State Fiscal Year 2021 Print Annual Reviews Quarter 3

Count	Category/Medication
1.	Actinic Keratosis Medications
2.	Allergen Immunotherapies
3.	Anti-Emetic Medications
4.	Antihistamine Medications (Oral)
5.	Antihypertensive Medications
6.	Anti-Ulcer Medications
7.	Bladder Control Medications
8.	Hereditary Angioedema (HAE) Medications
9.	Inhaled Anti-Infective Medications
10.	Injectable and Vaginal Progesterone Products
11.	Iron Chelating Agents
12.	Korlym® (Mifepristone)
13.	Ophthalmic Allergy Medications
14.	Ophthalmic Antibiotic Medications
15.	Osteoporosis Medications
16.	Parkinson's Disease Medications
17.	Phenylketonuria Medications
18.	Procysbi® (Cysteamine Bitartrate)
19.	Short-Acting $Beta_2$ Agonists (SABAs)
20.	Strensiq® (Asfotase Alfa)
21.	Xgeva® (Denosumab)
22.	Xiaflex® (Collagenase Clostridium Histolyticum)

Fiscal Year 2021 = July 1, 2020 – June 30, 2021

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

Fiscal Year 2021 Annual Review of Actinic Keratosis Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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 Picato® *Prescribing Information* 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. Sizes 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 with Solaraze® *Prescribing Information* and FDA approved dosing regimen.

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

1. An FDA approved diagnosis of actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults or topical treatment of external genital and perianal warts/condyloma acuminate (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.

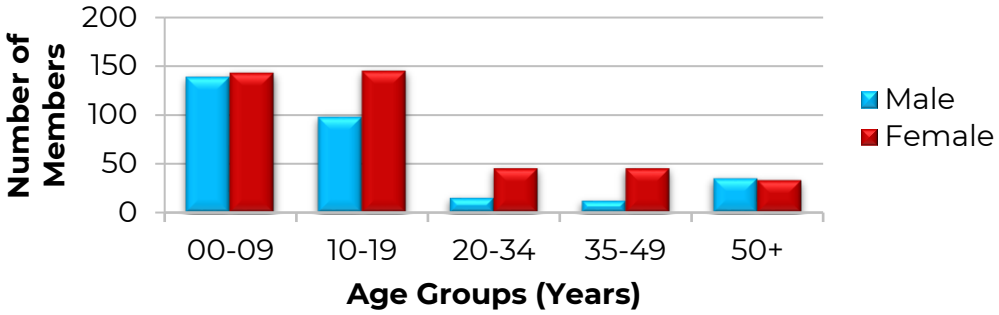
Utilization of Actinic Keratosis Medications: Fiscal Year 2021

Comparison of Fiscal Years

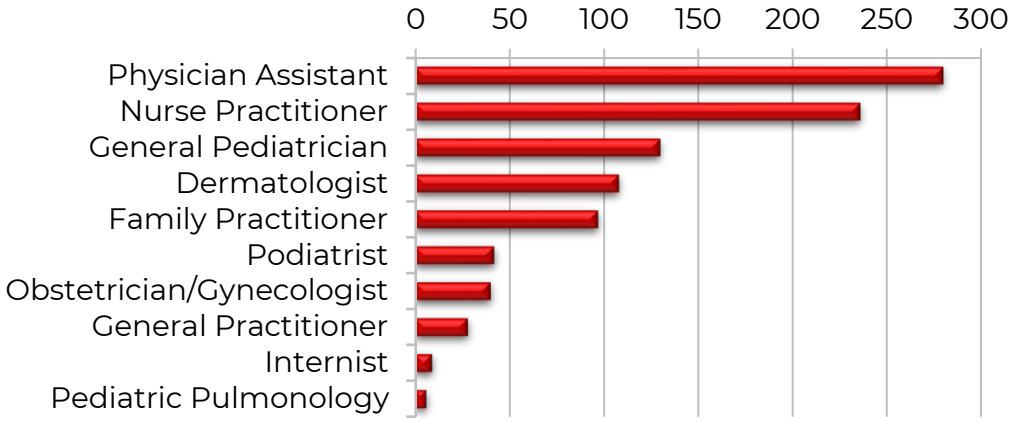
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	680	907	$32,754.90	$36.11	$1.03	15,185	31,946
2021	710	951	$29,621.62	$31.15	$0.87	15,659	33,903
% Change	**4.40%**	**4.90%**	**-9.60%**	**-13.70%**	**-15.50%**	**3.10%**	**6.10%**
Change	**30**	**44**	**-$3,133.28**	**-$4.96**	**-$0.16**	**474**	**1,957**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Actinic Keratosis Medications



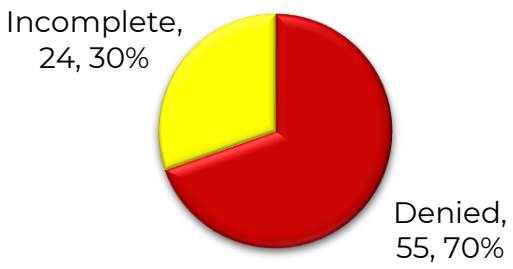
Top Prescriber Specialties of Actinic Keratosis Medications by Number of Claims



Prior Authorization of Actinic Keratosis Medications

There were 79 prior authorization requests submitted for actinic keratosis medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[1]

- Tolak® (fluorouracil 4% cream): July 2023
- Zyclara® (imiquimod 2.5% and 3.75% cream): December 2029
- Picato® (ingenol mebutate gel): May 2033

Recommendations

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 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
IMIQUIMOD CRE 5%	848	623	$22,530.58	$26.57	1.36	76.06%
FLUOROURACIL CRE 5%	103	93	$7,091.04	$68.85	1.11	23.94%
TOTAL	**951**	**710***	**$29,621.62**	**$31.15**	**1.34**	**100%**

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

[1] U.S. Food and Drug Administration (FDA). Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available online at: http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Last revised 03/2022. Last accessed 03/16/2022.

Fiscal Year 2021 Annual Review of Allergen Immunotherapies

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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

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

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

1. Member must be 18 to 65 years of age; and

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

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

1. Member must be 5 to 65 years of age; and
2. Member must have a positive skin test or *in vitro* testing for pollen specific immunoglobulin E (IgE) antibodies to 1 of the 5 grass pollens contained in Oralair®; and
3. Member must not have severe uncontrolled asthma; and
4. Member must have failed conservative attempts to control allergic rhinitis; and
5. Member must have failed pharmacological agents used to control allergies including the following (dates and duration of trials must be indicated on the prior authorization request):
    a. **Antihistamines:** Trials of 2 different products for 14 days each during a previous season; and

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

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

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

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

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

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

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

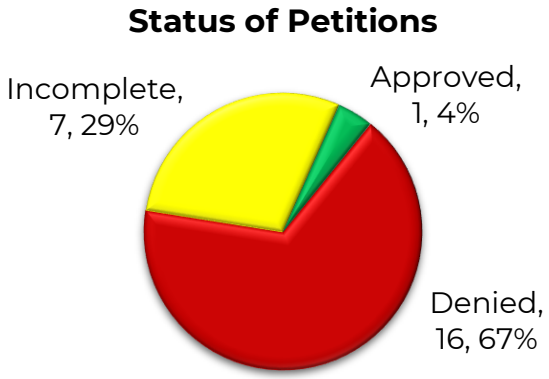
*Current prior authorization criteria is only applicable to allergen immunotherapies with a current federal drug rebate agreement. All criteria, regardless of coverage, are provided in this report for informational purposes.

Utilization of Allergen Immunotherapies: Fiscal Year 2021

There was no SoonerCare utilization of allergen immunotherapies during fiscal year 2021 (07/01/2020 to 06/30/2021).

Prior Authorization of Allergen Immunotherapies

There were 24 prior authorization requests submitted for allergen immunotherapies during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021. While there was 1 approved prior authorization request during fiscal year 2021, there were no paid claims.



Recommendations

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

Fiscal Year 2021 Annual Review of Anti-Emetic Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Akynzeo® (Netupitant/Palonosetron) and Akynzeo® IV (Fosnetupitant/ Palonosetron) Approval Criteria:

1. An FDA approved indication for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy; and
2. For Akynzeo® oral capsules, a previously failed trial of oral aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why oral aprepitant cannot be used must be provided; and
3. For Akynzeo® IV, a previously failed trial of intravenous (IV) fosaprepitant (Emend® IV) that resulted in an inadequate response, or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
4. Akynzeo® IV will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. Approval length will be based on duration of need; and
6. A quantity limit of 1 capsule or vial per chemotherapy cycle will apply; and
7. Akynzeo® oral capsules will not require prior authorization for members with cancer and claims will pay at the point of sale if the member has a reported oncology diagnosis within the past 6 months of claims history.
    a. Based on the current low net cost, Akynzeo® oral capsules will not require prior authorization for members with cancer; however, Akynzeo® oral capsules will follow the original criteria and require a previously failed trial of oral aprepitant if the net cost increases compared to other available products.

Anzemet® (Dolasetron), Cinvanti™ and Emend® (Aprepitant), Emend® IV (Fosaprepitant), and Kytril® and Sancuso® (Granisetron) Approval Criteria:

1. An FDA approved diagnosis; and
2. A recent trial of ondansetron (within the past 6 months) used for at least 3 days or 1 cycle that resulted in an inadequate response is required for authorization in members receiving moderately emetogenic chemotherapy; and

3. No ondansetron trial is required for authorization of Emend® (aprepitant) in members receiving highly emetogenic chemotherapy; and
4. For Emend® (aprepitant) oral suspension, an age restriction of 6 years and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why the oral capsule formulation cannot be used; and
5. For Cinvanti™ [aprepitant intravenous (IV) emulsion], a previously failed trial of IV fosaprepitant (Emend® IV) that resulted in an inadequate response, or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
6. Approval length will be based on duration of need.

Barhemsys® (Amisulpride) Approval Criteria:

1. An FDA approved indication of 1 of the following:
    a. Prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an anti-emetic of a different class; or
    b. Treatment of PONV in members who have received anti-emetic prophylaxis with an agent of a different class or who have not received prophylaxis; and
2. Member must be 18 years of age or older; and
3. Member must not have received a preoperative dopamine-2 (D2) antagonist (e.g., metoclopramide); and
4. A patient-specific, clinically significant reason why the member cannot use other cost-effective therapeutic alternatives for the prevention or treatment of PONV (e.g., ondansetron, dexamethasone) must be provided.

Cesamet® (Nabilone) and Marinol® and Syndros® (Dronabinol) Approval Criteria:

1. An FDA approved diagnosis; and
2. Approval length will be based on duration of need; and
3. For Marinol® (dronabinol) and Cesamet® (nabilone), a quantity limit of 60 capsules per 30 days will apply; and
4. Cesamet® (nabilone) will require a patient-specific, clinically significant reason why dronabinol oral capsules cannot be used; and
5. For Syndros® (dronabinol) oral solution, the quantity approved will be patient-specific depending on patient diagnosis, maximum recommended dosage, and manufacturer packaging; and
6. For Syndros® (dronabinol) oral solution, an age restriction of 6 years and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why dronabinol oral capsules cannot be used.

Doxylamine/Pyridoxine (Generic Diclegis®) Approval Criteria:

1. Authorization of the generic doxylamine/pyridoxine tablets requires a patient-specific, clinically significant reason why the brand formulation Diclegis® (doxylamine/pyridoxine) tablets are not appropriate.

Palonosetron 0.25mg/5mL Approval Criteria:

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

Sustol® (Granisetron Subcutaneous Injection) Approval Criteria:

1. An FDA approved indication for use in the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens; and
2. Chemotherapy regimen must be listed on the prior authorization request; and
3. A recent trial of ondansetron (within the past 6 months) used for at least 3 days or 1 cycle that resulted in inadequate response is required for authorization in members receiving MEC; and
4. No ondansetron trial is required for authorization of granisetron in members receiving AC combination chemotherapy regimens; and
5. A patient-specific, clinically significant reason why the member cannot use Kytril® (granisetron hydrochloride injection) must be provided; and
6. A quantity limit of 1 injection per chemotherapy cycle will apply.

Varubi® and Varubi® IV (Rolapitant) Approval Criteria:

1. An FDA approved indication for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy; and
2. For oral Varubi® (rolapitant oral tablets), a previously failed trial of oral aprepitant (Emend®) that resulted in an inadequate response, or a patient-specific, clinically significant reason why oral aprepitant cannot be used must be provided; and
3. For Varubi® IV [rolapitant intravenous (IV) emulsion], a previously failed trial of IV fosaprepitant (Emend® IV) that resulted in an inadequate response, or a patient-specific, clinically significant reason why IV fosaprepitant cannot be used must be provided; and
4. Approval length will be based on duration of need; and
5. A quantity limit of 2 tablets or 2 vials per chemotherapy cycle will apply.

Zuplenz® (Ondansetron) Approval Criteria:

1. An FDA approved diagnosis; and

2. A patient-specific, clinically significant reason why the member cannot take all other available formulations of generic ondansetron must be provided.

Utilization of Annual Review of Anti-Emetic Medications: Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	67,901	94,040	$1,587,722.68	$16.88	$2.37	1,626,970	669,993
2021	54,630	80,524	$1,365,350.26	$16.96	$2.18	1,512,952	627,197
% Change	**-19.5%**	**-14.4%**	**-14.0%**	**0.5%**	**-8.0%**	**-7.0%**	**-6.4%**
Change	**-13,271**	**-13,516**	**-$222,372.42**	**$0.08**	**-$0.19**	**-114,018**	**-42,796**

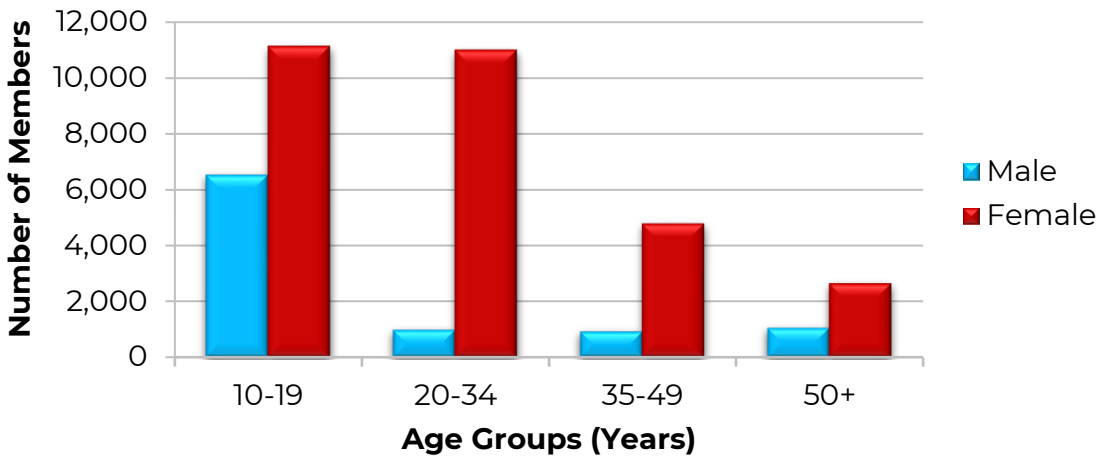
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Utilization: Medical Claims

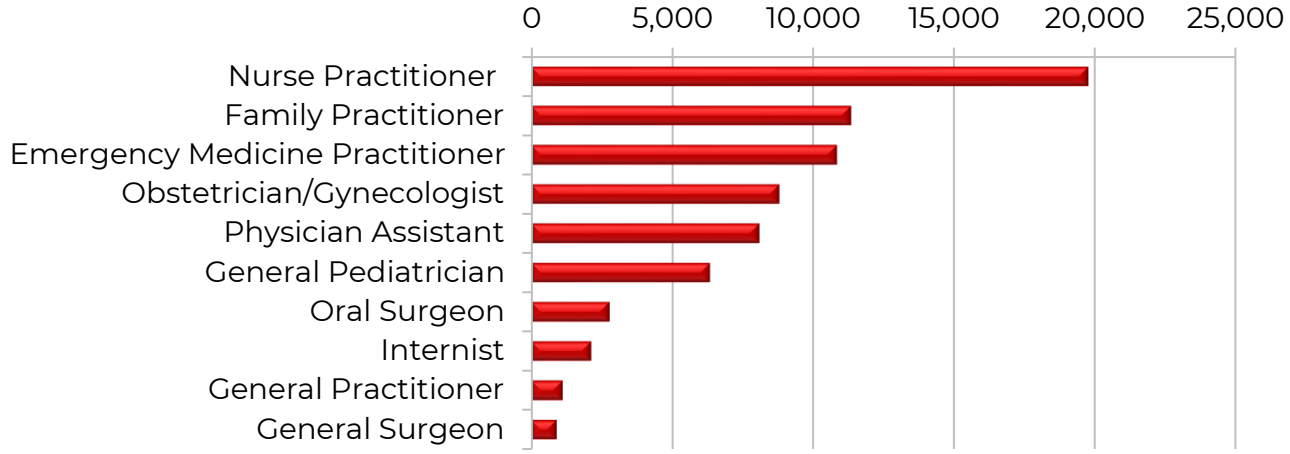
Fiscal Year	*Total Members	+Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2021	25,831	36,195	$348,236.52	$9.62	1.40

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

Demographics of Members Utilizing Anti-Emetic Medications



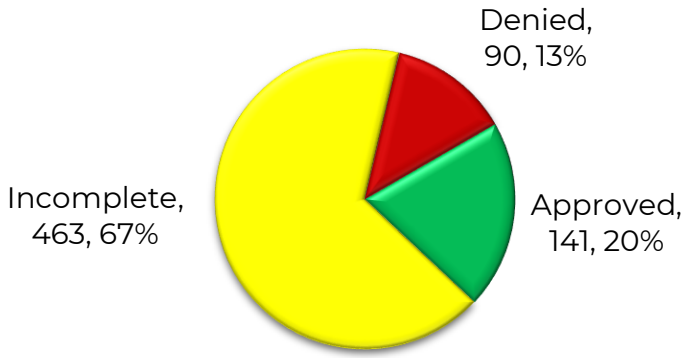
Top Prescriber Specialties of Anti-Emetic Medications by Number of Claims



Prior Authorization of Anti-Emetic Medications

There were 694 prior authorization requests submitted for anti-emetic medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[2]

- Sustol® [granisetron subcutaneous (sub-Q) injection]: September 2024
- Sancuso® (granisetron transdermal patch): January 2025
- Syndros® (dronabinol oral solution): August 2028
- Varubi® (rolapitant tablet): October 2029

[2] 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 03/2022. Last accessed 03/11/2022.

