129.86</b>	<b>3.05</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

INJ = injection; PA = prior authorization; SOL = solution; TAB = tablet

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

## Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER
ZOLEDRONIC ACID J3489	438	179	\$15,771.36	\$36.01	2.45
PROLIA J0897	95	64	\$129,617.40	\$1,364.39	1.48
<b>TOTAL</b>	<b>243</b>	<b>533</b>	<b>\$145,388.76</b>	<b>\$272.77</b>	<b>2.19</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated claims.

\*Total number of unduplicated utilizing members.

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



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<sup>1</sup> 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 03/2024. Last accessed 03/13/2024.

<sup>2</sup> U.S. FDA. FDA Adds Boxed Warning for Increased Risk of Severe Hypocalcemia in Patients with Advanced Chronic Kidney disease Taking Osteoporosis Medicine Prolia® (Denosumab). Available online at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-increased-risk-severe-hypocalcemia-patients-advanced-chronic-kidney-disease>. Issued 01/19/2024. Last accessed 03/14/2024.

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# Fiscal Year 2023 Annual Review of Parkinson's Disease (PD) Medications

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Oklahoma Health Care Authority  
Fiscal Year 2023 Print Report

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## Current Prior Authorization Criteria

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### **Duopa® (Carbidopa/Levodopa Enteral Suspension) Approval Criteria:**

1. An FDA approved diagnosis of advanced Parkinson's disease (PD); and
2. For long-term administration, member or caregivers must be willing and able to administer Duopa® through a percutaneous endoscopic gastrostomy; and
3. Member must be experiencing 3 hours or more of "off" time on current PD drug treatment and must have demonstrated a clear responsiveness to treatment with levodopa; and
4. Approvals will be for a quantity of 1 cassette per day.

### **Gocovri® [Amantadine Extended-Release (ER)] Approval Criteria:**

1. An FDA approved indication for the treatment of dyskinesia in members with Parkinson's disease (PD) receiving levodopa-based therapy; and
2. Member must use Gocovri® concomitantly with levodopa therapy; and
3. Member must not have end-stage renal disease [ESRD; creatinine clearance (CrCl) <15mL/min/1.73m<sup>2</sup>]; and
4. A minimum of a 6-month trial of amantadine immediate-release (IR) that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with amantadine ER; and
5. A patient-specific, clinically significant reason why amantadine IR products cannot be used must be provided; and
6. A patient-specific, clinically significant reason why Osmolex® ER (amantadine ER) cannot be used must be provided; and
7. A quantity limit of (1) 68.5mg capsule or (2) 137mg capsules per day will apply.

### **Inbrija® (Levodopa Inhalation Powder) Approval Criteria:**

1. An FDA approved indication for the treatment of "off" episodes in members with Parkinson's disease (PD) treated with carbidopa/levodopa; and
2. Member must be taking carbidopa/levodopa in combination with Inbrija®. Inbrija® has been shown to be effective only in combination with carbidopa/levodopa; and

3. Member must be experiencing motor fluctuations with a minimum of 2 hours of “off” time and demonstrate levodopa responsiveness; and
4. Member must not be taking nonselective monoamine oxidase inhibitors (MAOIs) concomitantly with Inbrija® or within 2 weeks prior to initiating Inbrija® and
5. A previous failed trial of immediate-release (IR) carbidopa/levodopa formulations alone or in combination with long-acting carbidopa/levodopa formulations or a reason why supplementation with IR carbidopa/levodopa formulations is not appropriate for the member must be provided; and
6. A quantity limit of 10 capsules for inhalation per day will apply.

**Kynmobi® [Apomorphine Sublingual (SL) Film] Approval Criteria:**

1. An FDA approved diagnosis of acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease (PD); and
2. Member must be taking carbidopa/levodopa in combination with Kynmobi®; and
3. Member should be experiencing at least 1 well defined “off” episode per day with a total daily “off” time duration of ≥2 hours during the waking day; and
4. Initial dose titration should occur in an “off” state and in a setting supervised by a health care provider to monitor blood pressure and heart rate; and
5. Member should not use apomorphine concomitantly with 5-HT<sub>3</sub> antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron); and
6. Prescriber must verify the member has been counseled on separating doses by at least 2 hours; and
7. The maximum single dose approvable is 30mg; and
8. A quantity limit of 5 doses per day will apply.

**Mirapex ER® (Pramipexole ER) and Requip XL® [Ropinirole Extended-Release (ER)] Approval Criteria:**

1. An FDA approved diagnosis of Parkinson’s disease (PD); and
2. A patient-specific, clinically significant reason why the immediate-release products cannot be used must be provided.

**Neupro® (Rotigotine Transdermal System) Approval Criteria:**

1. For the diagnosis of Parkinson’s disease (PD), the following criteria apply:
  - a. An FDA approved indication for the treatment of signs and symptoms of PD; and
  - b. Member must be 18 years of age or older; and

- c. Failed treatment, intolerance, or a patient-specific, clinically significant reason why the member cannot use oral dopamine agonists must be provided.
2. For the diagnosis of restless leg syndrome (RLS), the following criteria apply:
  - a. An FDA approved diagnosis of RLS; and
  - b. Member must be 18 years of age or older; and
  - c. Documented treatment attempts at the recommended dose with at least 2 of the following that did not yield adequate relief:
    - i. Carbidopa/levodopa; or
    - ii. Pramipexole; or
    - iii. Ropinirole.

**Nourianz® (Istradefylline) Approval Criteria:**

1. An FDA approved diagnosis of Parkinson's disease (PD); and
2. Member must be taking carbidopa/levodopa in combination with istradefylline (istradefylline has not been shown to be effective as monotherapy for the treatment of PD); and
3. Prescriber must verify the dose is appropriate for the member based on degree of hepatic impairment, concomitant strong CYP3A4 inhibitors, and smoking status of the member; and
4. Member must be experiencing at least 2 hours of "off" time per day; and
5. A quantity limit of 1 tablet per day will apply.

**Nuplazid® (Pimavanserin) Approval Criteria:**

1. An FDA approved diagnosis of hallucinations and delusions associated with Parkinson's disease (PD) psychosis; and
2. Member must have a concomitant diagnosis of PD; and
3. Member must not be taking concomitant medications known to prolong the QT interval including Class 1A antiarrhythmics (e.g., quinidine, procainamide) or Class 3 antiarrhythmics (e.g., amiodarone, sotalol), certain antipsychotic medications (e.g., ziprasidone, chlorpromazine, thioridazine), and certain antibiotics (e.g., gatifloxacin, moxifloxacin); and
4. Member must not have a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death, including symptomatic bradycardia, hypokalemia, hypomagnesemia, and the presence of congenital prolongation of the QT interval; and
5. Nuplazid® will not be approved for the treatment of patients with dementia-related psychosis unrelated to the hallucinations and delusions associated with PD psychosis; and

6. Initial approvals will be for the duration of 3 months. For continuation, the prescriber must include information regarding improved response/effectiveness of this medication; and
7. A quantity limit of 1 tablet per day will apply.

**Ongentys® (Opicapone) Approval Criteria:**

1. An FDA approved indication of adjunctive treatment to levodopa/carbidopa in members with Parkinson's disease (PD) experiencing "off" episodes; and
2. Member must be taking levodopa/carbidopa in combination with Ongentys®; and
3. Member must not use non-selective monoamine-oxidase inhibitors (MAOIs) concomitantly with Ongentys®; and
4. Member must not have a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; and
5. Prescriber must verify member has been counseled to avoid eating food 1 hour before and at least 1 hour after taking Ongentys®; and
6. For members with moderate hepatic impairment, the prescriber must verify the dose of Ongentys® will be reduced in accordance with package labeling; and
7. Prescriber must agree to monitor member for changes in heart rate, heart rhythm, and blood pressure in members concurrently taking medications known to be metabolized by catechol-O-methyltransferase (COMT); and
8. A patient-specific, clinically significant reason why the member cannot use entacapone must be provided; and
9. A quantity limit of 30 capsules per 30 days will apply.

**Osmolex® ER [Amantadine Extended-Release (ER)] Approval Criteria:**

1. An FDA approved indication for the treatment of Parkinson's disease (PD) or drug-induced extrapyramidal reactions in adult members; and
2. Member must not have end-stage renal disease [ESRD; creatinine clearance (CrCl) <15mL/min/1.73m<sup>2</sup>]; and
3. A minimum of a 6-month trial of amantadine immediate-release (IR) that resulted in inadequate effects or intolerable adverse effects that are not expected to occur with amantadine ER; and
4. A patient-specific, clinically significant reason why amantadine IR products cannot be used must be provided; and
5. A quantity limit will apply based on FDA approved dosing regimen(s).