- Zuplenz® (ondansetron oral soluble film): July 2030
- Barhemsys® (amisulpride injection): March 2031
- Bonjesta® [doxylamine/pyridoxine extended-release (ER) tablet]: February 2033
- Akynzeo® (netupitant/palonosetron capsule): September 2035
- Cinvanti® [aprepitant intravenous (IV) emulsion]: September 2035
- Akynzeo® IV (fosnetupitant/palonosetron powder and solution): June 2037

Recommendations

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

Utilization Details of Anti-Emetic Medications: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
ONDANSETRON PRODUCTS						
ONDANSETRON TAB 4MG ODT	45,400	35,196	$662,740.49	$14.60	1.29	48.54%
ONDANSETRON TAB 4MG	15,415	10,639	$187,258.62	$12.15	1.45	13.72%
ONDANSETRON TAB 8MG ODT	11,019	7,076	$171,742.45	$15.59	1.56	12.58%
ONDANSETRON TAB 8MG	4,217	2,511	$49,343.50	$11.70	1.68	3.61%
ONDANSETRON SOL 4MG/5ML	3,744	3,367	$66,500.64	$17.76	1.11	4.87%
ONDANSETRON INJ 40MG/20ML	6	4	$194.43	$32.41	1.5	0.01%
ONDANSETRON INJ 4MG/2ML	6	3	$175.15	$29.19	2	0.01%
SUBTOTAL	**79,807**	**58,796**	**$1,137,955.28**	**$14.26**	**1.36**	**83.34%**
DOXYLAMINE/PYRIDOXINE PRODUCTS						
DICLEGIS TAB 10-10MG	565	371	$193,784.86	$342.98	1.52	14.19%
BONJESTA TAB 20-20MG	3	1	$367.65	$122.55	3	0.03%
DOXYL/PYRID TAB 10-10MG	1	1	$250.24	$250.24	1	0.02%
SUBTOTAL	**569**	**373**	**$194,402.75**	**$341.66**	**1.53**	**14.24%**
GRANISETRON PRODUCTS						
GRANISETRON TAB 1MG	17	5	$1,130.62	$66.51	3.4	0.08%
SANCUSO DIS 3.1MG	14	7	$14,123.64	$1,008.83	2	1.03%
GRANISETRON INJ 1MG/ML	1	1	$31.41	$31.41	1	0.002%
SUBTOTAL	**32**	**13**	**$15,285.67**	**$477.68**	**2.46**	**1.11%**
DRONABINOL PRODUCTS						
DRONABINOL CAP 5MG	63	22	$8,727.07	$138.52	2.86	0.64%
DRONABINOL CAP 2.5MG	30	19	$2,343.93	$78.13	1.58	0.17%
DRONABINOL CAP 10MG	16	4	$3,795.32	$237.21	4	0.28%
SUBTOTAL	**109**	**45**	**$14,866.32**	**$136.39**	**2.42**	**1.09%**
APREPITANT PRODUCTS						
APREPITANT PAK 80MG & 125MG	4	4	$1,909.70	$477.43	1	0.14%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
APREPITANT CAP 80MG	3	2	$930.54	$310.18	1.5	0.07%
SUBTOTAL	**7**	**6**	**$2,840.24**	**$405.75**	**1.17**	**0.21%**
TOTAL	**80,524**	**54,630***	**$1,365,350.26**	**$16.96**	**1.47**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated members.
CAP = capsule; DIS = patches; DOXYL/PYRID = doxylamine/pyridoxine; INJ = injection;
ODT = orally disintegrating tablet; PAK = pack; SOL = solution, TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS+	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ONDANSETRON INJ (J2405)	32,861	25,465	$14,899.84	$0.45	1.29
PALONOSETRON INJ (J2469)	1,754	469	$73,497.03	$41.90	3.74
FOSAPREPITANT INJ (J1453)	760	226	$88,545.76	$116.51	3.36
APREPITANT INJ (J0185)	460	147	$134,327.40	$292.02	3.13
GRANISETRON INJ (J1626)	291	90	$655.47	$2.25	3.23
FOSNETUPITANT/PALONOSETRON INJ (J1454)	64	18	$36,189.27	$565.46	3.56
APREPITANT CAP (J8501)	5	5	$121.75	$24.35	1.00
TOTAL	**36,195**	**25,831***	**$348,236.52**	**$9.62**	**1.40**

Costs do not reflect rebated prices or net costs.
+Total number of unduplicated claims.
*Total number of unduplicated members.
CAP = capsule; INJ = injection
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Antihistamine Medications (Oral)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Oral Antihistamine Medications		
Tier-1[+]	**Tier-2**	**Tier-3**
OTC cetirizine (Zyrtec®)	OTC levocetirizine (Xyzal®)*	clemastine
OTC loratadine (Claritin®)		desloratadine (Clarinex®)[¥]

[+]Tier-1 products are covered for pediatric members with no authorization necessary. OTC products are only covered for pediatric members.
*Xyzal® tablets are not covered for members younger than 6 years of age. Xyzal® solution is available for members 6 months to 6 years of age.
[¥]An age restriction of 6 years to 11 years of age applies for Clarinex® RediTabs®.
OTC = over-the-counter

Oral Antihistamine Medications Tier-2 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of all Tier-1 products within the last 30 days; and
3. Approvals will be for the duration of 1 year.

Oral Antihistamine Medications Tier-3 Approval Criteria:

1. A diagnosis of a chronic allergic condition or asthma; and
2. Member must have a 14-day trial of all Tier-1 and Tier-2 products within the last 60 days (unless no age-appropriate Tier-2 product exists); and
3. Approvals will be for the duration of 1 year.

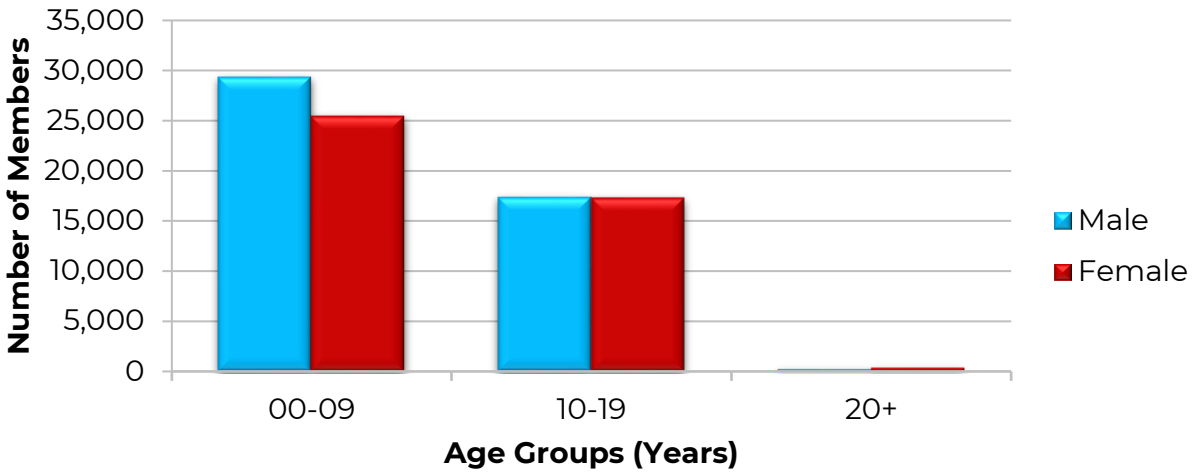
Utilization of Oral Antihistamine Medications: Fiscal Year 2021

Comparison of Fiscal Years

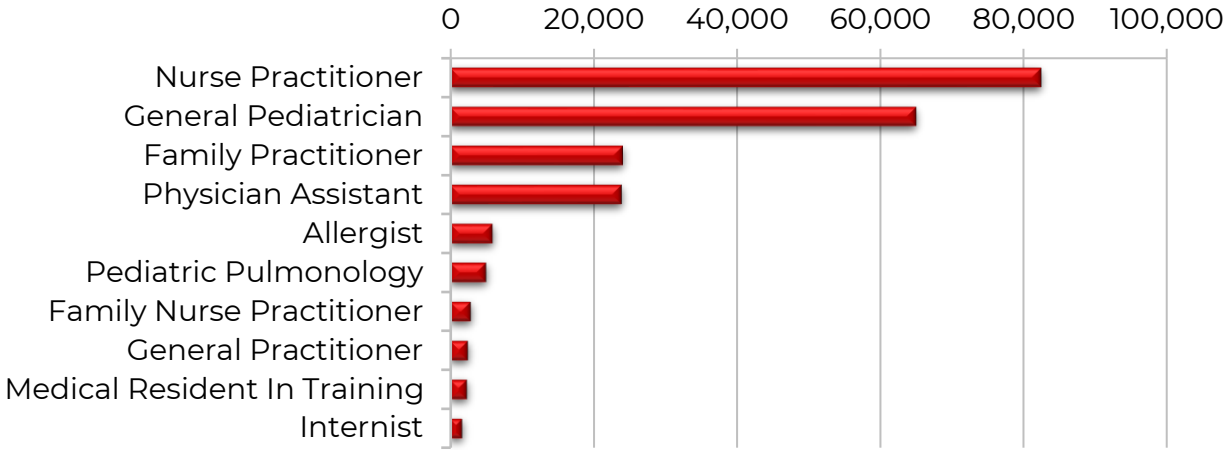
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	98,606	244,555	$2,836,481.96	$11.60	$0.36	23,212,999	7,952,562
2021	90,057	222,708	$2,567,903.39	$11.53	$0.35	21,524,703	7,426,561
% Change	**-8.70%**	**-8.90%**	**-9.50%**	**-0.60%**	**-2.80%**	**-7.30%**	**-6.60%**
Change	**-8,549**	**-21,847**	**-$268,578.57**	**-$0.07**	**-$0.01**	**-1,688,296**	**-526,001**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Oral Antihistamine Medications

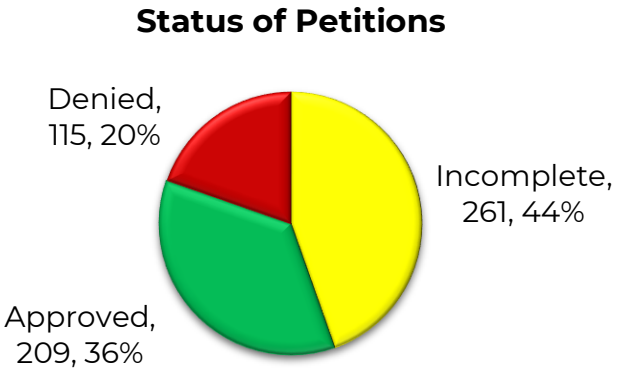


Top Prescriber Specialties of Oral Antihistamine Medications by Number of Claims



Prior Authorization of Oral Antihistamine Medications

There were 585 prior authorization requests submitted for oral antihistamine medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Recommendations

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

Utilization Details of Oral Antihistamine Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
CETIRIZINE PRODUCTS						
CETIRIZINE SOL 1MG/ML	85,720	39,168	$1,115,077.46	$13.01	2.19	43.42%
CETIRIZINE TAB 10MG	73,139	28,929	$689,472.91	$9.43	2.53	26.85%
CETIRIZINE SOL 5MG/5ML	19,145	10,983	$261,706.60	$13.67	1.74	10.19%
CETIRIZINE TAB 5MG	3,724	1,652	$35,532.72	$9.54	2.25	1.38%
ALL DAY ALLG SOL 5MG/5ML	987	632	$12,071.99	$12.23	1.56	0.47%
ALL DAY ALLG TAB 10MG	95	60	$1,194.02	$12.57	1.58	0.05%
ALLERGY RELIEF TAB 10MG	84	59	$914.76	$10.89	1.42	0.04%
ALL DAY ALLG SOL 1MG/ML	69	41	$945.52	$13.70	1.68	0.04%
GNP ALL DAY TAB ALLERGY 10MG	58	34	$743.74	$12.82	1.71	0.03%
ALLERGY RELIEF SOL 1MG/ML	1	1	$13.33	$13.33	1	0.00%
SUBTOTAL	**183,022**	**81,559**	**$2,117,673.05**	**$11.57**	**2.24**	**82.47%**
LORATADINE PRODUCTS						
LORATADINE TAB 10MG	19,795	7,821	$176,863.93	$8.93	2.53	6.89%
LORATADINE SOL 5MG/5ML	15,942	7,628	$208,105.46	$13.05	2.09	8.10%
LORATADINE SYP 5MG/5ML	2,060	1,145	$30,986.42	$15.04	1.8	1.21%
ALLERGY RELIEF TAB 10MG	455	153	$5,192.34	$11.41	2.97	0.20%
ALLERGY CHILD SYP 5MG/5ML	172	83	$2,722.45	$15.83	2.07	0.11%
SM ALLERGY SYP 5MG/5ML	103	84	$1,100.56	$10.69	1.23	0.04%

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SM LORATADINE TAB 10MG	62	35	$545.47	$8.80	1.77	0.02%
ALLERGY TAB 10MG	35	20	$421.49	$12.04	1.75	0.02%
ALLERGY CHILD SOL 5MG/5ML	13	5	$171.92	$13.22	2.6	0.01%
ALLERGY RELIEF SOL 5MG/5ML	6	5	$24.62	$4.10	1.2	0.00%
LORATADINE TAB 10MG	4	4	$79.82	$19.96	1	0.00%
SUBTOTAL	**38,647**	**16,983**	**$426,214.48**	**$11.03**	**2.28**	**16.60%**
TIER-1 SUBTOTAL	**221,669**	**89,947***	**$2,543,887.53**	**$11.48**	**2.46**	**99.06%**
TIER-2 PRODUCTS						
LEVOCETIRIZINE PRODUCTS						
LEVOCETIRIZINE TAB 5MG	698	141	$9,222.32	$13.21	4.95	0.36%
LEVOCETIRIZINE SOL 2.5MG/5ML	311	80	$14,094.37	$45.32	3.89	0.55%
TIER-2 SUBTOTAL	**1,009**	**218***	**$23,316.69**	**$23.11**	**4.63**	**0.91%**
TIER-3 PRODUCTS						
DESLORATADINE PRODUCTS						
DESLORATADINE TAB 5MG	30	5	$699.17	$23.31	6	0.03%
TIER-3 SUBTOTAL	**30**	**5***	**$699.17**	**$23.31**	**6**	**0.03%**
TOTAL	**222,708**	**90,057***	**$2,567,903.39**	**$11.53**	**2.47**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ALLG = allergy; SOL = solution; SYP = syrup; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Calendar Year 2021 Annual Review of Antihypertensive Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

There are 7 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. Calcium Channel Blockers (CCBs)
3. ACEI/CCB Combination Products
4. ACEI/Hydrochlorothiazide (HCTZ) Combination Products
5. Angiotensin II Receptor Blockers (ARBs)
6. ARB Combination Products
7. 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®)		

Angiotensin II Receptor Blockers (ARBs) and ARB Combination Products		
Tier-1	**Tier-2**	**Special PA**
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®)		
Calcium Channel Blockers (CCBs)		
Tier-1	**Tier-2**	**Special PA**
amlodipine (Norvasc®)	amlodipine/atorvastatin (Caduet®)	amlodipine oral suspension (Katerzia®)
diltiazem (Cardizem®)	diltiazem LA (Cardizem® LA, Matzim® LA)	amlodipine/celecoxib (Consensi®)
diltiazem (Tiazac®, Taztia XT®)	diltiazem SR (Cardizem® SR)	diltiazem CD 360mg (Cardizem® CD)
diltiazem CD (Cardizem® CD)*	isradipine (Dynacirc®, Dynacirc CR®)	levamlodipine (Conjupri®)
diltiazem ER (Cartia XT®, Diltia XT®)	nicardipine (Cardene®)	
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®, Isoptin®)		
verapamil SR (Calan® SR, Isoptin® SR)		
ACEI/CCB Combination Products		
Tier-1	**Tier-2**	**Special PA**
Tier-1 ACEI + Tier-1 CCB	trandolapril/verapamil (Tarka®)	perindopril/amlodipine (Prestalia®)
benazepril/amlodipine (Lotrel®)		

⁺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 for which the lower tiered antihypertensive medications lack.

Antihypertensive Medications Special Prior Authorization (PA) Approval Criteria:

1. **Angiotensin I Converting Enzyme Inhibitors (ACEIs):**
    a. **Epaned® (Enalapril Solution) Approval Criteria:**
        i. An age restriction of 7 years or older will apply with the following criteria:
            1. Consideration for approval requires a patient-specific, clinically significant reason why the member cannot use the oral tablet formulation even when crushed.
    b. **Qbrelis® (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. Authorization requires a patient-specific, clinically significant reason why the member cannot use the individual components.
3. **Calcium Channel Blockers (CCBs):**
   a. **Cardizem® CD (Diltiazem CD 360mg Capsules) Approval Criteria:**
      i. Authorization requires a patient-specific, clinically significant reason why the member cannot use (2) 180mg Cardizem® CD (diltiazem CD) capsules.
   b. **Conjupri® (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) Approval Criteria:**
      i. An FDA approved diagnosis of hypertension or coronary artery disease; and
      ii. A patient specific, clinically significant reason why the member cannot use amlodipine oral tablets, even when 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 of treatment of proliferating infantile hemangioma requiring systemic therapy.

Kapspargo™ 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 indication; 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® 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).

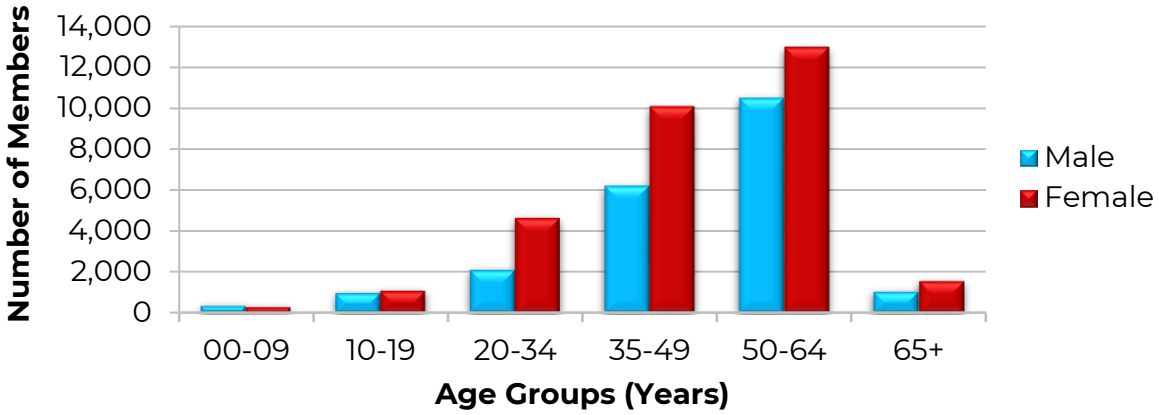
Utilization of Antihypertensive Medications: Calendar Year 2021

Comparison of Calendar Years

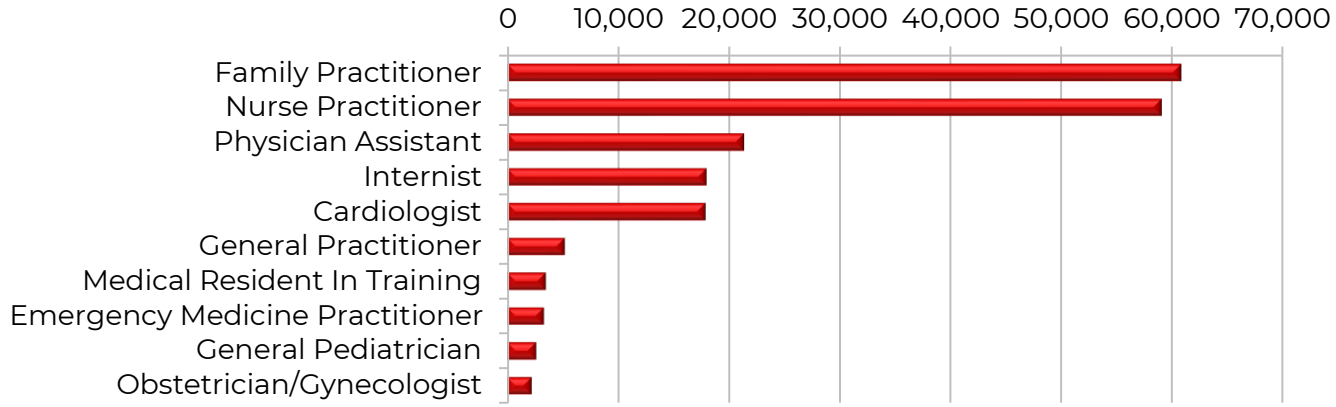
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	33,382	162,342	$2,795,233.38	$17.22	$0.33	10,350,985	8,591,853
2021	51,840	206,789	$3,428,913.84	$16.58	$0.30	13,668,720	11,550,751
% Change	**55.3%**	**27.4%**	**22.7%**	**-3.7%**	**-9.1%**	**32.1%**	**34.4%**
Change	**18,458**	**44,447**	**$633,680.46**	**-$0.64**	**-$0.03**	**3,317,735**	**2,958,898**

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

Demographics of Members Utilizing Antihypertensive Medications



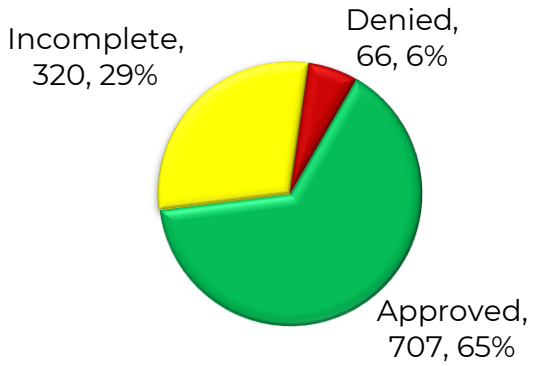
Top Prescriber Specialties of Antihypertensive Medications by Number of Claims



Prior Authorization of Antihypertensive Medications

There were 1,093 prior authorization requests submitted for antihypertensive medications during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[3]

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

Recommendations

The College of Pharmacy does not recommend any changes to the current antihypertensive medications PBPA category at this time.