**Rytary® [Carbidopa/Levodopa Extended-Release (ER) Capsule] Approval Criteria:**

1. An FDA approved diagnosis of Parkinson's disease (PD), post-encephalitic parkinsonism, or parkinsonism that may follow carbon monoxide intoxication or manganese intoxication; and

2. A patient-specific, clinically significant reason why the member cannot use other generic carbidopa/levodopa combinations including Sinemet® CR (carbidopa/levodopa ER tablet) must be provided.

**Xadago® (Safinamide) Approval Criteria:**

1. An FDA approved indication as adjunctive treatment to carbidopa/levodopa in members with Parkinson’s disease (PD) experiencing “off” episodes; and
2. Member must be taking carbidopa/levodopa in combination with safinamide (safinamide has not been shown to be effective as monotherapy for the treatment of PD); and
3. A patient-specific, clinically significant reason why the member cannot use rasagiline or other cost-effective monoamine oxidase type B (MAO-B) inhibitors must be provided; and
4. Member must not have severe hepatic impairment; and
5. Member must not be taking any of the following medications concomitantly with safinamide:
  - a. Monoamine oxidase inhibitors (MAOIs); or
  - b. Linezolid; or
  - c. Opioid analgesics (including tramadol); or
  - d. Selective norepinephrine reuptake inhibitors (SNRIs); or
  - e. Tri- or tetra-cyclic or triazolopyridine antidepressants; or
  - f. St. John’s wort; or
  - g. Cyclobenzaprine; or
  - h. Methylphenidate and its derivatives; or
  - i. Amphetamine and its derivatives; or
  - j. Dextromethorphan; and
6. Prescriber must verify member has been counseled on avoiding foods that contain a large amount of tyramine while taking safinamide; and
7. A quantity limit of 1 tablet per day will apply.

**Utilization of PD Medications: Fiscal Year 2023**

**Comparison of Fiscal Years: Pharmacy Claims**

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
<b>2022</b>	6,947	33,312	\$899,163.57	\$26.99	\$0.78	2,293,307	1,149,666
<b>2023</b>	7,693	36,608	\$910,100.38	\$24.86	\$0.69	2,532,453	1,312,575
<b>% Change</b>	<b>10.7%</b>	<b>9.9%</b>	<b>1.2%</b>	<b>-7.9%</b>	<b>-11.5%</b>	<b>10.4%</b>	<b>14.2%</b>
<b>Change</b>	<b>746</b>	<b>3,296</b>	<b>\$10,936.81</b>	<b>-\$2.13</b>	<b>-\$0.09</b>	<b>239,146</b>	<b>162,909</b>

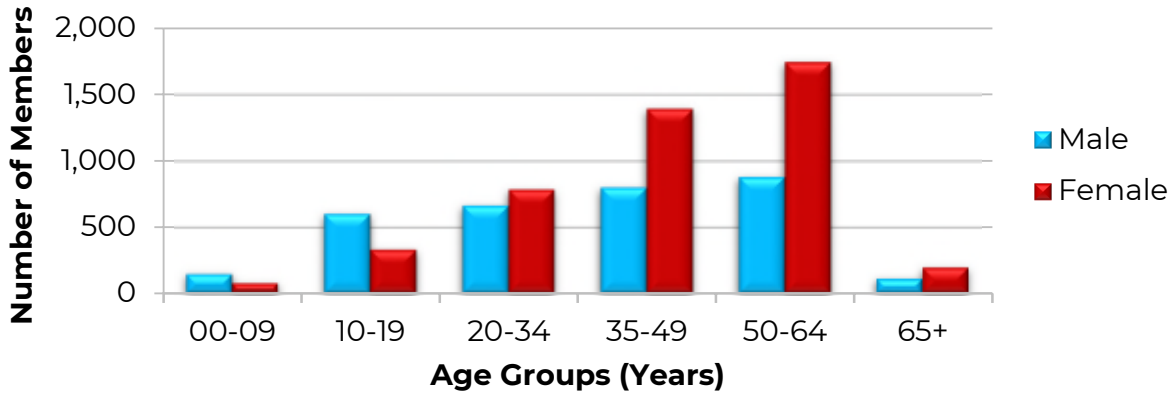
Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

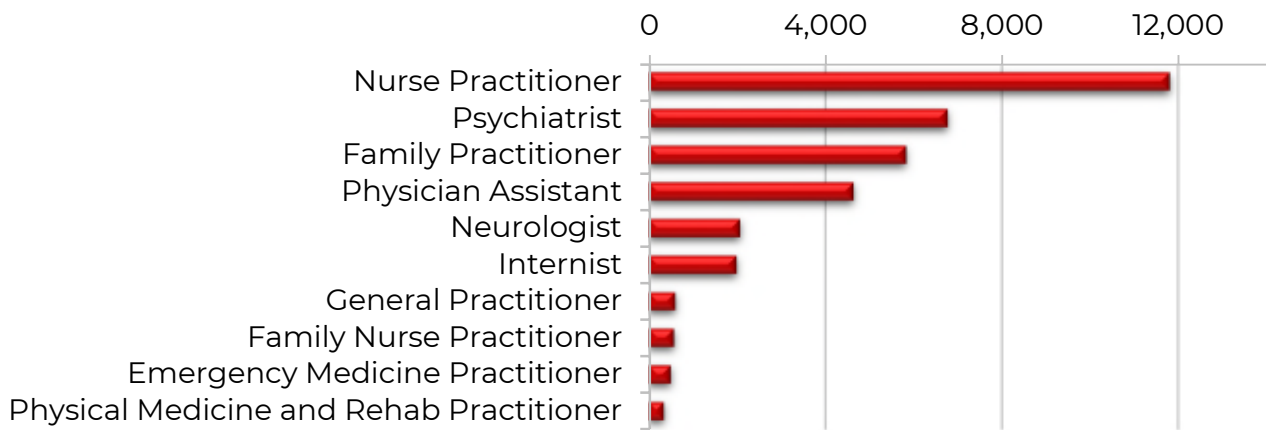
Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

- There were no SoonerCare paid medical claims for Duopa® (carbidopa/levodopa enteral suspension) during fiscal year 2022 or 2023.

### Demographics of Members Utilizing PD Medications



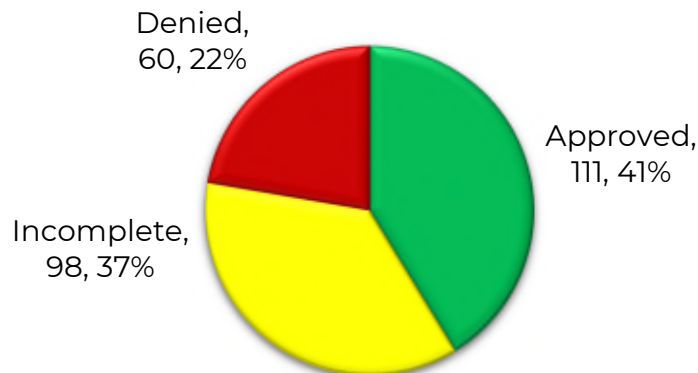
### Top Prescriber Specialties of PD Medications by Number of Claims



### Prior Authorization of PD Medications

There were 269 prior authorization requests submitted for PD medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

#### Status of Petitions



## Market News and Updates<sup>1,2,3,4</sup>

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### Anticipated Patent Expiration(s):

- Azilect® (rasagiline tablet): August 2027
- Nourianz® (istradefylline tablet): January 2028
- Rytary® [carbidopa/levodopa extended-release (ER) capsule]: December 2028
- Xadago® (safinamide tablet): March 2031
- Neupro® (rotigotine transdermal patch): March 2032
- Inbrija® (levodopa inhalation powder): November 2032
- Ongentys® (opicapone capsule): May 2035
- Kynmobi® [apomorphine sublingual (SL) film]: April 2036
- Osmolex® ER (amantadine ER tablet): February 2038
- Gocovri® (amantadine ER capsule): August 2038
- Nuplazid® (pimavanserin tablet): August 2038

### Pipeline:

- **ABBV-951:** ABBV-951 is a solution of foscarbidopa and foslevodopa for continuous subcutaneous (sub-Q) delivery that is being investigated for the treatment of motor fluctuations in patients with advanced PD. A New Drug Application (NDA) was submitted, and AbbVie received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) requesting more information about the device. The FDA did not request any additional efficacy or safety info and AbbVie intends to resubmit the NDA.
- **IPX203:** IPX203 is an oral formulation of carbidopa/levodopa ER capsules being investigated for the treatment of PD. IPX203 contains immediate-release (IR) granules of carbidopa and levodopa and ER coated beads of levodopa. The ER beads are coated with a sustained release polymer to allow for slow release of the drug, a mucoadhesive polymer to keep the granules adhered to the area of absorption longer, and an enteric coating to prevent the granules from disintegrating prematurely in the stomach. A Prescription Drug User Fee Act (PDUFA) date was set for June 2023, however Amneal received a CRL on July 3<sup>rd</sup>, 2023. The CRL requested additional pharmacokinetic data, as the scientific bridge for the safety of carbidopa was not adequately established.