Utilization Details of Antihypertensive Medications: Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ANGIOTENSIN I CONVERTING ENZYME INHIBITORS (ACEIs)					
TIER-1 UTILIZATION					
LISINOPRIL TAB 20MG	18,422	7,389	$182,283.32	$9.89	2.49
LISINOPRIL TAB 10MG	17,910	7,369	$167,413.31	$9.35	2.43
LISINOPRIL TAB 40MG	9,356	3,444	$112,042.59	$11.98	2.72
LISINOPRIL TAB 5MG	8,136	3,186	$76,681.04	$9.42	2.55
LISINOPRIL TAB 2.5MG	3,747	1,369	$35,779.07	$9.55	2.74
LISINOPRIL TAB 30MG	1,289	487	$14,351.65	$11.13	2.65
ENALAPRIL TAB 2.5MG	728	146	$12,725.17	$17.48	4.99
ENALAPRIL TAB 5MG	689	161	$13,005.50	$18.88	4.28
ENALAPRIL TAB 20MG	645	187	$14,291.68	$22.16	3.45
ENALAPRIL TAB 10MG	630	176	$11,554.46	$18.34	3.58
BENAZEPRIL TAB 20MG	325	111	$3,887.12	$11.96	2.93
BENAZEPRIL TAB 40MG	211	75	$2,497.13	$11.83	2.81
BENAZEPRIL TAB 10MG	204	61	$2,551.16	$12.51	3.34
RAMIPRIL CAP 10MG	143	50	$1,840.42	$12.87	2.86

[3] 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 03/2022. Last accessed 03/11/2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
RAMIPRIL CAP 5MG	76	29	$807.25	$10.62	2.62
QUINAPRIL TAB 40MG	74	20	$1,183.48	$15.99	3.7
QUINAPRIL TAB 20MG	62	15	$976.37	$15.75	4.13
BENAZEPRIL TAB 5MG	59	21	$730.72	$12.39	2.81
FOSINOPRIL TAB 20MG	46	9	$808.47	$17.58	5.11
RAMIPRIL CAP 2.5MG	44	23	$487.17	$11.07	1.91
RAMIPRIL CAP 1.25MG	43	17	$621.95	$14.46	2.53
FOSINOPRIL TAB 40MG	26	6	$503.20	$19.35	4.33
FOSINOPRIL TAB 10MG	25	10	$480.02	$19.20	2.5
PERINDOPRIL TAB 8MG	11	3	$265.50	$24.14	3.67
QUINAPRIL TAB 10MG	10	3	$125.98	$12.60	3.33
QUINAPRIL TAB 5MG	4	1	$76.27	$19.07	4
PERINDOPRIL TAB 2MG	3	1	$70.47	$23.49	3
PERINDOPRIL TAB 4MG	2	2	$60.69	$30.35	1
TRANDOLAPRIL TAB 2MG	2	1	$32.06	$16.03	2
TRANDOLAPRIL TAB 4MG	2	1	$43.12	$ 21.56	2
MOEXIPRIL TAB 15MG	2	1	$130.11	$65.06	2
TIER-1 SUBTOTAL	**62,926**	**24,374**	**$658,306.45**	**$10.46**	**2.58**
TIER-2 UTILIZATION					
CAPTOPRIL TAB 25MG	70	13	$3,326.71	$47.52	5.38
CAPTOPRIL TAB 50MG	39	7	$2,802.43	$71.86	5.57
CAPTOPRIL TAB 100MG	11	1	$1,073.40	$97.58	11
CAPTOPRIL TAB 12.5MG	4	2	$233.12	$58.28	2
TIER-2 SUBTOTAL	**124**	**23**	**$7,435.66**	**$59.97**	**5.39**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
EPANED SOL 1MG/ML	1,173	218	$372,807.29	$317.82	5.38
ENALAPRIL SOL 1MG/ML	222	107	$64,140.79	$288.92	2.07
QBRELIS SOL 1MG/ML	106	20	$49,286.46	$464.97	5.3
SPECIAL PA SUBTOTAL	**1,501**	**345**	**$486,234.54**	**$323.94**	**4.35**
ACEI TOTAL	**64,551**	**24,742**	**$1,151,976.65**	**$17.85**	**2.61**
CALCIUM CHANNEL BLOCKERS (CCBs)					
TIER-1 UTILIZATION					
AMLODIPINE TAB 10MG	19,999	7,369	$199,805.61	$9.99	2.71
AMLODIPINE TAB 5MG	15,761	6,258	$153,651.40	$9.75	2.52
AMLODIPINE TAB 2.5MG	2,333	913	$23,516.69	$10.08	2.56
NIFEDIPINE TAB 30MG ER	1,435	801	$28,793.54	$20.07	1.79
NIFEDIPINE TAB 60MG ER	850	350	$19,363.12	$22.78	2.43
DILTIAZEM CAP 120MG ER	757	301	$15,781.52	$20.85	2.51
DILTIAZEM CAP 240MG ER	642	215	$17,090.01	$26.62	2.99
NIFEDIPINE TAB 30MG ER	569	294	$11,370.09	$19.98	1.94
DILTIAZEM CAP 180MG ER	476	193	$12,401.88	$26.05	2.47
NIFEDIPINE TAB 60MG ER	439	177	$10,012.86	$22.81	2.48
NIFEDIPINE CAP 10MG	435	289	$14,956.70	$34.38	1.51

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
VERAPAMIL TAB 240MG ER	323	96	$6,062.36	$18.77	3.36
NIFEDIPINE TAB 90MG ER	277	114	$8,744.58	$31.57	2.43
VERAPAMIL TAB 120MG ER	254	98	$6,328.82	$24.92	2.59
DILTIAZEM TAB 30MG	251	97	$4,651.62	$18.53	2.59
DILTIAZEM TAB 60MG	250	86	$5,425.95	$21.70	2.91
DILTIAZEM TAB 120MG	203	64	$5,146.80	$25.35	3.17
VERAPAMIL TAB 180MG ER	191	65	$3,815.65	$19.98	2.94
NIFEDIPINE TAB 90MG ER	182	80	$5,839.99	$32.09	2.28
VERAPAMIL TAB 40MG	151	50	$3,059.60	$20.26	3.02
VERAPAMIL TAB 80MG	123	55	$1,626.31	$13.22	2.24
NIFEDIPINE CAP 20MG	106	57	$9,857.36	$92.99	1.86
VERAPAMIL TAB 120MG	105	34	$1,558.25	$14.84	3.09
DILTIAZEM CAP 360MG ER	95	35	$4,092.87	$43.08	2.71
DILTIAZEM CAP 120MG/24HR	88	48	$2,222.50	$25.26	1.83
DILT-XR CAP 240MG	88	35	$4,162.61	$47.30	2.51
DILTIAZEM CAP 240MG/24HR	70	29	$3,085.27	$44.08	2.41
CARTIA XT CAP 120/24HR	69	35	$1,403.79	$20.34	1.97
DILTIAZEM TAB 90MG	65	17	$1,888.84	$29.06	3.82
CARTIA XT CAP 240/24HR	65	43	$1,791.24	$27.56	1.51
DILT-XR CAP 180MG	64	20	$2,125.79	$33.22	3.2
DILT-XR CAP 120MG	63	30	$1,606.47	$25.50	2.1
DILTIAZEM CAP 300MG ER	62	27	$2,388.24	$38.52	2.3
CARTIA XT CAP 180/24HR	45	29	$1,186.59	$26.37	1.55
DILTIAZEM CAP 180MG/24HR	37	21	$1,191.45	$32.20	1.76
CARTIA XT CAP 300/24HR	24	10	$786.34	$32.76	2.4
FELODIPINE TAB 5MG ER	21	11	$370.31	$17.63	1.91
DILTIAZEM CAP 240MG ER	16	5	$549.63	$34.35	3.2
FELODIPINE TAB 10MG ER	13	7	$295.13	$22.70	1.86
NIMODIPINE CAP 30MG	11	7	$1,529.71	$39.06	1.57
DILTIAZEM CAP 300MG ER	10	4	$499.42	$49.94	2.5
DILTIAZEM CAP 420MG/24HR	7	3	$613.15	$87.59	2.33
TIADYLT CAP 120MG/24HR	4	3	$121.64	$30.41	1.33
TIADYLT CAP 240MG/24HR	3	3	$141.64	$47.21	1
DILTIAZEM CAP 180MG ER	3	2	$61.35	$20.45	1.5
VERAPAMIL INJ 2.5MG/ML	1	1	$137.95	$137.95	1
TAZTIA XT CAP 360MG/24HR	1	1	$64.16	$64.16	1
TIADYLT CAP 360MG/24HR	1	1	$24.61	$24.61	1
DILTIAZEM CAP 120MG ER	1	1	$18.10	$18.10	1
TIER-1 SUBTOTAL	**47,039**	**18,484**	**$601,219.51**	**$12.78**	**2.54**
TIER-2 UTILIZATION					
VERAPAMIL CAP 240MG SR	36	12	$3,168.29	$88.01	3
VERAPAMIL CAP 360MG SR	32	11	$8,700.47	$271.89	2.91
VERAPAMIL CAP 180MG SR	31	13	$3,108.01	$100.26	2.38

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
DILTIAZEM ER TAB 180MG	28	9	$3,417.67	$122.06	3.11
VERAPAMIL CAP 120MG SR	26	4	$1,549.60	$59.60	6.5
AMLOD/ATORVA TAB 10-40MG	15	6	$2,197.14	$146.48	2.5
AMLOD/ATORVA TAB 5-40MG	15	4	$3,892.99	$259.53	3.75
DILTIAZEM ER TAB 240MG	15	7	$3,132.98	$208.87	2.14
AMLOD/ATORVA TAB 10-80MG	14	2	$2,874.24	$205.30	7
MATZIM LA TAB 420MG/24HR	14	2	$1,908.66	$136.33	7
VERAPAMIL CAP 300MG ER	14	4	$4,827.64	$344.83	3.5
DILTIAZEM CAP 120MG ER	13	5	$2,974.82	$228.83	2.6
DILTIAZEM CAP 60MG ER	13	4	$2,094.03	$161.08	3.25
AMLOD/ATORVA TAB 10-10MG	12	4	$1,937.05	$161.42	3
AMLOD/ATORVA TAB 10-20MG	11	3	$2,438.14	$221.65	3.67
AMLOD/ATORVA TAB 5-20MG	11	3	$1,806.80	$164.25	3.67
DILTIAZEM CAP 90MG ER	11	2	$1,115.54	$101.41	5.5
DILTIAZEM ER TAB 360MG	11	4	$1,498.57	$136.23	2.75
VERAPAMIL CAP 120MG ER	9	3	$604.55	$67.17	3
VERAPAMIL CAP 200MG ER	9	3	$2,108.36	$234.26	3
VERAPAMIL CAP 100MG ER	8	2	$1,490.47	$186.31	4
VERAPAMIL CAP 180MG ER	8	4	$772.36	$96.55	2
NICARDIPINE CAP 20MG	7	2	$1,993.37	$284.77	3.5
VERAPAMIL CAP 240MG ER	7	4	$617.55	$88.22	1.75
AMLOD/ATORVA TAB 5-10MG	5	1	$1,023.54	$204.71	5
MATZIM LA TAB 240MG/24HR	5	3	$966.71	$193.34	1.67
MATZIM LA TAB 360MG/24HR	5	1	$927.30	$185.46	5
AMLOD/ATORVA TAB 2.5-20MG	4	1	$2,170.23	$542.56	4
ISRADIPINE CAP 5MG	4	3	$491.15	$122.79	1.33
CARDIZEM LA TAB 120MG	4	3	$1,136.49	$284.12	1.33
MATZIM LA TAB 180MG/24	4	2	$761.77	$190.44	2
AMLOD/ATORVA TAB 2.5-10MG	2	1	$252.44	$126.22	2
ISRADIPINE CAP 2.5MG	2	2	$110.03	$55.02	1
TIER-2 SUBTOTAL	**405**	**134**	**$68,068.96**	**$168.07**	**3.02**
SPECIAL PA UTILIZATION					
KATERZIA SUS 1MG/ML	212	50	$83,940.14	$395.94	4.24
DILTIAZEM CAP 360MG CD	4	3	$533.48	$133.37	1.33
SPECIAL PA SUBTOTAL	**216**	**53**	**$84,473.62**	**$391.08**	**4.08**
CCB TOTAL	**47,660**	**18,671**	**$753,762.09**	**$15.82**	**2.55**
METOPROLOL PROUCTS					
NO PA REQUIRED					
METOPROLOL TARTRATE TAB 25MG	10,161	3,670	$100,581.45	$27.41	2.77
METOPROLOL SUCCINATE TAB 25MG	8,292	3,301	$120,897.16	$36.62	2.51
METOPROLOL TARTRATE TAB 50MG	7,024	2,390	$68,862.26	$28.81	2.94
METOPROLOL SUCCINATE TAB 50MG	6,663	2,509	$103,350.38	$41.19	2.66
METOPROLOL SUCCINATE TAB 100MG	3,454	1,208	$69,776.70	$57.76	2.86

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
METOPROLOL TARTRATE TAB 100MG	2,320	828	$23,688.36	$28.61	2.8
METOPROLOL SUCCINATE TAB 200MG	671	196	$17,486.20	$89.22	3.42
METOPROLOL TARTRATE TAB 75MG	82	41	$2,295.18	$55.98	2
METOPROLOL TARTRATE TAB 37.5MG	40	12	$616.55	$51.38	3.33
SUBTOTAL	**38,707**	**14,155**	**$507,554.24**	**$13.11**	**2.73**
SPECIAL PA UTILIZATION					
KAPSPARGO CAP 50MG	2	1	120.33	60.165	2
SPECIAL PA SUBTOTAL	**2**	**1**	**120.33**	**60.165**	**2**
METOPROLOL TOTAL	**38,709**	**14,156**	**$507,674.57**	**$13.12**	**2.73**
ANGIOTENSIN II RECEPTOR BLOCKERS (ARBs) AND ARB COMBINATION PRODUCTS					
TIER-1 UTILIZATION					
LOSARTAN TAB 50MG	7,444	2,985	$99,978.47	$13.43	2.49
LOSARTAN TAB 100MG	6,301	2,388	$91,488.49	$14.52	2.64
LOSARTAN TAB 25MG	5,342	2,147	$61,984.29	$11.60	2.49
LOSARTAN/HCTZ TAB 100-25	1,318	519	$24,702.29	$18.74	2.54
LOSARTAN/HCTZ TAB 50-12.5	1,139	502	$16,830.58	$14.78	2.27
LOSARTAN/HCTZ TAB 100-12.5	692	277	$10,639.06	$15.37	2.5
OLMESARTAN TAB 40MG	497	159	$8,827.72	$17.76	3.13
OLMESARTAN TAB 20MG	436	152	$6,715.89	$15.40	2.87
VALSARTAN TAB 80MG	378	149	$8,004.30	$21.18	2.54
VALSARTAN TAB 160MG	347	158	$8,637.96	$24.89	2.2
IRBESARTAN TAB 150MG	272	85	$5,410.00	$19.89	3.2
TELMISARTAN TAB 40MG	230	80	$7,368.49	$32.04	2.88
IRBESARTAN TAB 300MG	215	76	$5,043.26	$23.46	2.83
VALSARTAN TAB 320MG	193	75	$5,670.71	$29.38	2.57
TELMISARTAN TAB 80MG	172	52	$5,374.41	$31.25	3.31
VALSARTAN TAB 40MG	166	77	$3,832.10	$23.08	2.16
OLMESARTAN/HCTZ TAB 40-25MG	154	62	$4,178.79	$27.14	2.48
VALSARTAN/HCTZ TAB 160-12.5MG	147	56	$3,409.30	$23.19	2.63
VALSARTAN/HCTZ TAB 160-25MG	136	45	$3,451.44	$25.38	3.02
VALSARTAN/HCTZ TAB 320-25MG	132	51	$4,071.13	$30.84	2.59
IRBESARTAN TAB 75MG	130	34	$2,454.58	$18.88	3.82
TELMISARTAN TAB 20MG	113	38	$2,988.57	$26.45	2.97
OLMESARTAN TAB 5MG	109	32	$1,572.91	$14.43	3.41
CANDESARTAN TAB 8MG	109	55	$6,293.63	$57.74	1.98
OLMESARTAN/HCTZ TAB 20-12.5MG	96	37	$1,599.28	$16.66	2.59
OLMESARTAN/HCTZ TAB 40-12.5MG	93	33	$2,985.89	$32.11	2.82
CANDESARTAN TAB 16MG	93	43	$4,478.82	$48.16	2.16
CANDESARTAN TAB 4MG	83	30	$4,488.67	$54.08	2.77
VALSARTAN/HCTZ TAB 80-12.5MG	81	30	$1,765.62	$21.80	2.7
AMLODIPINE/VALSARTAN TAB 10-320MG	75	23	$3,130.39	$41.74	3.26
AMLODIPINE/VALSARTAN TAB 5-160MG	60	28	$1,936.80	$32.28	2.14
IRBESARTAN/HCTZ TAB 150-12.5MG	59	22	$1,577.99	$26.75	2.68

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
IRBESARTAN/HCTZ TAB 300-12.5MG	58	22	$1,663.70	$28.68	2.64
AMLODIPINE/VALSARTAN TAB 10-160MG	47	24	$1,777.00	$37.81	1.96
AMLOD/OLMESA TAB 10-40MG	41	14	$1,426.86	$34.80	2.93
VALSARTAN/HCTZ TAB 320-12.5MG	39	19	$1,434.42	$36.78	2.05
AMLODIPINE/VALSARTAN TAB 5-320MG	22	9	$733.73	$33.35	2.44
AMLOD/OLMESA TAB 5-20MG	13	7	$481.45	$37.03	1.86
AMLOD/OLMESA TAB 5-40MG	12	5	$361.21	$30.10	2.4
AMLOD/OLMESA TAB 10-20MG	9	5	$379.17	$42.13	1.8
EXFORGE HCT TAB 10-320-25MG	9	1	$1,789.83	$198.87	9
EXFORGE HCT TAB 10-160-25MG	7	2	$2,163.35	$309.05	3.5
BENICAR TAB 20MG	5	1	$1,176.80	$235.36	5
MICARDIS TAB 40MG	4	1	$2,558.05	$639.51	4
COZAAR TAB 50MG	3	1	$1,466.67	$488.89	3
AMLOD/VALSAR/HCTZ TAB 10-320-25MG	1	1	$50.02	$50.02	1
AMLOD/VALSAR/HCTZ TAB 5-160-25MG	1	1	$36.11	$36.11	1
TIER-1 SUBTOTAL	**27,083**	**10,613**	**$438,390.20**	**$16.19**	**2.55**
TIER-2 UTILIZATION					
CANDESARTAN TAB 32MG	36	15	$2,377.90	$	2.4
TELMISARTAN/HCTZ TAB 40-12.5MG	33	7	$3,276.25	$	4.71
TELMISARTAN/HCTZ TAB 80-12.5MG	32	8	$2,384.00	$	4
TELMISARTAN/HCTZ TAB 80-25MG	23	5	$2,053.99	$	4.6
OLMESA/AMLOD/HCTZ TAB 40-10-25MG	18	3	$1,778.39	$	6
OLMESA/AMLOD/HCTZ TAB 20-5-12.5MG	11	2	$574.42	$	5.5
OLMESA/AMLOD/HCTZ TAB 40-5-25MG	9	3	$1,485.10	$	3
TIER-2 SUBTOTAL	**162**	**43**	**$ 13,930.05**	**$85.99**	**3.77**
SPECIAL PA UTILIZATION					
EDARBYCLOR TAB 40-12.5MG	14	3	$4,490.16	$320.73	4.67
CANDESARTAN/HCTZ TAB 16-12.5MG	12	2	$791.09	$65.92	6
EDARBYCLOR TAB 40-25MG	11	3	$2,273.98	$206.73	3.67
SPECIAL PA SUBTOTAL	**37**	**8**	**$7,555.23**	**$204.20**	**4.625**
ARB TOTAL	**27,282**	**10,664**	**$459,875.48**	**$16.86**	**2.56**
SPIRONOLACTONE PRODUCTS					
NO PA REQUIRED					
SPIRONOLACTONE TAB 25MG	6,781	2,490	$83,831.29	$12.36	2.72
SPIRONOLACTONE TAB 50MG	3,737	1,395	$63,324.22	$16.95	2.68
SPIRONOLACTONE TAB 100MG	2,266	841	$46,046.93	$20.32	2.69
SUBTOTAL	**12,784**	**4,726**	**$193,202.44**	**$15.11**	**2.71**
SPECIAL PA UTILIZATION					
CAROSPIR SUS 25MG/5ML	208	49	73548.14	$353.60	4.24
SPECIAL PA SUBTOTAL	208	49	73548.14	$353.60	4.24
SPIRONOLACTONE TOTAL	**12,992**	**4,775**	**$266,750.58**	**$20.53**	**2.72**
ACEI/HYDROCHLOROTHIAZIDE (HCTZ) COMBINATION PRODUCTS					
TIER-1 UTILIZATION					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LISINOPRIL/HCTZ TAB 20-12.5MG	4,769	1,905	$56,433.81	$11.83	2.5
LISINOPRIL/HCTZ TAB 20-25MG	4,535	1,748	$47,892.79	$10.56	2.59
LISINOPRIL/HCTZ TAB 10-12.5MG	2,982	1,217	$31,686.72	$10.63	2.45
ENALAPRIL/HCTZ TAB 10-25MG	93	29	$1,689.98	$18.17	3.21
BENAZEPRIL/HCTZ TAB 10-12.5MG	46	16	$1,995.00	$43.37	2.88
ENALAPRIL/HCTZ TAB 5-12.5MG	38	8	$717.48	$18.88	4.75
BENAZEPRIL/HCTZ TAB 20-12.5MG	36	14	$1,716.38	$47.68	2.57
BENAZEPRIL/HCTZ TAB 20-25MG	35	11	$1,592.09	$45.49	3.18
QUINAPRIL/HCTZ TAB 20-12.5MG	10	2	$323.58	$32.36	5
BENAZEPRIL/HCTZ TAB 5-6.25MG	9	4	$640.69	$71.19	2.25
QUINAPRIL/HCTZ TAB 10-12.5MG	2	1	$59.63	$29.82	2
QUINAPRIL/HCTZ TAB 20-25MG	1	1	$34.38	$34.38	1
TIER-1 SUBTOTAL	**12,556**	**4,956**	**$ 144,782.53**	**$11.53**	**2.53**
ACEI/HCTZ TOTAL	**12,556**	**4,956**	**$ 144,782.53**	**$11.53**	**2.53**
PROPRANOLOL SOLUTION PRODUCTS					
NO PA REQUIRED					
PROPRANOLOL SOL 20MG/5ML	919	215	$20,992.34	$22.84	4.27
PROPRANOLOL SOL 40MG/5ML	25	11	$646.69	$25.87	2.27
SUBTOTAL	**944**	**226**	**$21,639.03**	**$22.92**	**4.18**
SPECIAL PA UTILIZATION					
HEMANGEOL SOL 4.28MG/ML	57	16	$41,763.63	$732.70	3.56
SPECIAL PA SUBTOTAL	**57**	**16**	**$41,763.63**	**$732.70**	**3.56**
PROPRANOLOL TOTAL	**1,001**	**242**	**$ 63,402.66**	**$ 63.34**	**4.14**
ACEI/CCB COMBINATION PRODUCTS					
TIER-1 UTILIZATION					
AMLODIPINE/BENAZPRIL CAP 10-20MG	305	94	$4,976.34	$16.32	3.24
AMLODIPINE/BENAZPRIL CAP 10-40MG	206	71	$4,005.19	$19.44	2.9
AMLODIPINE/BENAZPRIL CAP 5-20MG	141	56	$2,388.86	$16.94	2.52
AMLODIPINE/BENAZPRIL CAP 5-10MG	110	47	$1,874.19	$17.04	2.34
AMLODIPINE/BENAZPRIL CAP 5-40MG	56	17	$966.79	$17.26	3.29
AMLODIPINE/BENAZPRIL CAP 2.5-10MG	10	6	$178.41	$17.84	1.67
TIER-1 SUBTOTAL	**828**	**291**	**$14,389.78**	**$17.38**	**2.85**
ACEI/CCB TOTAL	**828**	**291**	**$14,389.78**	**$17.38**	**2.85**
MISCELLANEOUS (MISC) COMBINATION PRODUCTS					
NO PA REQUIRED					
ATENOLOL/CHLOR TAB 50-25MG	203	70	$5,973.48	$29.43	2.9
BISOPROLOL/HCTZ TAB 10/6.25	181	56	$5,735.55	$31.69	3.23
BISOPROLOL/HCTZ TAB 5-6.25MG	163	55	$4,727.56	$29.00	2.96
ATENOLOL/CHLOR TAB 100-25MG	104	35	$4,502.57	$43.29	2.97
BISOPROLOL/HCTZ TAB 2.5/6.25	69	25	$2,003.05	$29.03	2.76
METOPROLOL/HCTZ TAB 50-25MG	66	23	$4,954.25	$75.06	2.87
METOPROLOL/HCTZ TAB 100-25MG	17	9	$1,540.48	$90.62	1.89
METOPROLOL/HCTZ TAB 100-50MG	1	1	$149.54	$149.54	1

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
SUBTOTAL	**804**	**274**	**$29,586.48**	**$36.80**	**2.93**
MISC TOTAL	**804**	**274**	**$29,586.48**	**$36.80**	**2.93**
SOTALOL PRODUCTS					
NO PA REQUIRED					
SOTALOL HCL TAB 80MG	230	59	$3,332.98	$14.49	3.9
SOTALOL HCL TAB 120MG	81	15	$1,458.97	$18.01	5.4
SOTALOL AF TAB 80MG	23	10	$426.03	$18.52	2.3
SOTALOL HCL TAB 160MG	13	4	$281.64	$21.66	3.25
SOTALOL AF TAB 120MG	1	1	$10.87	$10.87	1
SUBTOTAL	**348**	**89**	**$5,510.49**	**$15.83**	**3.91**
SPECIAL PA UTILIZATION					
SOTYLIZE SOL 5MG/ML	58	9	$31,202.53	$537.97	6.44
SPECIAL PA SUBOTAL	**58**	**9**	**$31,202.53**	**$537.97**	**6.44**
SOTALOL TOTAL	**406**	**98**	**$36,713.02**	**$ 90.43**	**4.14**
TOTAL	**206,789**	**51,840***	**$3,428,913.84**	**$16.58**	**2.62**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
AF = atrial fibrillation; AMLOD = amlodipine; ATORVA = atorvastatin; CAP = capsule;
CD = controlled-delivery; CHLOR = chlorthalidone; ER = extended-release; HCL = hydrochloride;
HCT = hydrochlorothiazide; HCTZ = hydrochlorothiazide; HR = hour; INJ = injection; LA = long-acting;
OLMESA = olmesartan; SOL = solution; SR = sustained-release; SUS = suspension; TAB = tablet;
VALSAR = valsartan; XR = extra-release; XT = extra-time

Calendar Year 2021 Annual Review of Anti-Ulcer Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Anti-Ulcer Medications*			
Tier-1	**Tier-2**	**Tier-3**	**Special PA⁺**
dexlansoprazole (Dexilant® caps)	pantoprazole (Protonix® I.V.)	esomeprazole (Nexium® I.V.)	bismuth subcitrate potassium/ metronidazole/ tetracycline (Pylera® capsule)
esomeprazole (Nexium® caps)		esomeprazole strontium caps	bismuth subsalicylate/ metronidazole/ tetracycline (Helidac® Therapy dose pack)
esomeprazole (Nexium® packet) – **Brand Preferred**		omeprazole (Prilosec® susp, powder)	cimetidine (Tagamet® tabs)
lansoprazole (Prevacid® caps)		pantoprazole (Protonix® susp)	esomeprazole kit (Esomep-EZS™)
lansoprazole (Prevacid® ODT) – **Brand Preferred**		rabeprazole (Aciphex® sprinkles)	famotidine (Pepcid® susp)
omeprazole (Prilosec® caps)			glycopyrrolate (Glycate® tabs)
pantoprazole (Protonix® tabs)			nizatidine (Axid® caps & soln)
rabeprazole (Aciphex® tabs)			omeprazole/ amoxicillin/rifabutin (Talicia® caps)
sucralfate susp (Carafate®) – **Brand Preferred**			omeprazole/sodium bicarbonate (Zegerid® caps & pack)
			sucralfate susp (generic)

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

Anti-Ulcer Medications Tier-2 Approval Criteria:

1. A 14-day trial of all available Tier-1 medications titrated up to the recommended dose that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 medications; or
3. An indication not covered by lower tiered medications.

Anti-Ulcer Medications Tier-3 Approval Criteria:

1. A 14-day trial of all available Tier-1 and Tier-2 medications that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Contraindication(s) to all available Tier-1 and Tier-2 medications; or
3. An indication not covered by lower tiered medications; and
4. Special formulations including orally disintegrating tablets (ODTs), sprinkle capsules, granules, suspensions, and intravenous (IV) solutions require special reasoning for use.

Proton Pump Inhibitors for Pediatric Members Approval Criteria:

1. A recent 14-day trial of an H_2 receptor antagonist that has resulted in inadequate relief of symptoms or intolerable adverse effects; or
2. Recurrent or severe disease such as:
    a. Gastrointestinal (GI) bleed; or
    b. Zollinger-Ellison Syndrome or similar disease; and
3. Tier structure rules still apply.

Axid® (Nizatidine Capsules) Approval Criteria:

1. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.

Axid® (Nizatidine Solution) Approval Criteria:

1. A previous 14-day trial of famotidine suspension or a patient-specific, clinically significant reason why famotidine suspension is not appropriate for the member must be provided; and
2. Nizatidine solution (Axid®) will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral capsule formulation.

Esomep-EZS™ (Esomeprazole Kit) Approval Criteria:

1. A previous 14-day trial of esomeprazole magnesium and a patient-specific, clinically significant reason why other lower tiered proton pump inhibitors, including omeprazole and esomeprazole, along with over-the-counter (OTC) pill swallowing spray are not appropriate for the member must be provided; and

2. Current Tier structure rules will also apply.

Glycate® (Glycopyrrolate Tablets) Approval Criteria:

1. An FDA approved indication of adjunctive treatment of peptic ulcer disease (PUD) in members 12 years of age and older; and
2. A patient-specific, clinically significant reason why the member cannot use glycopyrrolate 1mg and 2mg tablets, which are available without a prior authorization, must be provided.

Helidac® Therapy (Bismuth Subsalicylate/Metronidazole/Tetracycline Dose Pack) and Pylera® (Bismuth Subcitrate Potassium/Metronidazole/ Tetracycline Capsule) Approval Criteria:

1. An FDA approved indication for the treatment of members with *Helicobacter pylori* (*H. pylori*) infection and active or previous duodenal ulcer disease; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components [bismuth subsalicylate, metronidazole, and tetracycline plus an histamine type 2 (H_2) receptor antagonist], must be provided; and
3. A patient-specific, clinically significant reason why the member cannot use the individual components of guideline recommended concomitant therapy for *H. pylori* infection (e.g., proton pump inhibitor (PPI)/H_2 receptor antagonist, amoxicillin, clarithromycin, and metronidazole), which are available without prior authorization, must be provided; and
4. A patient-specific, clinically significant reason why the member cannot use the individual components of triple-therapy treatments for *H. pylori* infection (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
5. For Helidac® Therapy, a quantity limit of 224 tablets/capsules per 14 days will apply; and
6. For Pylera®, a quantity limit of 120 capsules per 10 days will apply.

Pepcid® (Famotidine Suspension) Approval Criteria:

1. Famotidine suspension will have an age restriction of 6 years of age and younger. Members older than 6 years of age will require a patient specific, clinically significant reason why the member needs the liquid formulation and cannot use the oral tablet formulation.

Generic Sucralfate Suspension Approval Criteria:

1. Authorization consideration requires a patient specific, clinically significant reason why the member cannot use brand name Carafate® (sucralfate) suspension.

Tagamet® (Cimetidine Tablets) Approval Criteria:

1. A previous 14-day trial of famotidine or a patient-specific, clinically significant reason why famotidine is not appropriate for the member must be provided.

Talicia® (Omeprazole/Amoxicillin/Rifabutin Capsules) Approval Criteria:

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason why the member cannot use the individual components of other triple-therapy regimens approved for the same diagnosis (e.g., omeprazole, amoxicillin, and clarithromycin), which are available without prior authorization, must be provided; and
3. A quantity limit of 168 capsules per 14 days will apply.

Zegerid® (Omeprazole/Sodium Bicarbonate Capsules) Approval Criteria:

1. A patient specific, clinically significant reason why the member cannot use omeprazole and over-the-counter (OTC) sodium bicarbonate must be provided.

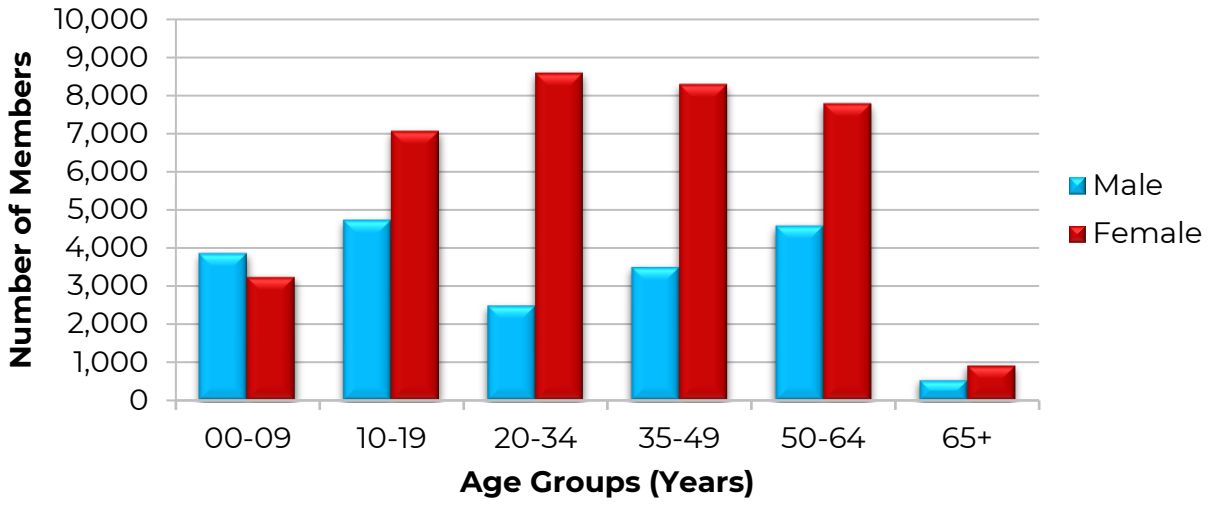
Utilization of Anti-Ulcer Medications: Calendar Year 2021

Comparison of Calendar Years

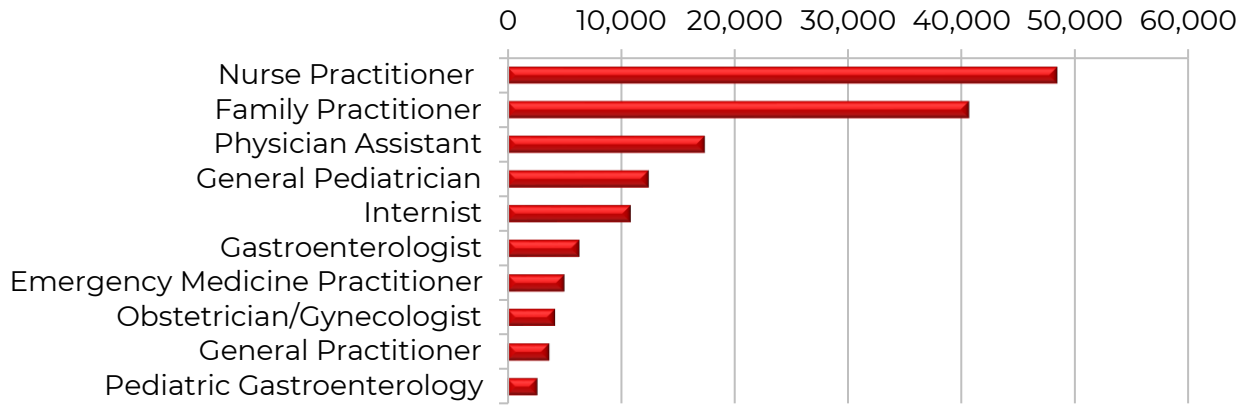
Calendar Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	40,481	136,751	$4,557,794.12	$33.33	$0.83	8,238,070	5,517,498
2021	55,487	166,853	$5,382,334.07	$32.26	$0.76	10,113,677	7,044,804
% Change	**37.1%**	**22.0%**	**18.1%**	**-3.2%**	**-8.4%**	**22.8%**	**27.7%**
Change	**15,006**	**30,102**	**$824,539.95**	**-$1.07**	**-$0.07**	**1,875,607**	**1,527,306**

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

Demographics of Members Utilizing Anti-Ulcer Medications



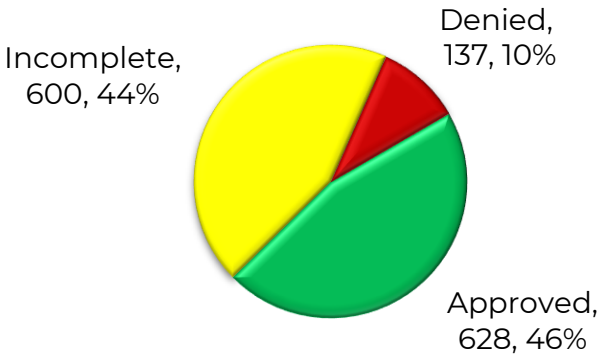
Top Prescriber Specialties of Anti-Ulcer Medications by Number of Claims



Prior Authorization of Anti-Ulcer Medications

There were 1,365 prior authorization requests submitted for anti-ulcer medications during calendar year 2021. The following chart shows the status of the submitted petitions for calendar year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[4]

- Dexilant® (dexlansoprazole capsule): March 2032
- Talicia® (omeprazole/amoxicillin/rifabutin capsule): February 2034

Recommendations

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

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[4] 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 03/2022. Last accessed 03/16/2022.