### Recommendations

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



## Utilization Details of PD Medications: Fiscal Year 2023

### Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
<b>BENZTROPINE PRODUCTS</b>						
BENZTROPINE TAB 1MG	6,847	1,563	\$93,542.80	\$13.66	4.38	10.28%
BENZTROPINE TAB 2MG	2,823	577	\$43,637.40	\$15.46	4.89	4.79%
BENZTROPINE TAB 0.5MG	2,484	563	\$33,517.57	\$13.49	4.41	3.68%
<b>SUBTOTAL</b>	<b>12,154</b>	<b>2,703</b>	<b>\$170,697.77</b>	<b>\$14.04</b>	<b>4.5</b>	<b>18.75%</b>
<b>ROPINIROLE PRODUCTS</b>						
ROPINIROLE TAB 1MG	2,675	823	\$32,162.93	\$12.02	3.25	3.53%
ROPINIROLE TAB 0.5MG	2,218	811	\$26,869.33	\$12.11	2.73	2.95%
ROPINIROLE TAB 0.25MG	1,660	620	\$19,552.75	\$11.78	2.68	2.15%
ROPINIROLE TAB 2MG	1,470	427	\$18,762.26	\$12.76	3.44	2.06%
ROPINIROLE TAB 3MG	454	120	\$6,909.90	\$15.22	3.78	0.76%
ROPINIROLE TAB 4MG	417	124	\$6,047.67	\$14.50	3.36	0.66%
ROPINIROLE TAB 5MG	197	50	\$3,174.67	\$16.12	3.94	0.35%
<b>SUBTOTAL</b>	<b>9,091</b>	<b>2,975</b>	<b>\$113,479.51</b>	<b>\$12.48</b>	<b>3.06</b>	<b>12.46%</b>
<b>AMANTADINE PRODUCTS</b>						
AMANTADINE CAP 100MG	3,170	676	\$65,253.13	\$20.58	4.69	7.17%
AMANTADINE TAB 100MG	2,950	571	\$119,946.57	\$40.66	5.17	13.18%
AMANTADINE SOL 50MG/5ML	364	72	\$6,795.07	\$18.67	5.06	0.75%
<b>SUBTOTAL</b>	<b>6,484</b>	<b>1,319</b>	<b>\$191,994.77</b>	<b>\$29.61</b>	<b>4.92</b>	<b>21.10%</b>
<b>TRIHEXYPHENIDYL PRODUCTS</b>						
TRIHEXYPHENIDYL TAB 2MG	1,595	408	\$18,434.78	\$11.56	3.91	2.03%
TRIHEXYPHENIDYL TAB 5MG	1,455	251	\$22,308.40	\$15.33	5.8	2.45%
TRIHEXYPHENIDYL SOL 0.4MG/ML	223	33	\$7,541.73	\$33.82	6.76	0.83%
<b>SUBTOTAL</b>	<b>3,273</b>	<b>692</b>	<b>\$48,284.91</b>	<b>\$14.75</b>	<b>4.73</b>	<b>5.31%</b>
<b>PRAMIPEXOLE PRODUCTS</b>						
PRAMIPEXOLE TAB 0.5MG	732	254	\$9,007.73	\$12.31	2.88	0.99%
PRAMIPEXOLE TAB 0.125MG	685	265	\$8,050.06	\$11.75	2.58	0.88%
PRAMIPEXOLE TAB 0.25MG	601	228	\$7,560.75	\$12.58	2.64	0.83%
PRAMIPEXOLE TAB 1MG	572	155	\$7,778.38	\$13.60	3.69	0.85%
PRAMIPEXOLE TAB 1.5MG	232	62	\$3,331.31	\$14.36	3.74	0.37%
PRAMIPEXOLE TAB 0.75MG	105	38	\$1,567.28	\$14.93	2.76	0.17%
<b>SUBTOTAL</b>	<b>2,927</b>	<b>1,002</b>	<b>\$37,295.51</b>	<b>\$12.74</b>	<b>2.92</b>	<b>4.09%</b>
<b>CARBIDOPA/LEVODOPA PRODUCTS</b>						
CARB/LEVO TAB 25-100MG	1,041	268	\$21,581.19	\$20.73	3.88	2.37%
CARB/LEVO ER TAB 50-200MG	195	28	\$6,045.66	\$31.00	6.96	0.66%
CARB/LEVO TAB 10-100MG	189	58	\$3,004.34	\$15.90	3.26	0.33%
CARB/LEVO TAB 25-250MG	161	40	\$4,420.95	\$27.46	4.03	0.49%
CARB/LEVO ER TAB 25-100MG	66	20	\$2,096.52	\$31.77	3.3	0.23%
RYTARY CAP 195MG	8	2	\$7,419.68	\$927.46	4	0.82%
RYTARY CAP 145MG	7	1	\$3,336.56	\$476.65	7	0.37%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
CARB/LEVO TAB 25-100MG	7	4	\$518.25	\$74.04	1.75	0.06%
CARB/LEVO TAB 25-250MG	3	2	\$248.15	\$82.72	1.5	0.03%
RYTARY CAP 245MG	3	1	\$1,367.40	\$455.80	3	0.15%
RYTARY CAP 95MG	1	1	\$490.87	\$490.87	1	0.05%
<b>SUBTOTAL</b>	<b>1,681</b>	<b>425</b>	<b>\$50,529.57</b>	<b>\$30.06</b>	<b>3.96</b>	<b>5.56%</b>
<b>BROMOCRIPTINE PRODUCTS</b>						
BROMOCRIPTINE TAB 2.5MG	536	108	\$44,721.71	\$83.44	4.96	4.91%
BROMOCRIPTINE CAP 5MG	215	37	\$48,500.15	\$225.58	5.81	5.33%
<b>SUBTOTAL</b>	<b>751</b>	<b>145</b>	<b>\$93,221.86</b>	<b>\$124.13</b>	<b>5.18</b>	<b>10.24%</b>
<b>ENTACAPONE PRODUCTS</b>						
ENTACAPONE TAB 200MG	72	11	\$2,956.84	\$41.07	6.55	0.32%
<b>SUBTOTAL</b>	<b>72</b>	<b>11</b>	<b>\$2,956.84</b>	<b>\$41.07</b>	<b>6.55</b>	<b>0.32%</b>
<b>CARBIDOPA/LEVODOPA/ENTACAPONE PRODUCTS</b>						
CARB/LEVO/EN 25-100-200MG	20	2	\$1,353.20	\$67.66	10	0.15%
CARB/LEVO/EN 12.5-50-200MG	17	3	\$1,966.56	\$115.68	5.67	0.22%
CARB/LEVO/EN 31.25-125-200MG	10	1	\$1,196.40	\$119.64	10	0.13%
CARB/LEVO/EN 37.5-150-200MG	3	1	\$423.18	\$141.06	3	0.05%
CARB/LEVO/EN 50-200-200MG	1	1	\$82.87	\$82.87	1	0.01%
<b>SUBTOTAL</b>	<b>51</b>	<b>8</b>	<b>\$5,022.21</b>	<b>\$98.47</b>	<b>6.38</b>	<b>0.56%</b>
<b>PIMAVANSERIN PRODUCTS</b>						
NUPLAZID CAP 34MG	40	6	\$179,364.79	\$4,484.12	6.67	19.71%
<b>SUBTOTAL</b>	<b>40</b>	<b>6</b>	<b>\$179,364.79</b>	<b>\$4,484.12</b>	<b>6.67</b>	<b>19.71%</b>
<b>RASAGILINE PRODUCTS</b>						
RASAGILINE TAB 1MG	22	6	\$975.35	\$44.33	3.67	0.11%
RASAGILINE TAB 0.5MG	14	3	\$1,047.18	\$74.80	4.67	0.12%
<b>SUBTOTAL</b>	<b>36</b>	<b>9</b>	<b>\$2,022.53</b>	<b>\$56.18</b>	<b>4</b>	<b>0.23%</b>
<b>SELEGILINE PRODUCTS</b>						
SELEGILINE CAP 5MG	28	4	\$1,023.50	\$36.55	7	0.11%
<b>SUBTOTAL</b>	<b>28</b>	<b>4</b>	<b>\$1,023.50</b>	<b>\$36.55</b>	<b>7</b>	<b>0.11%</b>
<b>ROTIGOTINE PRODUCTS</b>						
NEUPRO 4MG/24HR PATCH	13	2	\$10,008.36	\$769.87	6.5	1.10%
NEUPRO 2MG/24HR PATCH	2	1	\$1,520.20	\$760.10	2	0.17%
<b>SUBTOTAL</b>	<b>15</b>	<b>3</b>	<b>\$11,528.56</b>	<b>\$768.57</b>	<b>5</b>	<b>1.27%</b>
<b>CARBIDOPA PRODUCTS</b>						
CARBIDOPA TAB 25MG	3	2	\$211.74	\$70.58	1.5	0.02%
<b>SUBTOTAL</b>	<b>3</b>	<b>2</b>	<b>\$211.74</b>	<b>\$70.58</b>	<b>1.5</b>	<b>0.02%</b>
<b>ISTRADEFYLLINE PRODUCTS</b>						
NOURIANZ TAB 40MG	1	1	\$1,810.00	\$1,810.00	1	0.20%
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$1,810.00</b>	<b>\$1,810.00</b>	<b>1</b>	<b>0.20%</b>
<b>OPICAPONE PRODUCTS</b>						
ONGENTYS CAP 50MG	1	1	\$656.31	\$656.31	1	0.07%
<b>SUBTOTAL</b>	<b>1</b>	<b>1</b>	<b>\$656.31</b>	<b>\$656.31</b>	<b>1</b>	<b>0.07%</b>
<b>TOTAL</b>	<b>36,608</b>	<b>7,693*</b>	<b>\$910,100.38</b>	<b>\$24.86</b>	<b>4.76</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