Utilization Details of Anti-Ulcer Medications: Calendar Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
TIER-1 UTILIZATION					
OMEPRAZOLE PRODUCTS					
OMEPRAZOLE CAP 20MG	38,959	15,300	$458,280.89	$11.76	2.55
OMEPRAZOLE CAP 40MG	28,712	10,972	$376,034.69	$13.10	2.62
OMEPRAZOLE CAP 10MG	2,135	843	$31,417.36	$14.72	2.53
SUBTOTAL	**69,806**	**27,115**	**$865,732.94**	**$12.40**	**2.57**
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE TAB 40MG	33,039	12,711	$430,904.88	$13.04	2.6
PANTOPRAZOLE TAB 20MG	5,406	2,227	$68,707.30	$12.71	2.43
SUBTOTAL	**38,445**	**14,938**	**$499,612.18**	**$13.00**	**2.57**
FAMOTIDINE PRODUCTS					
FAMOTIDINE TAB 20MG	16,735	8,504	$201,590.09	$12.05	1.97
FAMOTIDINE TAB 40MG	4,704	2,295	$65,897.41	$14.01	2.05
FAMOTIDINE INJ 10MG/ML	107	9	$1,405.60	$13.14	11.89
FAMOTIDINE INJ 200MG/20ML	52	6	$506.39	$9.74	8.67
FAMOTIDINE INJ 40MG/4ML	49	2	$974.31	$19.88	24.5
FAMOTIDINE INJ 20MG/2ML	35	5	$603.43	$17.24	7
SUBTOTAL	**21,682**	**10,821**	**$270,977.23**	**$12.50**	**2.00**
SUCRALFATE PRODUCTS					
SUCRALFATE TAB 1GM	7,372	4,255	$188,253.37	$25.54	1.73
CARAFATE SUS 1GM/10ML	145	47	$63,762.97	$39.74	3.09
SUBTOTAL	**7,517**	**4,302**	**$252,016.34**	**$33.53**	**1.75**
ESOMEPRAZOLE PRODUCTS					
ESOMEPRAZOLE CAP 40MG DR	2,993	1,072	$63,758.11	$21.30	2.79
ESOMEPRAZOLE CAP 20MG DR	1,310	583	$29,693.08	$22.67	2.25
NEXIUM GRA 10MG DR	651	207	$199,215.93	$306.02	3.14
NEXIUM GRA 20MG DR	395	89	$118,898.60	$301.01	4.44
NEXIUM GRA 5MG DR	307	136	$91,264.95	$297.28	2.26
NEXIUM GRA 2.5MG DR	164	102	$45,587.40	$277.97	1.61
NEXIUM GRA 40MG DR	153	33	$44,518.61	$290.97	4.64
ESOMEPRAZOLE GRA 20MG DR	4	2	$699.60	$174.90	2
ESOMEPRAZOLE GRA 40MG DR	2	1	$352.46	$176.23	2
NEXIUM CAP 40MG	2	1	$1,599.72	$799.86	2
SUBTOTAL	**5,981**	**2,226**	**$595,588.46**	**$99.58**	**2.69**
DEXLANSOPRAZOLE PRODUCTS					
DEXILANT CAP 60MG DR	3,415	618	$1,022,063.98	$299.29	5.53
DEXILANT CAP 30MG DR	734	177	$223,057.54	$303.89	4.15
SUBTOTAL	**4,149**	**795**	**$1,245,121.52**	**$300.10**	**5.22**
LANSOPRAZOLE PRODUCTS					
LANSOPRAZOLE CAP 30MG DR	1,862	623	$30,830.24	$16.56	2.99
LANSOPRAZOLE CAP 15MG DR	549	222	$12,627.59	$23.00	2.47

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
LANSOPRAZOLE 30MG ODT	238	42	$47,074.63	$197.79	5.67
LANSOPRAZOLE 15MG ODT	226	49	$49,217.18	$217.78	4.61
PREVACID 30MG STB	69	10	$29,210.89	$423.35	6.9
PREVACID 15MG STB	59	11	$24,711.61	$418.84	5.36
LANSOPRAZOLE TAB 30MG	23	10	$4,501.77	$195.73	2.3
SUBTOTAL	**3,026**	**967**	**$198,173.91**	**$65.49**	**3.13**
GLYCOPYRROLATE PRODUCTS					
GLYCOPYRROLATE TAB 1MG	1,465	278	$32,520.12	$22.20	5.27
GLYCOPYRROLATE TAB 2MG	866	121	$25,892.12	$29.90	7.16
SUBTOTAL	**2,331**	**399**	**$58,412.24**	**$25.06**	**5.84**
RABEPRAZOLE PRODUCTS					
RABEPRAZOLE TAB 20MG	252	86	$5,488.92	$21.78	2.93
SUBTOTAL	**252**	**86**	**$5,488.92**	**$21.78**	**2.93**
CIMETIDINE PRODUCTS					
CIMETIDINE SOL 300MG/5ML	219	138	$9,976.50	$45.55	1.59
SUBTOTAL	**219**	**138**	**$9,976.50**	**$45.55**	**1.59**
TIER-1 SUBTOTAL	**153,408**	**61,787**	**$4,001,100.24**	**$26.08**	**2.48**
TIER-2 UTILIZATION					
PANTOPRAZOLE PRODUCTS					
PANTOPRAZOLE INJ SOD 40MG	56	4	$2,699.46	$48.20	14
PROTONIX INJ 40MG	9	2	$374.07	$41.56	4.5
SUBTOTAL	**65**	**6**	**$3,073.53**	**$47.29**	**10.83**
TIER-2 SUBTOTAL	**65**	**6**	**$3,073.53**	**$47.29**	**10.83**
TIER-3 UTILIZATION					
OMEPRAZOLE PRODUCTS					
PRILOSEC POW 10MG	17	3	$6,309.45	$371.14	5.67
PRILOSEC POW 2.5MG	8	2	$5,839.12	$729.89	4
SUBTOTAL	**25**	**5**	**$12,148.57**	**$485.94**	**5.00**
PANTOPRAZOLE PRODUCTS					
PROTONIX PAK 40MG	24	3	$11,195.89	$466.50	8
SUBTOTAL	**24**	**3**	**$11,195.89**	**$466.50**	**8**
RABEPRAZOLE PRODUCTS					
ACIPHEX SPR CAP 10MG	3	1	$2,447.15	$815.72	3
SUBTOTAL	**3**	**1**	**$2,447.15**	**$815.72**	**3**
TIER-3 SUBTOTAL	**52**	**9**	**$25,791.61**	**$495.99**	**5.78**
SPECIAL PRIOR AUTHORIZATION (PA) UTILIZATION					
FAMOTIDINE PRODUCTS					
FAMOTIDINE SUS 40MG/5ML	11,641	4,933	$977,076.83	$83.93	2.36
SUBTOTAL	**11,641**	**4,933**	**$977,076.83**	**$83.93**	**2.36**
SUCRALFATE PRODUCTS					
SUCRALFATE SUS 1GM/10ML	1,394	842	$334,048.28	$239.63	1.66
SUBTOTAL	**1,394**	**842**	**$334,048.28**	**$239.63**	**1.66**
NIZATIDINE PRODUCTS					

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
NIZATIDINE SOL 15MG/ML	225	118	$34,092.98	$151.52	1.91
SUBTOTAL	**225**	**118**	**$34,092.98**	**$151.52**	**1.91**
CIMETIDINE PRODUCTS					
CIMETIDINE TAB 300MG	24	8	$552.47	$23.02	3
CIMETIDINE TAB 400MG	20	12	$808.59	$40.43	1.67
CIMETIDINE TAB 800MG	11	7	$970.13	$88.19	1.57
CIMETIDINE TAB 200MG	6	6	$189.50	$31.58	1
SUBTOTAL	**61**	**33**	**$2,520.69**	**$41.32**	**1.85**
TRIPLE THERAPY COMBINATIONS					
TALICIA CAP 10/250/12.5MG	7	7	$4,629.91	$661.42	1
SUBTOTAL	**7**	**7**	**$4,629.91**	**$661.42**	**1**
SPECIAL PA SUBTOTAL	**13,328**	**5,933**	**$1,352,368.69**	**$101.47**	**2.25**
TOTAL	**166,853**	**55,487***	**$5,382,334.07**	**$32.26**	**3.01**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; DR = delayed-release; GRA = granules; INJ = injection; ODT = orally disintegrating tablet; PAK = pack; POW = powder; SOD = sodium; SOL = solution; SPR = sprinkle; STB = solutab; SUS = suspension; TAB = tablet
Please note: Brand name Nexium® granules and Prevacid® ODT are preferred.

Fiscal Year 2021 Annual Review of Bladder Control Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Bladder Control Medications			
Tier-1	**Tier-2**	**Tier-3**	**Special PA**
fesoterodine (Toviaz®)	tolterodine (Detrol®)	darifenacin (Enablex®)	desmopressin acetate SL tablets (Nocdurna®)+
oxybutynin (Ditropan®)	tolterodine ER (Detrol LA®)	mirabegron (Myrbetriq®)Δ tablets and granulesβ	oxybutynin patch (Oxytrol®)+
oxybutynin ER (Ditropan XL®)		oxybutynin gel (Gelnique®)	vibegron (Gemtesa®)+
solifenacin (VESIcare®)Δ		trospium ER (Sanctura XR®)	
solifenacin oral susp (VESIcare LS™)α			
trospium (Sanctura®)			

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).
ΔUnique criteria specific to use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin) applies.
αAn age restriction of 2 to 10 years of age will apply for VESIcare LS™. Members older than 10 years of age will require a patient-specific, clinically significant reason why the oral tablet formulation cannot be used.
βThe Myrbetriq® granule formulation is covered for members 3 years of age or older weighing <35kg. Members weighing ≥35kg will require a patient-specific, clinically significant reason why the granule formulation is needed in place of the regular tablet formulation.
+Unique criteria specific to Gemtesa® (vibegron), Oxytrol® (oxybutynin patch), and Nocdurna® (desmopressin acetate SL tablets) applies.
ER = extended-release; PA = prior authorization; SL = sublingual; susp = suspension

Bladder Control Medications Tier-2 Approval Criteria:

1. A trial of all Tier-1 medications that yielded an inadequate clinical response or adverse effects; or
2. A unique indication which the Tier-1 medications lack.

Bladder Control Medications Tier-3 Approval Criteria:

1. A trial of all Tier-2 medications that yielded inadequate clinical response or adverse effects; or
2. A unique indication which the Tier-2 medications lack; and

3. For use of Myrbetriq® (mirabegron) in combination with VESIcare® (solifenacin), the member must have failed monotherapy with either mirabegron or solifenacin (minimum 4-week trial) defined by continued symptoms of urge urinary incontinence, urgency, and urinary frequency. Current tier structure rules will also apply.

Gemtesa® (Vibegron) Approval Criteria:

1. An FDA approved indication of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; and
2. Member must be 18 years of age or older; and
3. A patient-specific, clinically significant reason why all lower tiered medications are not appropriate for the member must be provided; and
4. A quantity limit of 30 tablets per 30 days will apply.

Nocdurna® (Desmopressin Acetate Sublingual Tablet) Approval Criteria:

1. An FDA approved diagnosis of nocturia due to nocturnal polyuria in adult members who awaken at least 2 times per night to void; and
2. All other causes of nocturia have been ruled out or adequately treated [e.g., benign prostatic hyperplasia (BPH), overactive bladder (OAB), obstructive sleep apnea (OSA)]; and
3. The prescriber must confirm the member has a 6-month history of at least 2 nocturic episodes per night; and
4. Member has failed behavior modifications including reducing caffeine intake, alcohol intake, and nighttime fluid intake; and
5. Member must have failed a trial of DDAVP® (desmopressin acetate tablets) or a patient-specific, clinically significant reason why the standard tablet formulation of desmopressin cannot be used must be provided; and
6. The prescriber must be willing to measure serum sodium levels prior to starting treatment and document levels are acceptable; and
7. The prescriber must agree to monitor serum sodium levels within the first week and approximately 1 month after starting treatment, and periodically during treatment; and
8. The prescriber must confirm the member is not taking loop diuretics; and
9. The prescriber must confirm the member does not have renal impairment with an estimated glomerular filtration rate (eGFR) $<50 mL/min/1.73 m^2$; and
10. Initial approvals will be for the duration of 3 months. For continued authorization, the prescriber must provide the following:
    a. Documentation that serum sodium levels are acceptable to the prescriber; and

b. Documentation that the member is responding to treatment; and

11. Approvals will be limited to the 27.7mcg dose for female members; and
12. A quantity limit of 30 tablets per 30 days will apply.

Oxytrol® (Oxybutynin 3.9mg/Day Patch) Approval Criteria:

1. An FDA approved diagnosis of overactive bladder; 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 quantity limit of 8 patches per 30 days will apply.

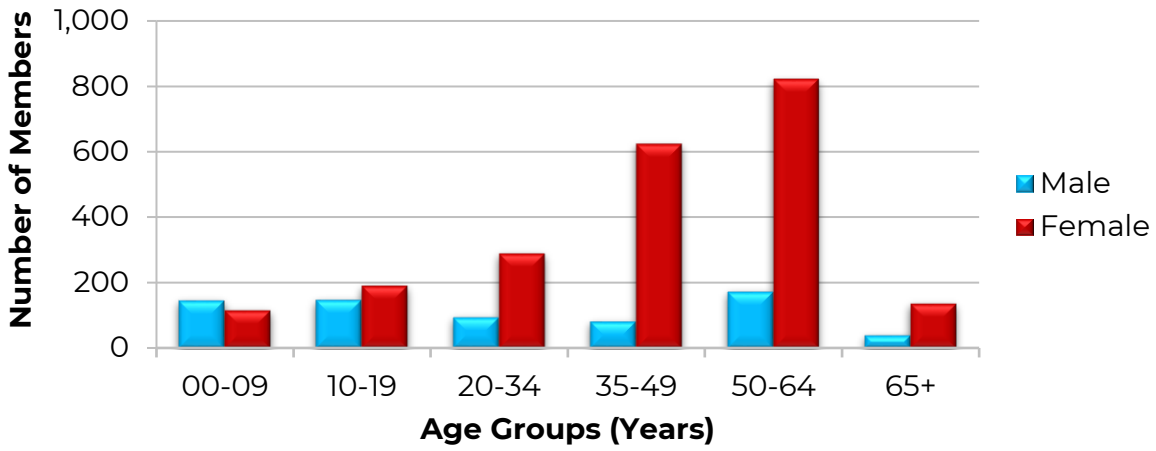
Utilization of Bladder Control Medications: Fiscal Year 2021

Comparison of Fiscal Years

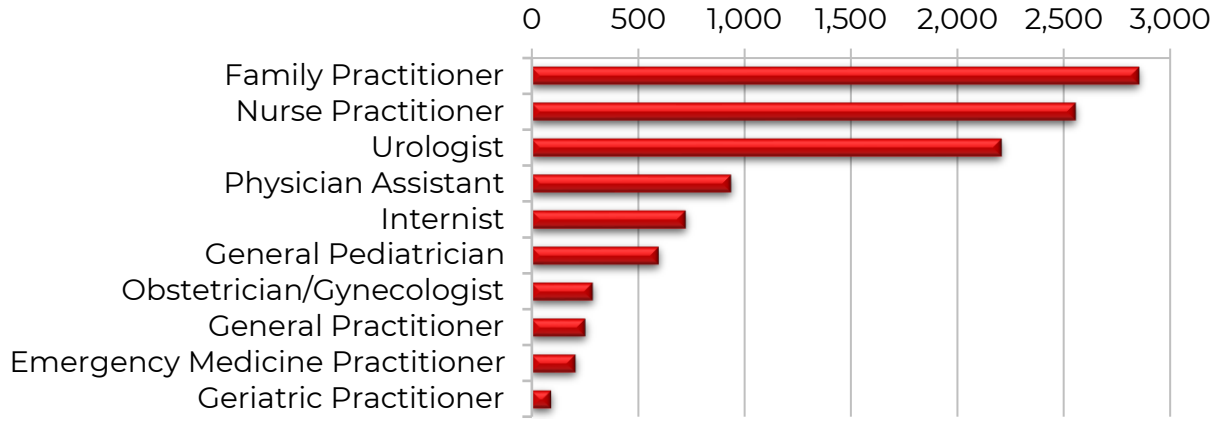
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	2,603	11,720	$654,078.92	$55.81	$1.60	804,673	408,883
2021	2,852	11,198	$658,702.73	$58.82	$1.50	830,693	439,035
% Change	**9.60%**	**-4.50%**	**0.70%**	**5.40%**	**-6.30%**	**3.20%**	**7.40%**
Change	**249**	**-522**	**$4,623.81**	**$3.01**	**-$0.10**	**26,020**	**30,152**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Bladder Control Medications



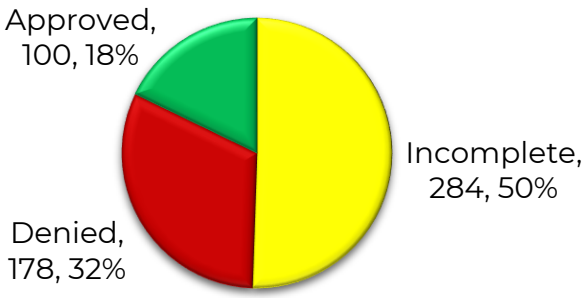
Top Prescriber Specialties of Bladder Control Medications by Number of Claims



Prior Authorization of Bladder Control Medications

There were 562 prior authorization requests submitted for bladder control medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[5]

- Toviaz® (fesoterodine tablet): December 2027
- Myrbetriq® (mirabegron tablet): March 2030
- Nocdurna® (desmopressin acetate sublingual tablet): April 2030
- Gemtesa® (vibegron tablet): December 2030
- Gelnique® (oxybutynin gel): March 2031
- VESIcare LS™ (solifenacin oral suspension): May 2031

[5] 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 02/2022. Last accessed 02/28/2022.

- Myrbetriq® (mirabegron granule): October 2036

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

- **June 2021:** The FDA approved Toviaz® (fesoterodine) for a new indication for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older weighing >25kg. Toviaz® was previously FDA approved for the treatment of adults with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency. Toviaz® is available as 4mg and 8mg extended-release tablets which must be swallowed whole and should not be chewed, crushed, or divided.[6,7]

Pipeline:

- **URO-902:** Urovant Sciences is developing URO-902, a novel gene therapy product for patients with OAB who have failed oral pharmacologic therapy. URO-902 is administered as an intradetrusor injection into the bladder wall under local anesthesia. A Phase 2A study evaluating the efficacy, safety, and tolerability of a single administration of URO-902 is ongoing and has enrolled 80 female patients with OAB. In March 2022, Urovant announced positive topline results of the study, which showed statistically significant effects on the number of micturitions, urgency episodes, and quality of life indicators compared to placebo at 12 weeks after administration. The study is expected to be completed later in 2022.[8,9]

Recommendations

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

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[6] Toviaz® (Fesoterodine Fumarate) – New Indication. OptumRx®. Available online at: https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/clinical-updates/clinicalupdates_toviaz_2021-0624.pdf. Issued 06/2021. Last accessed 02/28/2022.
[7] Toviaz® (Fesoterodine) Prescribing Information. Pfizer, Inc. Available online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022030s019lbl.pdf. Last revised 06/2021. Last accessed 02/28/2022.
[8] Urovant Sciences. Urovant Product Pipeline. Available online at: https://urovant.com/science. Last accessed 03/08/2022.
[9] Urovant Sciences. Urovant Sciences Announces Positive Topline Results of Phase 2A Trial of its Potential Novel Gene Therapy, URO-902. Available online at: https://media.urovant.com/news-releases/news-release-details/urovant-sciences-announces-positive-topline-results-phase-2a. Issued 03/07/2022. Last accessed 03/08/2022.

Utilization Details of Bladder Control Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 UTILIZATION						
OXYBUTYNIN PRODUCTS						
OXYBUTYNIN TAB 5MG	3,753	1,101	$61,243.90	$16.32	3.41	9.30%
OXYBUTYNIN TAB 10MG ER	2,090	606	$43,083.67	$20.61	3.45	6.54%
OXYBUTYNIN TAB 5MG ER	1,474	472	$29,846.68	$20.25	3.12	4.53%
OXYBUTYNIN SYP 5MG/5ML	787	220	$13,421.21	$17.05	3.58	2.04%
OXYBUTYNIN TAB 15MG ER	770	209	$17,253.29	$22.41	3.68	2.62%
SUBTOTAL	**8,874**	**2,608**	**$164,848.75**	**$18.58**	**3.4**	**25.03%**
FESOTERODINE PRODUCTS						
TOVIAZ TAB 8MG	414	95	$179,907.30	$434.56	4.36	27.31%
TOVIAZ TAB 4MG	338	101	$151,465.94	$448.12	3.35	22.99%
SUBTOTAL	**752**	**196**	**$331,373.24**	**$440.66**	**3.84**	**50.31%**
SOLIFENACIN PRODUCTS						
SOLIFENACIN TAB 10MG	395	118	$7,942.42	$20.11	3.35	1.21%
SOLIFENACIN TAB 5MG	283	124	$5,988.47	$21.16	2.28	0.91%
VESICARE TAB 10MG	14	6	$8,264.86	$590.35	2.33	1.25%
VESICARE TAB 5MG	12	6	$12,647.75	$1,053.98	2	1.92%
VESICARE LS SUS 5MG/5ML	1	1	$268.41	$268.41	1	0.04%
SUBTOTAL	**705**	**255**	**$35,111.91**	**$49.80**	**2.76**	**5.33%**
TROSPIUM PRODUCTS						
TROSPIUM CL TAB 20MG	172	56	$6,261.59	$36.40	3.07	0.95%
SUBTOTAL	**172**	**56**	**$6,261.59**	**$36.40**	**3.07**	**0.95%**
TIER-1 SUBTOTAL	**10,503**	**2,786***	**$537,595.49**	**$51.18**	**3.77**	**81.61%**
TIER-2 UTILIZATION						
TOLTERODINE PRODUCTS						
TOLTERODINE TAB 2MG	154	24	$6,782.12	$44.04	6.42	1.03%
TOLTERODINE CAP 4MG ER	132	24	$6,372.71	$48.28	5.5	0.97%
TOLTERODINE CAP 2MG ER	38	4	$1,502.83	$39.55	9.5	0.23%
TOLTERODINE TAB 1MG	12	2	$159.33	$13.28	6	0.02%
TIER-2 SUBTOTAL	**336**	**52***	**$14,816.99**	**$44.10**	**6.46**	**2.25%**
TIER-3 UTILIZATION						
MIRABEGRON PRODUCTS						
MYRBETRIQ TAB 50MG	161	24	$63,556.42	$394.76	6.71	9.65%
MYRBETRIQ TAB 25MG	63	11	$25,284.99	$401.35	5.73	3.84%
SUBTOTAL	**224**	**35**	**$88,841.41**	**$396.61**	**6.4**	**13.49%**
TROSPIUM PRODUCTS						
TROSPIUM CL CAP 60MG ER	107	15	$13,769.93	$128.69	7.13	2.09%
SUBTOTAL	**107**	**15**	**$13,769.93**	**$128.69**	**7.13**	**2.09%**
DARIFENACIN PRODUCTS						
DARIFENACIN TAB 15MG	23	2	$1,644.21	$71.49	11.5	0.25%
SUBTOTAL	**23**	**2**	**$1,644.21**	**$71.49**	**11.5**	**0.25%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OXYBUTYNIN PRODUCTS						
GELNIQUE GEL 10%	5	1	$2,034.70	$406.94	5	0.31%
SUBTOTAL	**5**	**1**	**$2,034.70**	**$406.94**	**5**	**0.31%**
TIER-3 SUBTOTAL	**359**	**50***	**$106,290.25**	**$296.07**	**7.18**	**16.14%**
TOTAL	**11,198**	**2,852***	**$658,702.73**	**$58.82**	**3.93**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CL = chloride; ER = extended-release; SUS = suspension; SYP = syrup; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Hereditary Angioedema (HAE) Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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. Must be used for *prophylaxis* of HAE; and
3. Not currently 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® Dosing:

a. The recommended dose of Orladeyo® is 150mg by mouth once daily; and
b. A quantity limit of 28 capsules per 28 days will apply; or

11. Takhzyro® Dosing:
    a. The recommended dose of Takhzyro® is 300mg sub-Q every 2 weeks (dosing every 4 weeks may be considered in some members); and
    b. Prescriber must verify member or caregiver has been trained by a health care professional on proper storage and sub-Q administration of Takhzyro®; and
    c. A quantity limit of (2) 300mg/2mL vials per 28 days will apply.

Berinert® (C1 Esterase Inhibitor), Firazyr® (Icatibant), Kalbitor® (Ecallantide), and Ruconest® (C1 Esterase Inhibitor) Approval Criteria:

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

Utilization of HAE Medications: Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	2	2	$78,925.51	$39,462.76	$2,721.57	13	29
2021	5	25	$807,343.31	$32,293.73	$1,408.98	127	573
% Change	**150.00%**	**1,150.00%**	**922.90%**	**-18.20%**	**-48.20%**	**876.90%**	**1,875.90%**
Change	**3**	**23**	**$728,417.80**	**-$7,169.03**	**-$1,312.59**	**114**	**544**

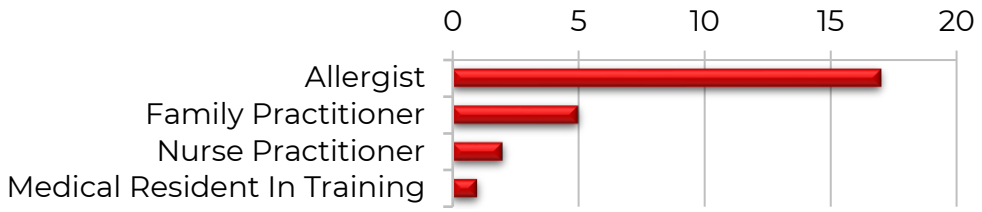
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

- There were no SoonerCare paid medical claims for HAE medications during fiscal year 2021.

Demographics of Members Utilizing HAE Medications

- Due to the limited number of members utilizing HAE medications during fiscal year 2021, detailed demographic information could not be provided.

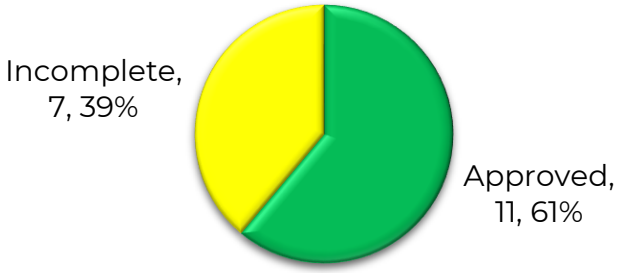
Top Prescriber Specialties of HAE Medications by Number of Claims



Prior Authorization of HAE Medications

There were 18 prior authorization requests submitted for HAE medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[10]

- Orladeyo® (berotralstat): November 2039

New U.S. Food and Drug Administration (FDA) Approval(s):[11]

- **February 2022:** The FDA approved Takhzyro® (lanadelumab-flyo) injection single-dose prefilled syringe (PFS) to prevent attacks of HAE in adult and pediatric patients 12 years of age and older. The PFS is ready to use and requires fewer preparation steps than the current Takhzyro® vial injection, while also reducing supplies and waste.

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[10] 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 03/2022. Last accessed 03/07/2022.

[11] Takeda. Takeda Receives U.S. FDA Approval for Prefilled Syringe Presentation of Takhzyro® (Lanadelumab-flyo) for Use as a Preventive Treatment for Hereditary Angioedema Attacks. Available online at: https://www.takeda.com/en-us/newsroom/news-releases/2022/takeda-receives-us-fda-approval-for-prefilled-syringe-presentation-of-takhzyro/. Issued 02/09/2022. Last accessed 03/08/2022.

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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TAKHZYRO INJ 300MG/2ML	15	3	$595,265.51	$39,684.37	5	73.73%
FIRAZYR INJ 30MG/3ML	4	1	$133,783.60	$33,445.90	4	16.57%
ICATIBANT INJ 30MG/3ML	4	2	$45,790.98	$11,447.75	2	5.67%
BERINERT INJ 500 UNIT	2	1	$32,503.22	$16,251.61	2	4.03%
TOTAL	**25**	**5***	**$807,343.31**	**$32,293.73**	**5**	**100%**

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

Fiscal Year 2021 Annual Review of Inhaled Anti-Infective Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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. Authorization of Tobi® Podhaler® requires a trial of tobramycin nebulized solution or a patient-specific, clinically significant reason why tobramycin nebulized solution is not appropriate for the member.
    b. Tobramycin nebulized solution (including Bethkis®, Kitabis® Pak, and generic 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.

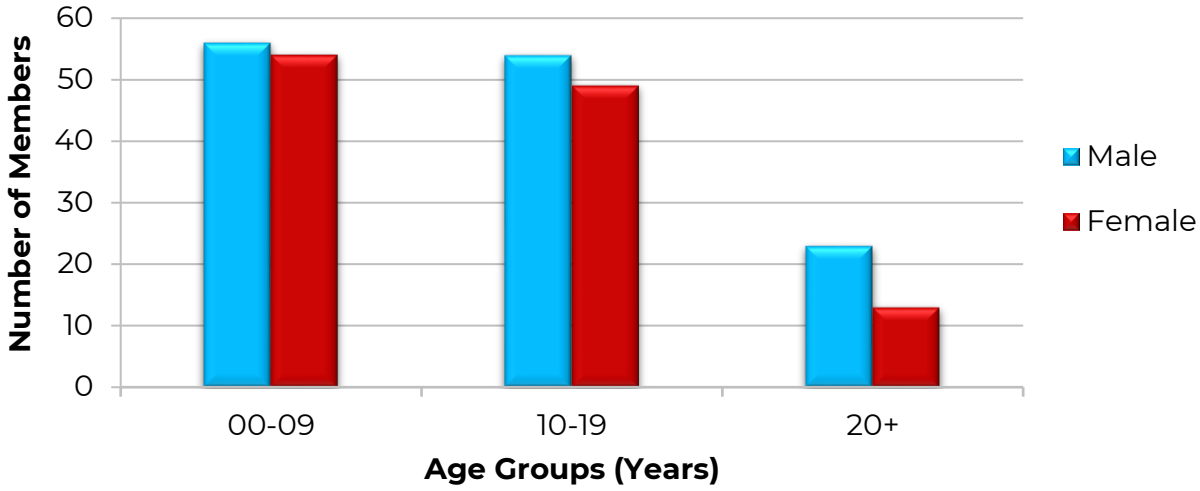
Utilization of Inhaled Anti-Infective Medications: Fiscal Year 2021

Comparison of Fiscal Years

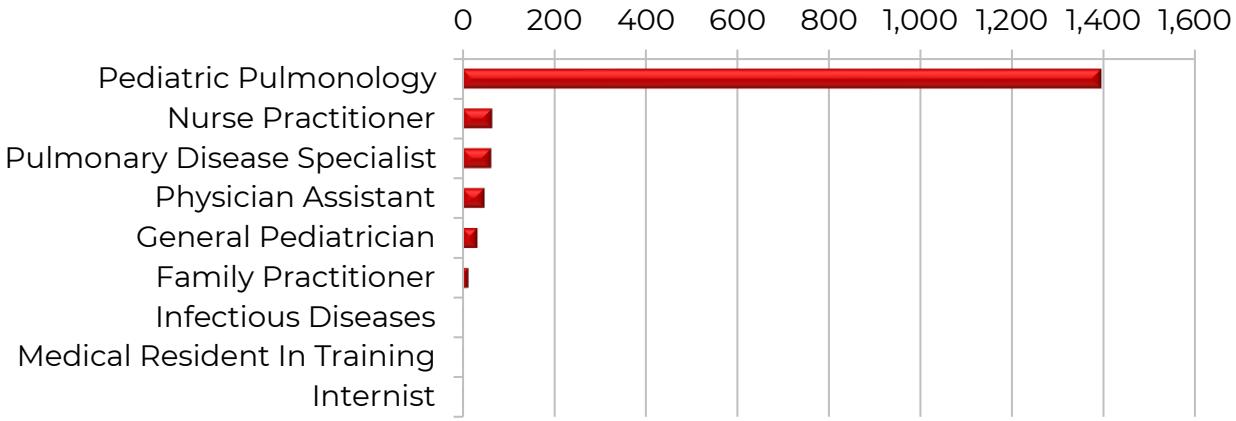
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	243	1,451	$5,235,977.81	$3,608.53	$94.88	190,092	55,187
2021	249	1,629	$5,751,005.68	$3,530.39	$91.21	222,311	63,055
% Change	**2.50%**	**12.30%**	**9.80%**	**-2.20%**	**-3.90%**	**16.90%**	**14.30%**
Change	**6**	**178**	**$515,027.87**	**-$78.14**	**-$3.67**	**32,219**	**7,868**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Inhaled Anti-Infective Medications



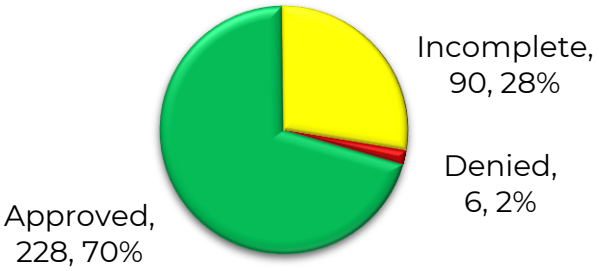
Top Prescriber Specialties of Inhaled Anti-Infective Medications by Number of Claims



Prior Authorization of Inhaled Anti-Infective Medications

There were 324 prior authorization requests submitted for inhaled anti-infective medications during fiscal year 2021. 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. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[12]

- Bethkis® (tobramycin inhalation solution): September 2022
- Tobi® Podhaler® (tobramycin inhalation powder): November 2030
- Arikayce® (amikacin liposome inhalation suspension): May 2035

Pipeline:

- **Opelconazole (PC945):** Pulmocide is developing opelconazole, an inhaled azole antifungal medication, for the treatment of pulmonary aspergillosis. Opelconazole is 30- to 100-fold more potent than voriconazole against *Aspergillus fumigatus*, with minimal systemic bioavailability after inhaled administration with a nebulizer. In September 2021, the U.S. Food and Drug Administration (FDA) granted Orphan Drug and Fast Track designations to opelconazole for the treatment of invasive pulmonary aspergillosis (IPA). A Phase 3 study in adult patients with refractory IPA has been planned but is not yet recruiting.[13,14,15]

Recommendations

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

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[12] 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 03/2022. Last Accessed 03/02/2022.

[13] Pulmocide Ltd. PC945. Available online at: https://pulmocide.com/product/pc945/. Last accessed 03/02/2022.

[14] Pulmocide Ltd. Pulmocide's Lead Drug Candidate Opelconazole (PC945) Granted Orphan Drug, Fast Track and Qualified Infectious Disease Product Designations by U.S. FDA. Available online at: https://www.biospace.com/article/releases/-pulmocide-s-lead-drug-candidate-opelconazole-pc945-granted-orphan-drug-fast-track-and-qualified-infectious-disease-product-designations-by-us-fda/. Issued 09/15/2021. Last accessed 03/02/2022.

[15] Safety and Efficacy of PC945 in Combination with Other Antifungal Therapy for the Treatment of Refractory Invasive Pulmonary Aspergillosis. *ClinicalTrials.gov.* Available online at: https://clinicaltrials.gov/ct2/show/NCT05238116. Last revised 02/14/2022. Last accessed 03/02/2022.

Utilization Details of Inhaled Anti-Infective Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DORNASE ALFA PRODUCTS						
PULMOZYME SOL 1MG/ML	1,086	157	$3,917,507.14	$3,607.28	6.92	68.12%
SUBTOTAL	**1,086**	**157***	**$3,917,507.14**	**$3,607.28**	**6.92**	**68.12%**
TOBRAMYCIN NEBULIZED PRODUCTS						
TOBRAMYCIN NEB 300MG/5ML	379	123	$474,079.09	$1,250.87	3.08	8.24%
TOBRAMYCIN NEB 300MG/4ML	19	7	$95,805.97	$5,042.42	2.71	1.67%
KITABIS PAK NEB 300MG/5ML	12	4	$54,136.92	$4,511.41	3	0.94%
BETHKIS NEB 300MG/4ML	11	6	$38,192.33	$3,472.03	1.83	0.66%
SUBTOTAL	**421**	**135***	**$662,214.31**	**$1,572.96**	**3.12**	**11.51%**
AZTREONAM PRODUCTS						
CAYSTON INH 75MG	77	20	$710,296.98	$9,224.64	3.85	12.35%
SUBTOTAL	**77**	**20***	**$710,296.98**	**$9,224.64**	**3.85**	**12.35%**
TOBRAMYCIN POWDER PRODUCTS						
TOBI PODHALER CAP 28MG	32	8	$305,166.91	$9,536.47	4	5.31%
SUBTOTAL	**32**	**8***	**$305,166.91**	**$9,536.47**	**4**	**5.31%**
AMIKACIN PRODUCTS						
ARIKAYCE SUS 590MG/8.4ML	13	2	$155,820.34	$11,986.18	6.5	2.71%
SUBTOTAL	**13**	**2***	**$155,820.34**	**$11,986.18**	**6.5**	**2.71%**
TOTAL	**1,629**	**249***	**$5,751,005.68**	**$3,530.39**	**6.54**	**100%**

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 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Injectable and Vaginal Progesterone Products

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Crinone® (Progesterone Vaginal Gel) Approval Criteria:

1. Current singleton pregnancy; and
2. Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and
3. Cervical length of ≤20mm; and
4. Gestational age between 20 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. A patient-specific, clinically significant reason why the member cannot use Endometrin® (progesterone vaginal insert) must be provided; and
6. Authorizations will be given for treatment through 36 weeks, 6 days of gestation; and
7. Crinone® will not be approved for use with assisted reproductive technology (ART) for female infertility.