CAP = capsule; CARB = carbidopa; EN = entacapone; ER = extended release; HR = hour; INJ = injection;

LEVO = levodopa; SOL = solution; TAB = tablet

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

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<sup>1</sup> 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 03/2024. Last accessed 03/11/2024.

<sup>2</sup> AbbVie. Pipeline. Available online at: <https://www.abbvie.com/science/pipeline.html>. Last accessed 03/11/2024.

<sup>3</sup> AbbVie. AbbVie Provides Regulatory Update on ABBV-951 (Foscarbidopa/Foslevodopa) New Drug Application. *PR Newswire*. Available online at: <https://www.prnewswire.com/news-releases/abbvie-provides-regulatory-update-on-abbv-951-foscarbidopafoslevodopa-new-drug-application-301777945.html>. Issued 03/22/2023. Last accessed 03/11/2024.

<sup>4</sup> Amneal Pharmaceuticals. Amneal Receives U.S. FDA Complete Response Letter for IPX203. *Businesswire*. Available online at: <https://www.businesswire.com/news/home/20230703031013/en/Amneal-Receives-U.S.-FDA-Complete-Response-Letter-for-IPX203>. Issued 07/03/2023. Last accessed 03/11/2024.

# Fiscal Year 2023 Annual Review of Prenatal Vitamins

Oklahoma Health Care Authority  
Fiscal Year 2023 Print Report

## Current Prior Authorization Criteria

### Prenatal Vitamins Approval Criteria:

- Most brand formulation prenatal vitamins require prior authorization for SoonerCare members and require a reason why the member cannot use a preferred prenatal vitamin. Preferred products do not require prior authorization. Products that are not listed on the preferred product list are non-preferred and require prior authorization.
- Updated versions of the preferred products list can be downloaded from the Oklahoma Health Care Authority (OHCA) website at: <https://oklahoma.gov/ohca/rx>.
- The SoonerCare prenatal vitamins category is modified throughout the fiscal year and adjusted for price fluctuations and supplemental rebate participation.

## Utilization of Prenatal Vitamins: Fiscal Year 2023

### Comparison of Fiscal Years

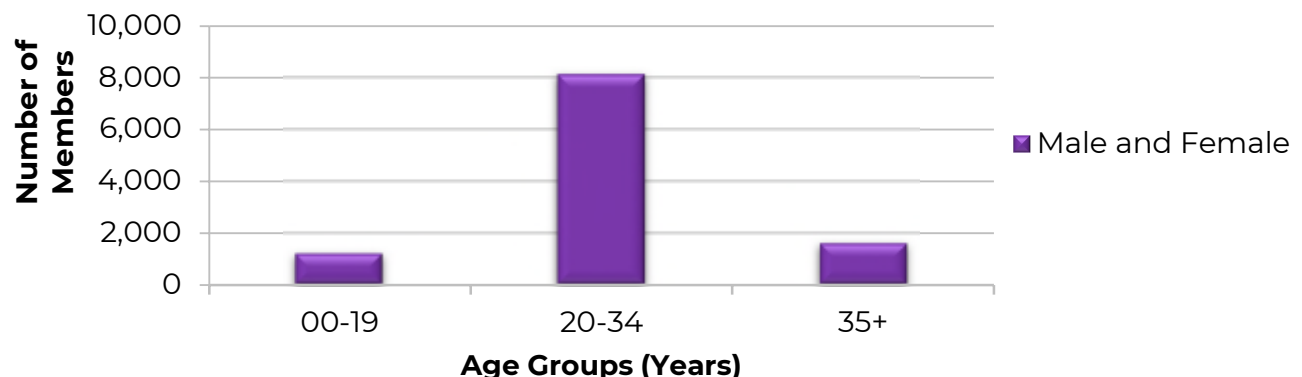
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	10,736	23,045	\$2,862,035.16	\$124.19	\$2.80	1,290,704	1,022,882
2023	10,865	23,064	\$2,973,123.16	\$128.91	\$2.87	1,341,095	1,034,528
<b>% Change</b>	<b>1.20%</b>	<b>0.10%</b>	<b>3.90%</b>	<b>3.80%</b>	<b>2.50%</b>	<b>3.90%</b>	<b>1.10%</b>
<b>Change</b>	<b>129</b>	<b>19</b>	<b>\$111,088.00</b>	<b>\$4.72</b>	<b>\$0.07</b>	<b>50,391</b>	<b>11,646</b>

Costs do not reflect rebated prices or net costs.

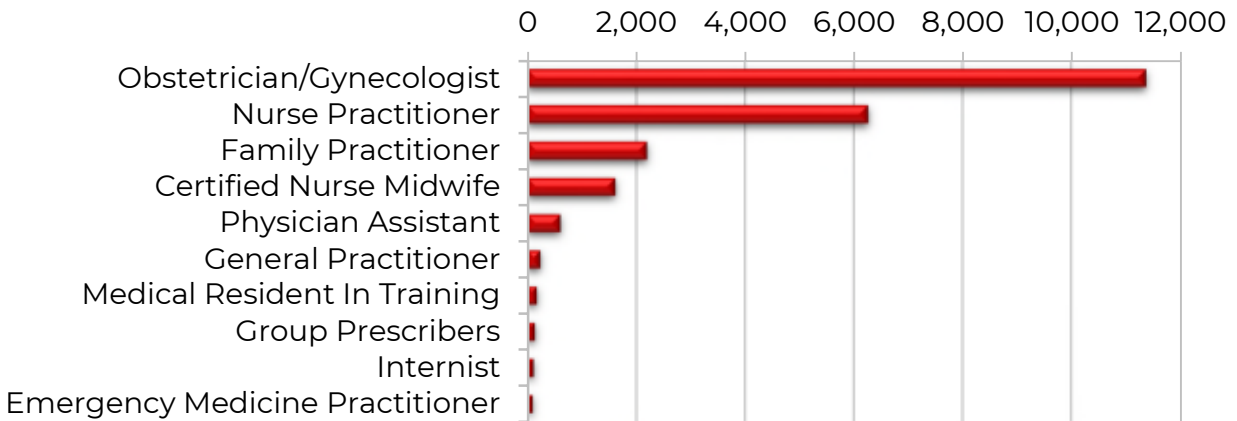
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