Endometrin® (Progesterone Vaginal Insert) Approval Criteria:

1. Current singleton pregnancy; and
2. Member must not have history of previous singleton spontaneous preterm delivery (SPTD); and
3. Cervical length of ≤20mm; and
4. Gestational age between 20 weeks, 0 days and 26 weeks, 6 days of gestation; and
5. Authorizations will be given for treatment through 36 weeks, 6 days of gestation; and
6. Endometrin® will not be approved for use with assisted reproductive technology (ART) for female infertility.

Hydroxyprogesterone Caproate 250mg/mL Injection (Generic Delalutin®/Delta-Lutin®) Approval Criteria:

1. An FDA approved indication of 1 of the following in non-pregnant women:
    a. For the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV); or
    b. For the management of amenorrhea (primary and secondary) or abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer; or

    c. As a test for endogenous estrogen production or for the production of secretory endometrium and desquamation; and
2. The quantity approved will be patient-specific depending on patient diagnosis, maximum recommended dosage, and manufacturer packaging; and
3. Requests for the prevention of preterm birth in pregnant women with a history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation will not be approved for generic Delalutin®/Delta-Lutin® and should be resubmitted for authorization consideration of Makena® (hydroxyprogesterone caproate injection).

Makena® [Hydroxyprogesterone Caproate Intramuscular (IM) Injection and Subcutaneous (Sub-Q) Auto-Injector] Approval Criteria:

1. Documented history of previous singleton spontaneous preterm delivery (SPTD) prior to 37 weeks gestation; and
2. Current singleton pregnancy; and
3. Gestational age between 16 weeks, 0 days and 26 weeks, 6 days of gestation; and
4. Authorizations will be for once weekly administration by a health care professional through 36 weeks, 6 days of gestation; and
5. For Makena® sub-Q auto-injector:
    a. Initial dose must be administered by a health care professional; and
    b. For self-administration, member or caregiver must be trained by a health care professional on sub-Q administration and storage of Makena® sub-Q auto-injector; and
    c. A patient-specific, clinically significant reason why Makena® IM injection cannot be used must be provided.* (*The manufacturer of Makena® has currently provided a supplemental rebate to make the sub-Q auto-injector available with the current Makena® criteria; however, use of Makena® sub-Q auto-injector will require a reason why Makena® IM injection cannot be used if the manufacturer chooses not to participate in supplemental rebates.)

When it is determined to be appropriate to use the compounded hydroxyprogesterone caproate product, this product is covered through SoonerCare as a medical-only benefit without a prior authorization requirement.

Utilization of Injectable and Vaginal Progesterone Products: Fiscal Year 2021

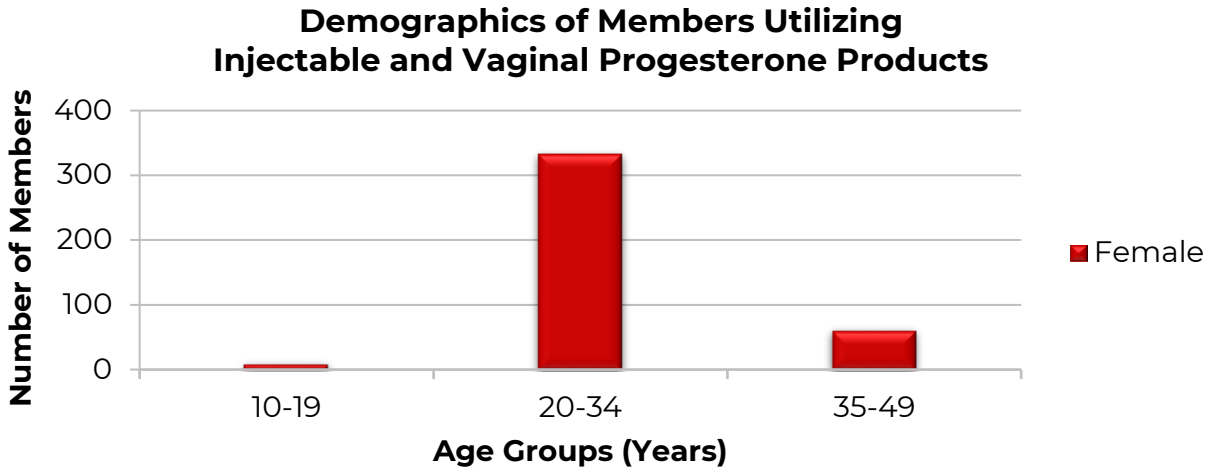
Please note, the compounded hydroxyprogesterone caproate product is billed by medical claims only and not reflected in the following pharmacy claims data. Fiscal year 2021 medical claim utilization details for the compounded hydroxyprogesterone caproate product can be found at the

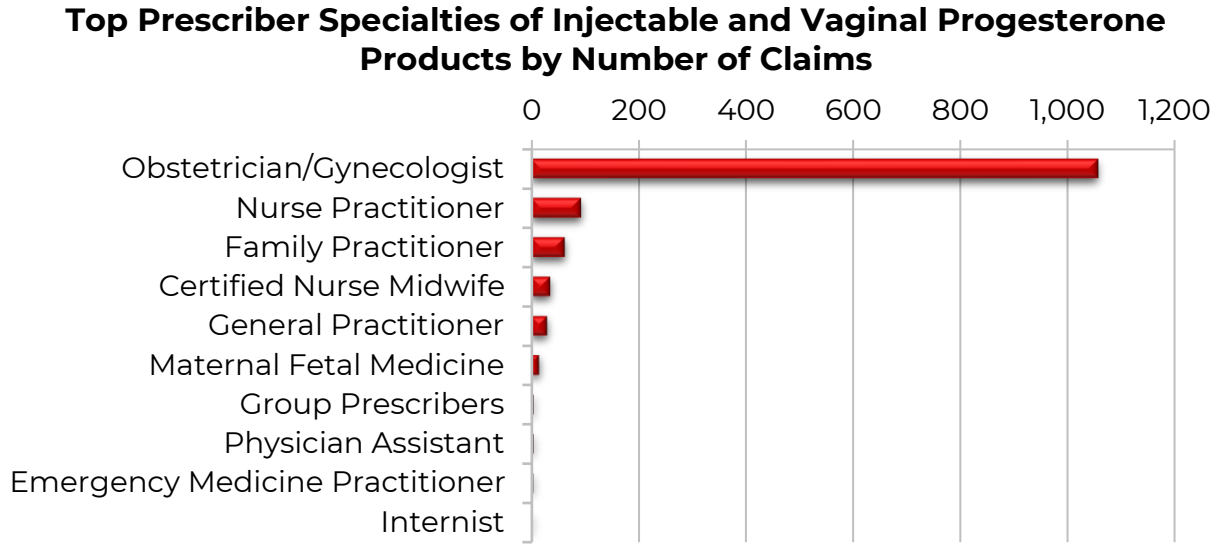
end of this report. The following utilization details include pharmacy claims data only.

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	584	1,855	$5,197,176.65	$2,801.71	$101.45	7,878	51,228
2021	403	1,314	$3,632,774.68	$2,764.67	$98.67	5,602	36,817
% Change	**-31.00%**	**-29.20%**	**-30.10%**	**-1.30%**	**-2.70%**	**-28.90%**	**-28.10%**
Change	**-181**	**-541**	**-$1,564,401.97**	**-$37.04**	**-$2.78**	**-2,276**	**-14,411**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

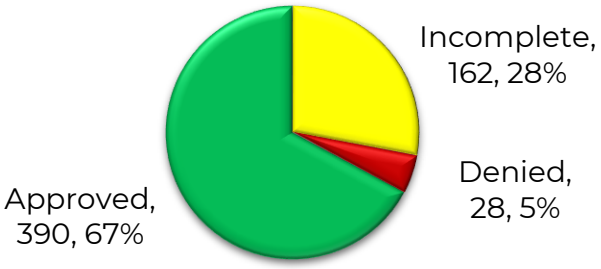




Prior Authorization of Injectable and Vaginal Progesterone Products

There were 580 prior authorization requests submitted for 385 unique members for injectable and vaginal progesterone products during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[16]

- Makena® [hydroxyprogesterone subcutaneous (sub-Q) auto-injector]: May 2036

News:

- **August 2021:** Previously in October 2020, the U.S. Food and Drug Administration (FDA) officially proposed the withdrawal of Makena® (hydroxyprogesterone caproate) and its generic equivalents from the market based on results of the PROLONG study which failed to show a reduction in preterm delivery or neonatal mortality and morbidity. Makena® received accelerated FDA approval in 2011 to reduce the risk of preterm birth in women with a singleton pregnancy and history of singleton spontaneous preterm birth. In August 2021, the FDA announced it has granted a public hearing to discuss the proposed withdrawal of Makena®. A date for the hearing has not been announced, and Makena® currently remains FDA approved and available on the market pending the results of the public hearing.[17,18]

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[16] 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 03/2022. Last Accessed 03/03/2022.

[17] Park B. FDA Proposes Makena® Be Withdrawn From the Market. *MPR*. Available online at: https://www.empr.com/home/news/safety-alerts-and-recalls/fda-center-drug-evaluation-research-cder-makena-hydroxyprogesterone-caproate/. Issued 10/07/2020. Last accessed 03/07/2022.

[18] Keown A. FDA Grants Public Hearing for Preterm Birth Drug Amidst Controversy. *BioSpace*. Available online at: https://www.biospace.com/article/preterm-birth-drug-makena-may-get-fda-hearing-following-decision-to-withdraw-approval/. Issued 08/20/2021. Last accessed 03/07/2022.

Guideline Updates:

- **August 2021:** The American College of Obstetricians and Gynecologists (ACOG) published updated guidelines for the prediction and prevention of spontaneous preterm birth, replacing the previous guidance from 2012. At this time, the ACOG continues to recommend considering progesterone supplementation for patients with a singleton pregnancy and a prior spontaneous preterm birth. Key recommendations regarding progesterone supplementation from the guidelines include:
  - Vaginal progesterone is recommended for asymptomatic individuals without a history of preterm birth with a singleton pregnancy and a short cervix (*Level A, based on good and consistent scientific evidence)*.
  - Intramuscular hydroxyprogesterone is not recommended in patients who do not have a history of spontaneous preterm delivery (*Level A, based on good and consistent scientific evidence)*.
  - Patients with a singleton pregnancy and a prior spontaneous preterm birth should be offered progesterone supplementation (either vaginal or intramuscular) in the context of a shared decision-making process incorporating the available evidence and the patient's preferences (*Level A, based on good and consistent scientific evidence)*.[19]

Recommendations

The College of Pharmacy does not recommend any changes to the current injectable and vaginal progesterone products prior authorization criteria at this time.

[19] American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Obstetrics. Prediction and Prevention of Spontaneous Preterm Birth: ACOG Practice Bulletin, Number 234. *Obstet Gynecol* 2021; 138(2):e65-e90.

Utilization Details of Injectable and Vaginal Progesterone Products: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
HYDROXYPROGESTERONE INJECTABLE PRODUCTS						
MAKENA INJ 275MG	855	254	$2,652,193.36	$3,101.98	3.37	73.01%
HYDROXYPROG INJ 250MG/ML	458	154	$980,305.24	$2,140.40	2.97	26.99%
SUBTOTAL	**1,313**	**402***	**$3,632,498.60**	**$2,766.56**	**3.27**	**99.99%**
PROGESTERONE VAGINAL PRODUCTS						
ENDOMETRIN SUP 100MG	1	1	$276.08	$276.08	1	0.01%
SUBTOTAL	**1**	**1***	**$276.08**	**$276.08**	**1**	**0.01%**
TOTAL	**1,314**	**403***	**$3,632,774.68**	**$2,764.67**	**3.26**	**100%**

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

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS†	TOTAL MEMBERS*	TOTAL COST	COST/ CLAIM
S5000 HYDROXYPROGESTERONE CAPROATE INJ	6	5	$66.78	$11.13
TOTAL	**6**	**5**	**$66.78**	**$11.13**

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

Fiscal Year 2021 Annual Review of Iron Chelating Agents

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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

1. An FDA approved diagnosis; and
2. A patient-specific, clinically significant reason other than convenience why the member cannot use Exjade® (deferasirox) must be provided; and
3. For Jadenu® Sprinkle (deferasirox oral granules), an age restriction of 6 years of age and younger will apply. Members older than 6 years of age will require a patient-specific, clinically significant reason why Jadenu® oral tablets cannot be used even when the tablets are crushed; and
4. The member's recent weight must be provided on the prior authorization request in order to authorize the appropriate amount of drug required according to package labeling.

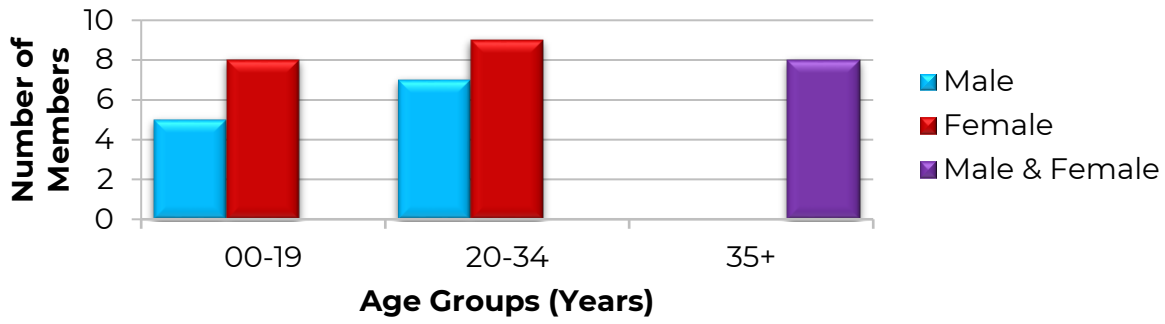
Utilization of Iron Chelating Agents: Fiscal Year 2021

Comparison of Fiscal Years

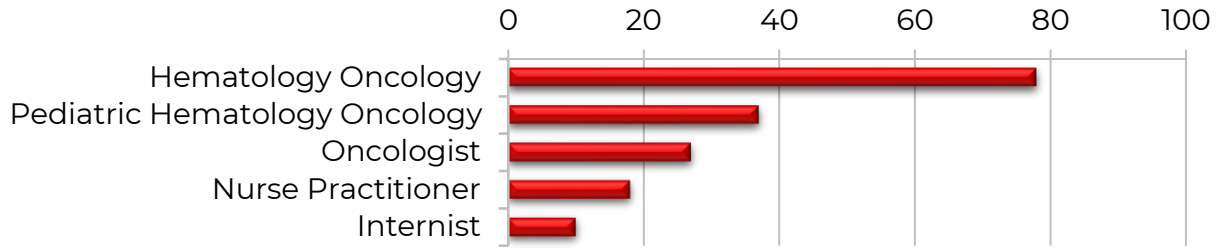
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	41	174	$1,598,308.75	$9,185.68	$303.63	13,596	5,264
2021	37	170	$953,634.47	$5,609.61	$188.39	11,967	5,062
% Change	**-9.8%**	**-2.3%**	**-40.3%**	**-38.9%**	**-38%**	**-12%**	**-3.8%**
Change	**-4**	**-4**	**-$644,674.28**	**-$3,576.07**	**-$115.24**	**-1,629**	**-202**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Iron Chelating Agents



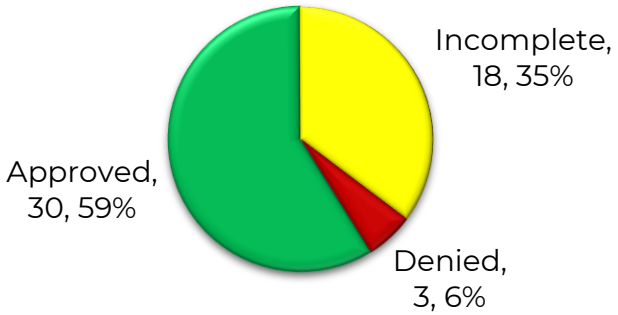
Top Prescriber Specialties of Iron Chelating Agents by Number of Claims



Prior Authorization of Iron Chelating Agents

There were 51 prior authorization requests submitted for iron chelating agents during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[20]

- Jadenu® (deferasirox): November 2034
- Ferriprox® (deferiprone): October 2038

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

- **May 2021:** The U.S. Food and Drug Administration (FDA) approved Ferriprox® (deferiprone) for new indications for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with sickle cell disease (SCD) or other anemias, adding to the previous FDA approved indication in patients with thalassemia syndromes. The new approval was based on a controlled study which compared the efficacy of Ferriprox® to deferoxamine in patients with SCD and other transfusion-dependent anemias which met the non-inferiority criterion for change in liver iron concentration from baseline

[20] 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 02/2022. Last Accessed 02/05/2022.

to month 12. Data from an extension study confirmed that liver iron concentration continued to decrease progressively over time with the mean value dropping from 14.93mg/g dry weight (DW) at baseline to 12.3mg/g DW after 1 year, to 11.19mg/g DW after 2 years, and to 10.45mg/g DW after 3 years of Ferriprox® treatment.[21]

News:

- **June 2021:** Aucta Pharmaceuticals, in partnership with Oakrum Pharma, announced the United States launch of a generic version of Jadenu® Sprinkle (deferasirox granules) in 90mg, 180mg, and 360mg strengths.[22]

Pipeline:

- **CN128:** CN128 is an orally active hydroxypyridinone iron chelator being developed and patented by Zede Pharma. CN128 is designed specifically to be an oral chelation agent for iron-overload conditions and to overcome deferiprone's myelosuppressive side effects and low pharmacodynamic efficiency. Currently CN128 has successfully passed Phase 1 clinical studies and Phase 2 studies are ongoing.[23]
- **Rusfertide (PTG-300):** Rusfertide is a novel injectable synthetic mimetic of the natural hormone hepcidin that offers greater potency, solubility, and stability, which translates to better *in vivo* pharmacokinetic and pharmacodynamic characteristics and manufacturability in comparison to the natural hormone. Hepcidin is a key regulator of iron absorption, storage, and distribution in the body and thereby controls the production of red blood cells (RBC) and abnormal tissue storage of iron. Rusfertide is currently in an ongoing Phase 2 study in patients for the treatment of polycythemia vera.[24]

Recommendations

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

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[21] Chiesi Global Rare Diseases. Chiesi Global Rare Diseases Announces FDA Approval of Ferriprox® (Deferiprone) for Treatment of Transfusional Iron Overload due to Sickle Cell Disease. Available online at: https://www.prnewswire.com/news-releases/chiesi-global-rare-diseases-announces-fda-approval-of-ferriprox-deferiprone-for-treatment-of-transfusional-iron-overload-due-to-sickle-cell-disease-301281606.html. Issued 05/01/2021. Last accessed 03/12/2022.