### Demographics of Members Utilizing Prenatal Vitamins



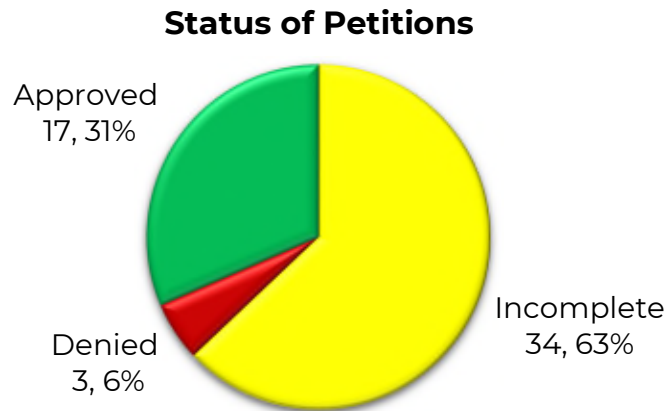
## Top Prescriber Specialties of Prenatal Vitamins by Number of Claims



## Prior Authorization of Prenatal Vitamins

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There were 54 prior authorization requests submitted for prenatal vitamins during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



## Recommendations

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

## Utilization Details of Prenatal Vitamins: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
VITAFOL CAP ULTRA	7,514	3,413	\$1,401,874.81	\$186.57	2.2	47.15%
VITAFOL CHW GUMMIES	4,033	1,868	\$530,800.73	\$131.61	2.16	17.85%
PRENATAL TAB 27-IMG	1,607	1,115	\$28,414.95	\$17.68	1.44	0.96%
CITRANATAL CAP HARMONY	1,475	662	\$250,905.54	\$170.11	2.23	8.44%
FOLIVANE-OB CAP	1,009	618	\$37,500.59	\$37.17	1.63	1.26%
WESTAB PLUS TAB 27-IMG	919	629	\$14,487.84	\$15.76	1.46	0.49%
M-NATAL PLUS TAB	888	641	\$15,047.33	\$16.95	1.39	0.51%
VITAFOL-OB TAB 65-IMG	792	476	\$179,066.12	\$226.09	1.66	6.02%
CITRANATAL B-CALM	778	442	\$92,589.10	\$119.01	1.76	3.11%
TARON-C DHA CAP	660	387	\$25,920.63	\$39.27	1.71	0.87%
SE-NATAL 19 TAB	573	313	\$18,473.43	\$32.24	1.83	0.62%
CITRANATAL 90 DHA	549	219	\$70,419.46	\$128.27	2.51	2.37%
VITAFOL FE+ CAP	470	237	\$90,264.70	\$192.05	1.98	3.04%
VITAFOL-ONE CAP	389	196	\$73,145.95	\$188.04	1.98	2.46%
CITRANATAL PAK DHA	312	162	\$37,576.47	\$120.44	1.93	1.26%
VITAFOL-OB PAK +DHA	229	103	\$32,586.45	\$142.30	2.22	1.10%
CITRANATAL PAK ASSURE	218	111	\$26,620.32	\$122.11	1.96	0.90%
COMPLETE NATAL PAK DHA	123	58	\$3,760.67	\$30.57	2.12	0.13%
CITRANATAL TAB BLOOM	108	52	\$19,606.98	\$181.55	2.08	0.66%
TRINATAL RX TAB 1	80	38	\$1,510.18	\$18.88	2.11	0.05%
SE-NATAL 19 CHW	75	60	\$2,587.05	\$34.49	1.25	0.09%
VIRT-C DHA CAP	53	37	\$1,831.28	\$34.55	1.43	0.06%
TRICARE TAB PRENATAL	51	31	\$1,155.81	\$22.66	1.65	0.04%
SELECT-OB+ PAK DHA	39	13	\$5,285.98	\$135.54	3	0.18%
COMPLETENATE CHW	33	22	\$1,346.37	\$40.80	1.5	0.05%
VITAFOL-NANO TAB	31	19	\$5,693.88	\$183.67	1.63	0.19%
OB COMPLETE TAB	14	7	\$1,123.97	\$80.28	2	0.04%
ELITE-OB TAB	13	11	\$1,192.53	\$91.73	1.18	0.04%
NIVA-PLUS TAB	10	4	\$320.49	\$32.05	2.5	0.01%
WESCAP-C DHA CAP	9	7	\$343.05	\$38.12	1.29	0.01%
PRENATAL TAB PLUS	3	2	\$87.10	\$29.03	1.5	0.00%
PRENAISSANCE CAP PLUS	2	2	\$113.16	\$56.58	1	0.00%
CITRANATAL TAB RX	2	2	\$344.79	\$172.40	1	0.01%
PRENATE DHA CAP	2	1	\$675.68	\$337.84	2	0.02%
PRENATE TAB ELITE	1	1	\$449.77	\$449.77	1	0.02%
<b>TOTAL</b>	<b>23,064</b>	<b>10,865*</b>	<b>\$2,973,123.16</b>	<b>\$128.91</b>	<b>2.12</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

CAP = capsule; CHW = chewable; DHA = omega-3 fatty acid; FE = iron; PAK = package; TAB = tablet; VIT = vitamin

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

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# Fiscal Year 2023 Annual Review of Qbrexza® (Glycopyrronium)

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## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

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### Current Prior Authorization Criteria

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#### Qbrexza® (Glycopyrronium) Approval Criteria:

1. An FDA approved diagnosis of primary axillary hyperhidrosis in pediatric members 9 years of age to 20 years of age; and
2. Documentation of assessment by a licensed behavior specialist or the prescribing physician indicating the member's hyperhidrosis is causing social anxiety, depression, or similar mental health-related issues that impact the member's ability to function in day-to-day living must be provided; and
3. Member must have failed a trial of Drysol™ (aluminum chloride 20%) at least 3 weeks in duration; and
4. Prescriber must verify that the member has received counseling on the safe and proper use of Qbrexza®; and
5. A quantity limit of 1 box (30 cloths) per 30 days will apply.

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### Utilization of Qbrexza® (Glycopyrronium): Fiscal Year 2023

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#### Fiscal Year 2023 Utilization

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2023	4	4	\$2,531.76	\$632.94	\$21.10	120	120

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

Please note: There were no paid pharmacy claims for Qbrexza® during fiscal year 2022 to allow for a fiscal year comparison.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

#### Demographics of Members Utilizing Qbrexza® (Glycopyrronium)

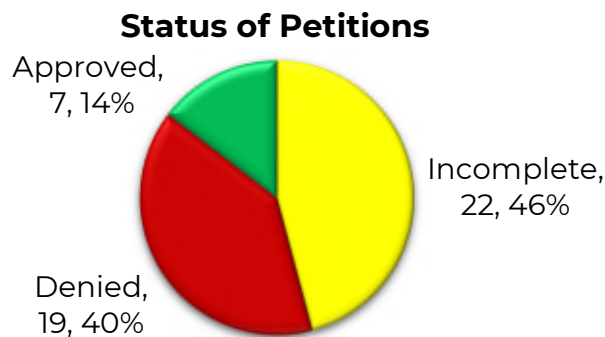
- Due to the limited number of members utilizing Qbrexza® (glycopyrronium) during fiscal year 2023, detailed demographic information could not be provided.

## Top Prescriber Specialties of Qbrexza® (Glycopyrronium) by Number of Claims



## Prior Authorization of Qbrexza® (Glycopyrronium)

There were 48 prior authorization requests submitted for 25 unique members for Qbrexza® (glycopyrronium) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



## Market News and Updates<sup>1</sup>

### Anticipated Patent Expiration(s):

- Qbrexza® (glycopyrronium): February 2033

## Recommendations

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

## Utilization Details of UCD Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
QBREXZA PAD 2.4%	4	4	\$2,531.76	\$632.94	1	100%
<b>TOTAL</b>	<b>4</b>	<b>4*</b>	<b>\$2,531.76</b>	<b>\$632.94</b>	<b>1</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members

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

<sup>1</sup> 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 03/2024. Last accessed 03/12/2024.



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# Fiscal Year 2023 Annual Review of Qalaaquin® (Quinine Sulfate)

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Oklahoma Health Care Authority  
Fiscal Year 2023 Print Report

## Current Prior Authorization Criteria

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### Qalaaquin® (Quinine Sulfate) Approval Criteria:

1. An FDA approved diagnosis of malaria; and
2. Off-label use for the prevention/treatment of leg cramps and other related conditions will not be covered.

## Utilization of Qalaaquin® (Quinine Sulfate): Fiscal Year 2023

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

## Prior Authorization of Qalaaquin® (Quinine Sulfate)

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There were no prior authorization requests submitted for Qalaaquin® (quinine sulfate) during fiscal year 2023.

## Recommendations

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

# Fiscal Year 2023 Annual Review of Short-Acting Beta<sub>2</sub> Agonists (SABAs)

Oklahoma Health Care Authority  
Fiscal Year 2023 Print Report

## Current Prior Authorization Criteria

Short-Acting Beta <sub>2</sub> Agonists	
Tier-1	Tier-2
albuterol HFA (ProAir <sup>®</sup> HFA) – <b>Brand Preferred</b>	albuterol HFA (generic)
albuterol inhalation powder (ProAir <sup>®</sup> RespiClick <sup>®</sup> )	albuterol inhalation powder (ProAir <sup>®</sup> Digihaler <sup>®</sup> )*
albuterol HFA (Proventil <sup>®</sup> HFA) – <b>Brand Preferred</b>	levalbuterol HFA (generic)
albuterol HFA (Ventolin <sup>®</sup> HFA) – <b>Brand Preferred</b>	
levalbuterol HFA (Xopenex <sup>®</sup> HFA) – <b>Brand Preferred</b>	

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).

\*Additional criteria applies.

HFA = hydrofluoroalkane

### Short-Acting Beta<sub>2</sub> Agonists Tier-2 Approval Criteria:

1. An FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member cannot use all available Tier-1 medications must be provided; and
3. Approval of generic albuterol HFA or levalbuterol HFA requires a patient-specific, clinically significant reason the member cannot use the brand formulation.

### ProAir<sup>®</sup> Digihaler<sup>®</sup> (Albuterol Inhalation Powder) Approval Criteria:

1. An FDA approved or clinically accepted indication; and
2. A patient-specific, clinically significant reason why the member requires the ProAir<sup>®</sup> Digihaler<sup>®</sup> formulation over all available Tier-1 medications must be provided; and
3. The prescriber agrees to closely monitor member adherence; and
4. The member should be capable and willing to use the Companion Mobile App and follow the *Instructions for Use* and ensure the ProAir<sup>®</sup> Digihaler<sup>®</sup> Companion Mobile App is compatible with their specific smartphone; and
5. Member's phone camera must be functional and able to scan the inhaler QR code and register the ProAir<sup>®</sup> Digihaler<sup>®</sup> inhaler; and

- Approvals will be for the duration of 3 months. For continuation consideration, documentation demonstrating positive clinical response and patient compliance >80% with prescribed therapy must be provided. In addition, a patient-specific, clinically significant reason why the member cannot transition to Tier-1 medications must be provided. Tier structure rules continue to apply.

**Xopenex® (Levalbuterol) Nebulizer Solution Approval Criteria:**

- A free-floating 90 days of therapy per 365 days will be in place.
- Use of this product in excess of 90 days of therapy in a 365-day period will require a patient-specific, clinically significant reason why the member is unable to use long-acting bronchodilator and/or inhaled corticosteroid (ICS) therapy for long-term control as recommended in the National Asthma Education and Prevention Program (NAEPP) guidelines; and
- A patient-specific, clinically significant reason why the member cannot use a metered-dose inhaler (MDI) must be provided; and
- Clinical exceptions will be made for members with chronic obstructive pulmonary disease (COPD); and
- A quantity limit of 288mL per 30 days will apply.

**Utilization of SABAs: Fiscal Year 2023**

**Comparison of Fiscal Years: Pharmacy Claims**

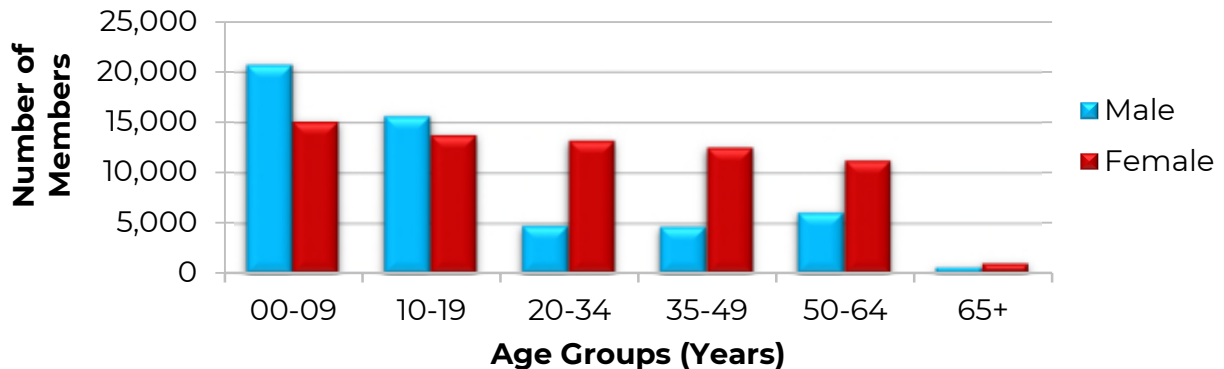
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	108,557	236,301	\$10,890,385.30	\$46.09	1.90	7,129,387	5,721,416
2023	119,041	260,002	\$12,789,010.07	\$49.19	\$2.07	8,343,424	6,173,532
%	9.7%	10.0%	17.4%	6.7%	8.9%	17.0%	7.9%
Change	10,484	23,701	\$1,898,624.77	\$3.10	\$0.17	1,214,037	452,116

Costs do not reflect rebated prices or net costs.

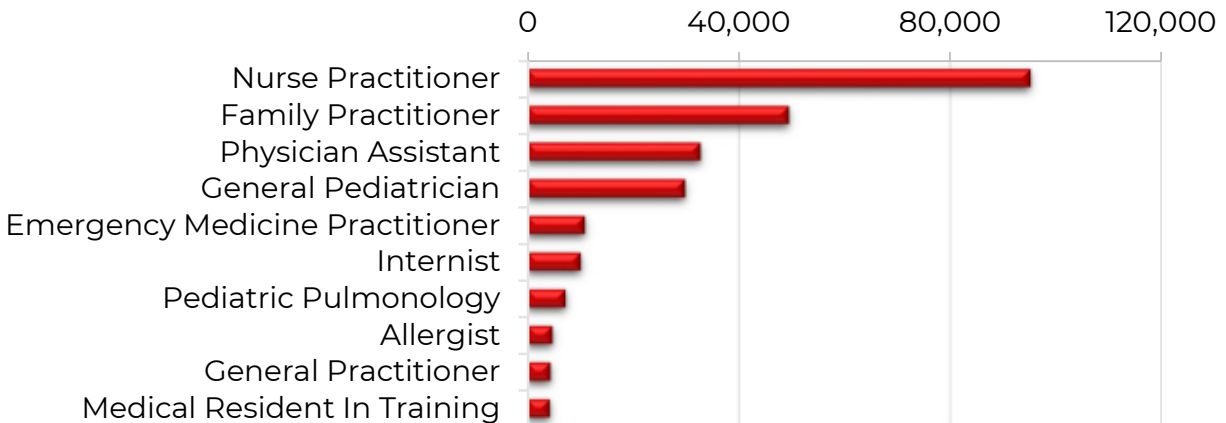
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

**Demographics of Members Utilizing SABAs**

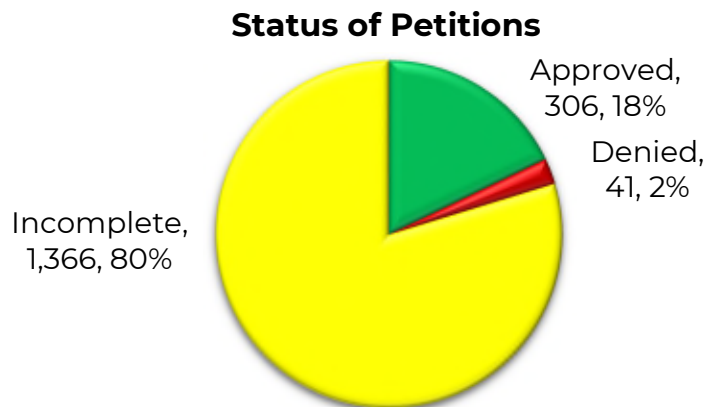


## Top Prescriber Specialties of SABAs by Number of Claims



## Prior Authorization of SABAs

There were 1,713 prior authorization requests submitted for SABAs during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



## Market News and Updates<sup>1</sup>

### Anticipated Patent Expiration(s):

- ProAir RespiClick® (albuterol sulfate inhalation powder): January 2032
- ProAir® Digihaler® (albuterol sulfate inhalation powder): December 2038

## Recommendations

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

## Utilization Details of SABAs: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
<b>SABA TIER-1 PRODUCTS</b>						
VENTOLIN HFA 90MCG/ACT	62,797	35,452	\$4,553,524.65	\$72.51	1.77	35.60%
PROAIR HFA 90MCG/ACT	14,576	11,885	\$1,370,038.48	\$93.99	1.23	10.71%
PROVENTIL HFA 90MCG/ACT	4,669	3,488	\$456,273.92	\$97.72	1.34	3.57%
PROAIR RESPICLICK 90MCG/ACT	1,881	1,153	\$146,358.96	\$77.81	1.63	1.14%
XOPENEX HFA 45MCG/ACT	1,064	426	\$94,140.94	\$88.48	2.5	0.74%
<b>SUBTOTAL</b>	<b>84,987</b>	<b>52,404</b>	<b>\$6,620,336.95</b>	<b>\$77.90</b>	<b>1.62</b>	<b>51.77%</b>
<b>SABA TIER-2 PRODUCTS</b>						
ALBUTEROL HFA 90MCG/ACT	143,510	81,544	\$5,123,480.01	\$35.70	1.76	40.06%
LEVALBUTEROL HFA 45MCG/ACT	5	2	\$484.49	\$96.90	2.5	0.00%
<b>SUBTOTAL</b>	<b>143,515</b>	<b>81,546</b>	<b>\$5,123,964.50</b>	<b>\$35.70</b>	<b>1.76</b>	<b>40.07%</b>
<b>SABA NEBULIZER SOLUTION PRODUCTS</b>						
ALBUTEROL NEB 1.25MG/3ML	11,492	8,539	\$406,359.27	\$35.36	1.35	3.18%
IPRATR/ALBUT NEB 0.5-2.5MG/3ML	10,055	4,820	\$255,512.47	\$25.41	2.09	2.00%
ALBUTEROL NEB 0.63MG/3ML	7,086	5,377	\$248,056.38	\$35.01	1.32	1.94%
LEVALBUTEROL NEB 0.63MG	1,048	708	\$46,567.62	\$44.43	1.48	0.36%
LEVALBUTEROL NEB 1.25MG	1,046	642	\$49,264.18	\$47.10	1.63	0.39%
LEVALBUTEROL NEB 0.31MG	529	402	\$20,123.47	\$38.04	1.32	0.16%
ALBUTEROL NEB 5MG/ML	222	184	\$11,180.54	\$50.36	1.21	0.09%
LEVALBUTEROL NEB 1.25MG/0.5ML	16	11	\$3,088.59	\$193.04	1.45	0.02%
XOPENEX NEB 1.25MG/3ML	6	1	\$4,556.10	\$759.35	6	0.04%
<b>SUBTOTAL</b>	<b>31,500</b>	<b>20,684</b>	<b>\$1,044,708.62</b>	<b>\$33.17</b>	<b>1.52</b>	<b>8.17%</b>
<b>TOTAL</b>	<b>260,002</b>	<b>119,041*</b>	<b>\$12,789,010.07</b>	<b>\$49.19</b>	<b>2.18</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

ACT = actuation; HFA = hydrofluoroalkane inhaler; IPRATR/ALBUT = ipratropium/albuterol; NEB = nebulizer; SABA = short-acting beta<sub>2</sub> agonist

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

<sup>1</sup> 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 03/2024. Last accessed 03/12/2024.

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# Fiscal Year 2023 Annual Review of Strensiq® (Asfotase Alfa)

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## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

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### Current Prior Authorization Criteria

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#### Strensiq® (Asfotase Alfa) Approval Criteria:

1. An FDA approved indication for the treatment of members with perinatal/infantile-onset and juvenile-onset hypophosphatasia (HPP); and
2. Confirmed diagnosis by laboratory testing of:
  - a. Low age-adjusted alkaline phosphatase (ALP) activity; and
  - b. Elevated pyridoxal 5'-phosphate (PLP) levels; and
3. Member's weight (kg) must be provided and must have been taken within the last 4 weeks to ensure accurate weight-based dosing per package labeling; and
4. The 80mg/0.8mL vial should not be used in pediatric members weighing <40kg.

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### Utilization of Strensiq® (Asfotase Alfa): Fiscal Year 2023

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#### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	6	54	\$3,662,560.14	\$67,825.19	\$2,422.33	733	1,512
2023	9	66	\$5,079,938.74	\$76,968.77	\$2,748.88	1,037	1,848
% Change	50.0%	22.2%	38.7%	13.5%	13.5%	41.5%	22.2%
Change	3	12	\$1,417,378.60	\$9,143.58	\$326.58	304	336

Costs do not reflect rebated prices or net costs.

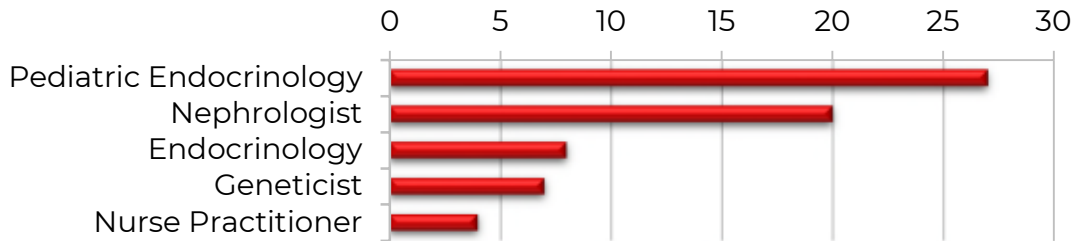
\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

#### Demographics of Members Utilizing Strensiq® (Asfotase Alfa)

- Due to the limited number of members utilizing Strensiq® (asfotase alfa), detailed demographic information could not be provided.

### Top Prescriber Specialties of Strensiq® (Asfotase Alfa) by Number of Claims



### Prior Authorization of Strensiq® (Asfotase Alfa):

There were 17 prior authorization requests submitted for 9 unique members for Strensiq® (asfotase alfa) during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.

#### Status of Petitions



### Recommendations

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

### Utilization Details of Strensiq® (Asfotase Alfa): Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
STRENSIQ INJ 80MG/0.8ML	34	5	\$3,844,093.62	\$113,061.58	6.8	75.67%
STRENSIQ INJ 40MG/ML	22	4	\$755,291.02	\$34,331.41	5.5	14.87%
STRENSIQ INJ 28MG/0.7ML	10	1	\$480,554.10	\$48,055.41	10	9.46%
<b>TOTAL</b>	<b>66</b>	<b>9*</b>	<b>\$5,079,938.74</b>	<b>\$76,968.77</b>	<b>7.33</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

INJ = injection

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

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# Fiscal Year 2023 Annual Review of Urea Cycle Disorder (UCD) Medications

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Oklahoma Health Care Authority  
Fiscal Year 2023

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## Current Prior Authorization Criteria

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### Carbaglu® (Carglumic Acid) Approval Criteria:

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



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

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

**Pheburane® (Sodium Phenylbutyrate Oral Pellets) Approval Criteria:**

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Member must be actively managing UCD with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®), which are available without a prior authorization, must be provided; and
4. A maximum daily dose of 20g sodium phenylbutyrate will apply; and
5. A quantity limit of 1,218g of pellets (equivalent to 588g of sodium phenylbutyrate) per 29 days will apply.

**Ravicti® (Glycerol Phenylbutyrate) Approval Criteria:**

1. An FDA approved diagnosis of urea cycle disorder (UCD); and
2. Active management with a protein restricted diet; and
3. A patient-specific, clinically significant reason why the member cannot use sodium phenylbutyrate powder and tablets (generic Buphenyl®) must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use Pheburane® (sodium phenylbutyrate oral pellets) must be provided; and
5. A maximum daily dose of 17.5mL (19g) of glycerol phenylbutyrate will apply; and
6. A quantity limit of 525mL per 30 days will apply.

## Utilization of UCD Medications: Fiscal Year 2023

### Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/Claim	Cost/Day	Total Units	Total Days
2022	10	116	\$5,180,127.26	\$44,656.27	\$1,605.25	24,215	3,227
2023	11	122	\$6,399,361.92	\$52,453.79	\$1,973.89	29,445	3,242
% Change	10.00%	5.20%	23.50%	17.50%	23.00%	21.60%	0.5%
Change	1	6	\$1,219,234.66	\$7,797.52	\$368.64	5,230	15

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

### Demographics of Members Utilizing UCD Medications

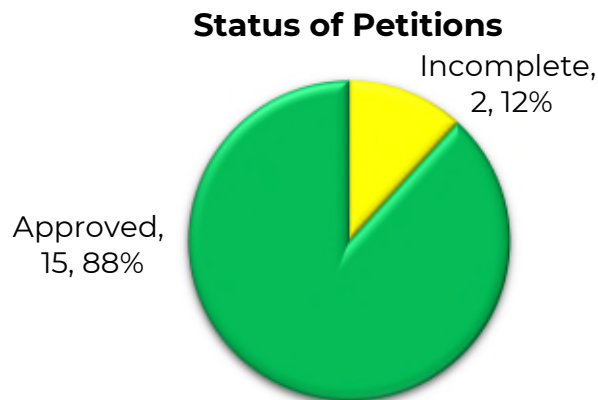
- There were 11 unique pediatric members utilizing UCD medications during fiscal year 2023; however, due to the limited number of members utilizing UCD medications, detailed demographic information could not be provided.

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

- There were 122 paid claims for UCD medications during fiscal year 2023, all of which were prescribed by a medical geneticist.

### Prior Authorization of UCD Medications

There were 17 prior authorization requests submitted for UCD medications during fiscal year 2023. The following chart shows the status of the submitted petitions for fiscal year 2023.



### Market News and Updates<sup>1,2,3</sup>

#### Anticipated Patent Expiration(s):

- Ravicti® (glycerol phenylbutyrate): March 2032
- Olpruva™ (sodium phenylbutyrate): October 2036

## Pipeline:

- **DTX301:** DTX301 is an investigational adeno-associated virus (AAV) gene therapy designed to deliver stable expression and activity of the ornithine transcarbamylase (OTC) gene using a single intravenous infusion. OTC deficiency, the most common UCD, is caused by a genetic defect in a liver enzyme (OTC enzyme) responsible for detoxification of ammonia within the urea cycle. The Phase 3 Enh3ance study is underway to evaluate the effect of DTX301 on ammonia and its ability to reduce patients' need for ammonia scavenger medication and a protein-restricted diet, the current standard of care. DTX301 was granted Orphan Drug and Fast Track designations by the FDA.

## Recommendations

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

## Utilization Details of UCD Medications: Fiscal Year 2023

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER	% COST
RAVICTI LIQ 1.1MG/ML	110	10	\$3,593,574.60	\$32,668.86	11	56.16%
CARBAGLU TAB 200MG	12	1	\$2,805,787.32	\$233,815.61	12	43.84%
<b>TOTAL</b>	<b>122</b>	<b>11*</b>	<b>\$6,399,361.92</b>	<b>\$52,453.79</b>	<b>11.09</b>	<b>100%</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members

LIQ = liquid; TAB = tablet

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

<sup>1</sup> U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: <https://www.accessdata.fda.gov/scripts/cder/ob/>. Last revised 12/2023. Last accessed 12/19/2023.

<sup>2</sup> Ultragenyx. Our Pipeline: DTX301 for OTC Deficiency. Available online at: <https://www.ultragenyx.com/our-research/pipeline/dtx301-for-otc/>. Last accessed 12/19/2023.

<sup>3</sup> Clinical Study of DTX301 AAV-Mediated Gene Transfer for Ornithine Transcarbamylase (OTC) Deficiency. *ClinicalTrials.gov*. Available online at: <https://clinicaltrials.gov/ct2/show/NCT05345171>. Last revised 12/19/2023. Last accessed 12/19/2023.

# Fiscal Year 2023 Annual Review of Xgeva® (Denosumab)

## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

### Current Prior Authorization Criteria

#### Xgeva® (Denosumab) Approval Criteria:

1. An FDA approved indication of 1 of the following:
  - a. Prevention of skeletal-related events in members with multiple myeloma and in members with bone metastases from solid tumors; or
  - b. Treatment of adults and skeletally mature adolescents with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity; and
    - i. Prescriber must document that tumor is unresectable or that surgical resection is likely to result in severe morbidity; or
  - c. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy; and
    - i. Member must have albumin-corrected calcium of >12.5mg/dL (3.1mmol/L) despite treatment with intravenous bisphosphonate therapy in the last 30 days prior to initiation of Xgeva® therapy.

### Utilization of Xgeva® (Denosumab): Fiscal Year 2023

#### Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	*Total Claims	Total Cost	Cost/Claim	Claims/ Members
2022	76	308	\$774,280.98	\$2,513.90	4.05
2023	91	502	\$1,111,464.00	\$2,214.07	5.52
% Change	19.74%	62.99%	43.55%	-11.93%	36.30%
Change	15	194	\$337,183.02	-\$299.83	1.47

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated utilizing members.

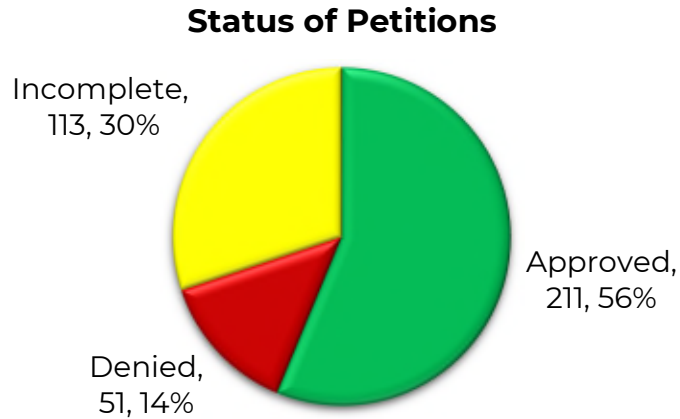
\*Total number of unduplicated claims.

Fiscal Year 2022 = 07/01/2021 to 06/30/2022; Fiscal Year 2023 = 07/01/2022 to 06/30/2023

### Prior Authorization of Xgeva® (Denosumab)

There were 375 prior authorization requests submitted for denosumab during fiscal year 2023. Xgeva® (denosumab) and Prolia® (denosumab) are billed using the same procedure code; therefore, the status of petitions includes prior authorization requests for both Xgeva® and Prolia®. Prolia® is reviewed annually with the osteoporosis medications. The Fiscal Year 2023 Annual

Review of Osteoporosis Medications is included in the State Fiscal Year 2023 Quarter 3 Print Annual Reviews Drug Utilization Review (DUR) Board Packet. The following chart shows the status of the submitted petitions for all denosumab products for fiscal year 2023.



### Recommendations

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

### Utilization Details of Xgeva® (Denosumab): Fiscal Year 2023

#### Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/CLAIM	CLAIMS/MEMBER
J0897 DENOSUMAB INJ (XGEVA)	502	91	\$1,111,464.00	\$2,214.07	5.52
<b>TOTAL</b>	<b>502*</b>	<b>91*</b>	<b>\$1,111,464.00</b>	<b>\$2,214.07</b>	<b>5.52</b>

Costs do not reflect rebated prices or net costs.

\*Total number of unduplicated claims.

\*Total number of unduplicated utilizing members.

INJ = injection

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

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# Fiscal Year 2023 Annual Review of Xuriden® (Uridine Triacetate)

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## Oklahoma Health Care Authority Fiscal Year 2023 Print Report

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### Current Prior Authorization Criteria

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#### Xuriden® (Uridine Triacetate) Approval Criteria:

1. An FDA approved diagnosis of hereditary orotic aciduria defined by at least 1 of the following:
  - a. Assay of the orotate phosphoribosyltransferase and orotidylic acid decarboxylase enzymes in the member's erythrocytes showing deficiency in both enzymes or deficiency in orotidylic acid decarboxylase alone; or
  - b. Evidence of megaloblastic anemia; and
    - i. Normal serum folate and vitamin B12 levels and no evidence of transcobalamine II deficiency; or
  - c. Orotic acid crystals visualized in the urine via microscopy; and
2. The member's current weight must be provided on the prior authorization request; and
  - a. Weights should be reassessed every 6 months to ensure proper dosing and effectiveness; or
  - b. Prescriber can indicate urine orotic acid levels are within normal ranges and dosing remains appropriate; and
3. The prescriber must verify the member or caregiver is able to properly measure and administer medication; and
4. A quantity limit of 4 packets per day will apply.

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#### Utilization of Xuriden® (Uridine Triacetate): Fiscal Year 2023

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

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#### Prior Authorization of Xuriden® (Uridine Triacetate)

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There were no prior authorization requests submitted for Xuriden® (uridine triacetate) during fiscal year 2023.

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#### Recommendations

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