[22] Aucta Pharmaceuticals, Inc. Aucta Pharma and Oakrum Pharma Announce Launch of Generic Version of Jadenu® Sprinkle (Deferasirox Granules). Available online at: https://www.prnewswire.com/news-releases/aucta-pharma-and-oakrum-pharma-announce-launch-of-generic-version-of-jadenur-sprinkle-deferasirox-granules-301310888.html. Issued 06/14/2021. Last accessed 03/12/2022.

[23] Zede Pharma, Inc. Technology. Available online at: http://zedepharma.com/importantnotice/index.html. Last accessed 02/05/2022.

[24] Protagonist Therapeutics, Inc. Our Technology: PTG-300. Available online at: https://www.protagonist-inc.com/our-science/product-candidates/default.aspx#product-rusfertide. Last accessed 02/05/2022.

Utilization Details of Iron Chelating Agents: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
DEFERASIROX PRODUCTS						
DEFERASIROX TAB 360MG	60	19	$112,412.03	$1,873.53	3.15	11.79%
DEFERASIROX TAB 500MG	26	7	$69,587.29	$2,676.43	3.71	7.3%
JADENU TAB 360MG	25	8	$309,352.45	$12,374.10	3.13	32.44%
DEFERASIROX TAB 250MG	15	2	$2,982.94	$198.86	7.5	0.31%
JADENU SPRKL GRA 180MG	14	3	$45,765.44	$3,268.96	4.67	4.80%
EXJADE TAB 500MG	9	2	$131,817.89	$14,646.43	4.5	13.82%
DEFERASIROX TAB 180MG	5	1	$2,556.83	$511.37	5	0.27%
EXJADE TAB 125MG	3	2	$3,834.78	$1,278.26	1.5	0.40%
SUBTOTAL	**157**	**36***	**$678,309.65**	**$4,320.44**	**4.36**	**71.13%**
DEFERIPRONE PRODUCTS						
FERRIPROX TAB 1,000MG	13	1	$275,324.82	$19,402.00	13	28.87%
SUBTOTAL	**13**	**1***	**$275,324.82**	**$19,402.00**	**13**	**28.87%**
TOTAL	**170**	**37***	**$953,634.47**	**$5,609.61**	**4.59**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
GRA = granule; SPRKL = sprinkle; TAB = tablet
Please note: Exjade® was first FDA approved in 2005 and has a significant federal rebate.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Korlym® (Mifepristone)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Korlym® (Mifepristone) Approval Criteria:

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

Utilization of Korlym® (Mifepristone): Fiscal Year 2021

Comparison of Fiscal Years

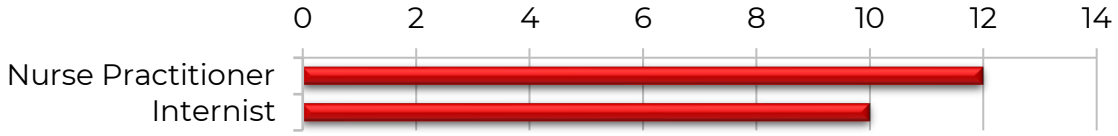
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	2	13	$192,668.27	$14,820.64	$529.31	378	378
2021	3	22	$556,954.95	$25,316.13	$881.26	1,050	1,050
% Change	**50%**	**69.2%**	**189.14%**	**70.8%**	**66.5%**	**177.8%**	**73.6%**
Change	**1**	**9**	**$364,286.68**	**$10,495.49**	**$351.95**	**672**	**268**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Korlym® (Mifepristone)

- There were 3 unique members utilizing Korlym® (mifepristone) during fiscal year 2021. Due to the limited number of utilizing members, detailed demographic information could not be provided.

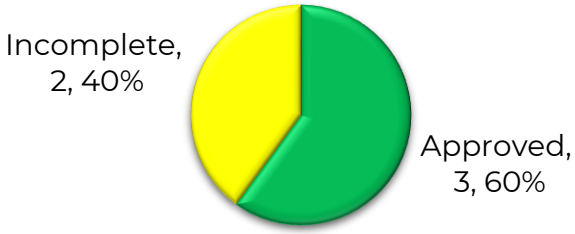
Top Prescriber Specialties of Korlym® (Mifepristone) by Number of Claims



Prior Authorization of Korlym® (Mifepristone)

There were 5 prior authorization requests submitted for Korlym® (mifepristone) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[25]

- Korlym® (mifepristone tablet): August 2038

[25] 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 01/2022. Last accessed 01/20/2022.

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

- **August 2020:** The FDA approved mifepristone 300mg tablets from Teva Pharmaceuticals as the first generic for Korlym® (mifepristone).[26]

News:

- **December 2021:** Teva Pharmaceuticals is trying to cancel the patent Corcept has over the drug Korlym® so that they can produce a generic version. Corcept sued Teva in 2018 over Teva's proposed generic infringing on their patent, and that case is still unresolved. Teva wants to cancel Corcept's patent, stating that their treatment was obvious from earlier publications. The ruling was in favor of Corcept in 2020 but Teva appealed. Chief U.S. Circuit Judge Kimberly Moore rejected Teva's appeal stating that it was not reasonable to assume Corcept's concept would be safe and effective based on prior knowledge. Teva was therefore unable to cancel the patent protecting Korlym® and Corcept's lawsuit against Teva regarding their generic mifepristone is still on-going. Teva's generic will not be available until Corcept's patents for Korlym® expire.[27]

Recommendations

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

Utilization Details of Korlym® (Mifepristone): Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
KORLYM TAB 300MG	22	3	$556,954.95	$25,316.13	7.33
SUBTOTAL	**22**	**3***	**$556,954.95**	**$25,316.13**	**7.33**

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

[26] U.S. FDA. 2020 First Generic Drug Approvals. Available online at: https://www.fda.gov/drugs/first-generic-drug-approvals/2020-first-generic-drug-approvals. Last revised 02/2021. Last accessed 01/20/2022.
[27] Brittain B. Teva Loses Bid to Cancel Corcept Drug Patent at Federal Circuit. *Reuters*. Available online at: https://www.reuters.com/legal/transactional/teva-loses-bid-cancel-corcept-drug-patent-federal-circuit-2021-12-07/. Issued 12/01/2021. Last accessed 01/20/2022.

Fiscal Year 2021 Annual Review of Ophthalmic Allergy Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Ophthalmic Allergy Medications		
Tier-1	**Tier-2**	**Tier-3**
cromolyn (Crolom®)	azelastine (Optivar®)	bepotastine (Bepreve®)
ketotifen (Alaway®, Zaditor® OTC)	epinastine (Elestat®)	cetirizine (Zerviate®)
	olopatadine 0.1% (Patanol®, Pataday® Twice Daily Relief OTC)	emedastine (Emadine®)
	olopatadine 0.7% (Pazeo®, Pataday® Once Daily Relief *Extra Strength* OTC)	lodoxamide (Alomide®)
		loteprednol (Alrex®)
		nedocromil (Alocril®)
		olopatadine 0.2% (Pataday®, Pataday® Once Daily Relief OTC)

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).
OTC = over-the-counter

Ophthalmic Allergy Medications Tier-2 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have a trial of 1 Tier-1 product for a minimum of 2 weeks in the last 30 days that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

Ophthalmic Allergy Medications Tier-3 Approval Criteria:

1. An FDA approved diagnosis; and
2. Member must have recent trials of 1 Tier-1 product and all available Tier-2 products for a minimum of 2 weeks each that did not yield adequate relief of symptoms or resulted in intolerable adverse effects; or
3. A contraindication to all lower tiered medications.

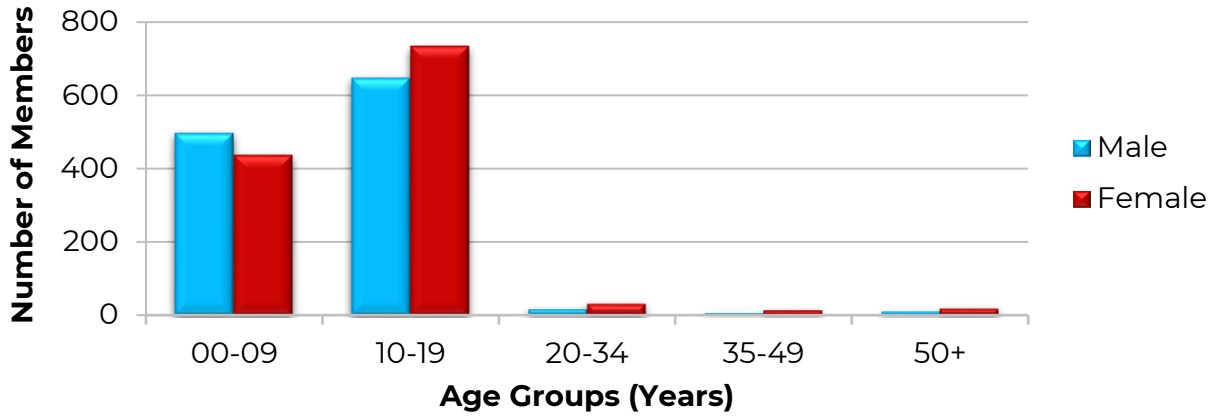
Utilization of Ophthalmic Allergy Medications: Fiscal Year 2021

Comparison of Fiscal Years

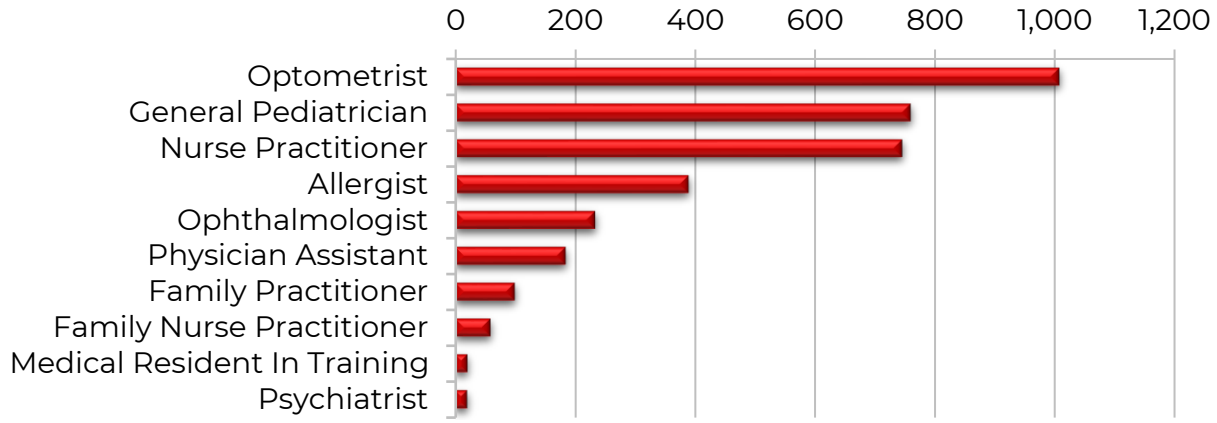
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	2,790	3,985	$70,470.19	$17.68	$0.55	25,812	128,462
2021	2,409	3,585	$60,596.37	$16.90	$0.52	22,737	116,559
% Change	**-13.70%**	**-10.00%**	**-14.00%**	**-4.40%**	**-5.50%**	**-11.90%**	**-9.30%**
Change	**-381**	**-400**	**-$9,873.82**	**-$0.78**	**-$0.03**	**-3,075**	**-11,903**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Ophthalmic Allergy Medications



Top Prescriber Specialties of Ophthalmic Allergy Medications by Number of Claims

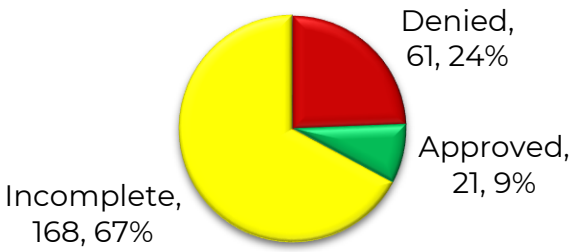


Prior Authorization of Ophthalmic Allergy Medications

There were 250 prior authorization requests submitted for ophthalmic allergy medications during fiscal year 2021. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate

automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[28]

- Bepreve® (bepotastine): January 2025
- Pataday® Once Daily Relief (olopatadine 0.7%): May 2032
- Zerviate® (cetirizine): January 2033

Pipeline:

- **Reproxalap:** Aldeyra Therapeutics is conducting Phase 3 studies of reproxalap for the treatment of allergic conjunctivitis and dry eye disease. Reproxalap is a novel, small-molecule reactive aldehyde species (RASP) inhibitor. RASP is elevated in ocular and systemic inflammatory diseases. In April 2021, Aldeyra announced positive topline results from the Phase 3 INVIGORATE study in patients with allergic conjunctivitis. The study showed statistically significant improvements in the primary endpoint of ocular itching at all prespecified time points (P<0.0001). Additionally, secondary outcomes such as ocular redness, ocular tearing, and total ocular severity score were met in patients receiving reproxalap vs. patients who received vehicle. Aldeyra plans to meets with the U.S. Food and Drug Administration (FDA) to discuss these results and a potential New Drug Application (NDA) submission for reproxalap.[29,30]

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[28] 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 03/2022. Last accessed 03/07/2022.

[29] Aldeyra Therapeutics, Inc. Aldeyra Pipeline. Available online at: https://www.aldeyra.com/pipeline-disease-areas/. Last accessed 03/07/2022.

[30] Aldeyra Therapeutics, Inc. Aldeyra Therapeutics Achieves Statistical Significance for Primary Endpoint and All Secondary Endpoints in Phase 3 INVIGORATE Clinical Trial of Reproxalap in Allergic Conjunctivitis. Available online at: https://ir.aldeyra.com/news-releases/news-release-details/aldeyra-therapeutics-achieves-statistical-significance-primary. Issued 04/27/2021. Last accessed 03/07/2022.

Recommendations

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

Utilization Details of Ophthalmic Allergy Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
KETOTIFEN PRODUCTS						
KETOTIFEN FUM DRO 0.025% OP	2,417	1,772	$37,298.37	$15.43	1.36	61.55%
ALAWAY DRO 0.025% OP	732	417	$10,593.35	$14.47	1.76	17.48%
ALAWAY CHILD DRO 0.025% OP	31	30	$440.70	$14.22	1.03	0.73%
EYE ITCH SOL RELIEF 0.025% OP	5	4	$88.75	$17.75	1.25	0.15%
EYE ITCH RELIEF DRO 0.025% OP	5	5	$102.89	$20.58	1	0.17%
SUBTOTAL	**3,190**	**2,228**	**$48,524.06**	**$15.21**	**1.43**	**80.08%**
CROMOLYN PRODUCTS						
CROMOLYN SOD SOL 4% OP	246	163	$4,266.55	$17.34	1.51	7.04%
SUBTOTAL	**246**	**163**	**$4,266.55**	**$17.34**	**1.51**	**7.04%**
TIER-1 SUBTOTAL	**3,436**	**2,381***	**$52,790.61**	**$15.36**	**1.44**	**87.12%**
TIER-2 PRODUCTS						
OLOPATADINE PRODUCTS						
OLOPATADINE DRO 0.1%	85	17	$1,884.67	$22.17	5	3.11%
PAZEO DRO 0.7%	20	9	$4,159.16	$207.96	2.22	6.86%
SUBTOTAL	**105**	**26**	**$6,043.83**	**$57.56**	**4.04**	**9.97%**
AZELASTINE PRODUCTS						
AZELASTINE DRO 0.05%	29	11	$515.15	$17.76	2.64	0.85%
SUBTOTAL	**29**	**11**	**$515.15**	**$17.76**	**2.64**	**0.85%**
EPINASTINE PRODUCTS						
EPINASTINE DRO 0.05%	12	4	$550.09	$45.84	3	0.91%
SUBTOTAL	**12**	**4**	**$550.09**	**$45.84**	**3**	**0.91%**
TIER-2 SUBTOTAL	**146**	**40***	**$7,109.07**	**$48.69**	**3.65**	**11.73%**
TIER-3 PRODUCTS						
ALCAFTADINE PRODUCTS						
LASTACAFT SOL 0.25%	2	1	$453.65	$226.83	2	0.75%
SUBTOTAL	**2**	**1**	**$453.65**	**$226.83**	**2**	**0.75%**
BEPOTASTINE PRODUCTS						
BEPREVE DRO 1.5%	1	1	$243.04	$243.04	1	0.40%
SUBTOTAL	**1**	**1**	**$243.04**	**$243.04**	**1**	**0.40%**
TIER-3 SUBTOTAL	**3**	**2***	**$696.69**	**$232.23**	**1.5**	**1.15%**
TOTAL	**3,585**	**2,409***	**$60,596.37**	**$16.90**	**1.49**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
DRO = drops; FUM = fumarate; OP = ophthalmic; SOD = sodium; SOL = solution
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Ophthalmic Antibiotic Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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

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

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

Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC), Wholesale Acquisition Costs (WAC), or State Maximum Allowable Costs (SMAC).
HC= hydrocortisone; oint= ointment; susp= suspension

Ophthalmic Antibiotic Medications Tier-2 Approval Criteria:

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

Ophthalmic Antibiotic Medications Tier-3 Approval Criteria:

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

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

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

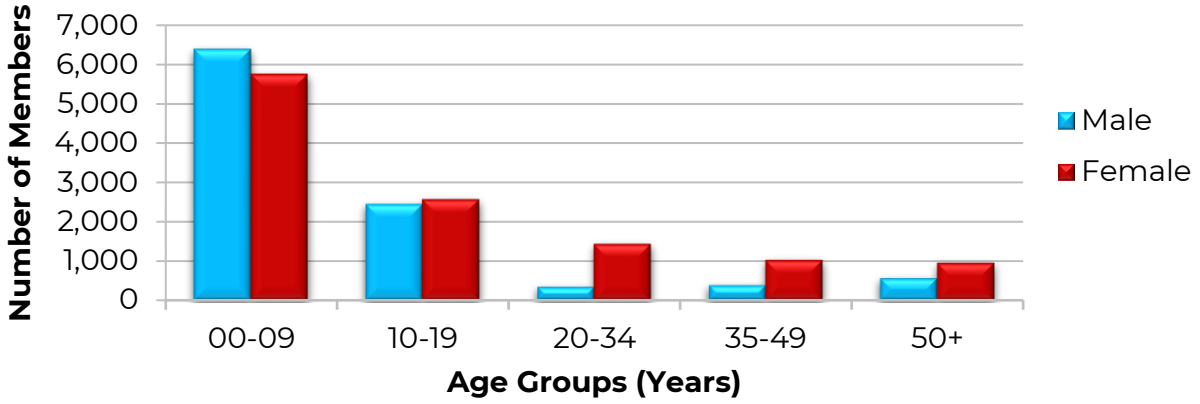
Utilization of Ophthalmic Antibiotic Medications: Fiscal Year 2021

Comparison of Fiscal Years

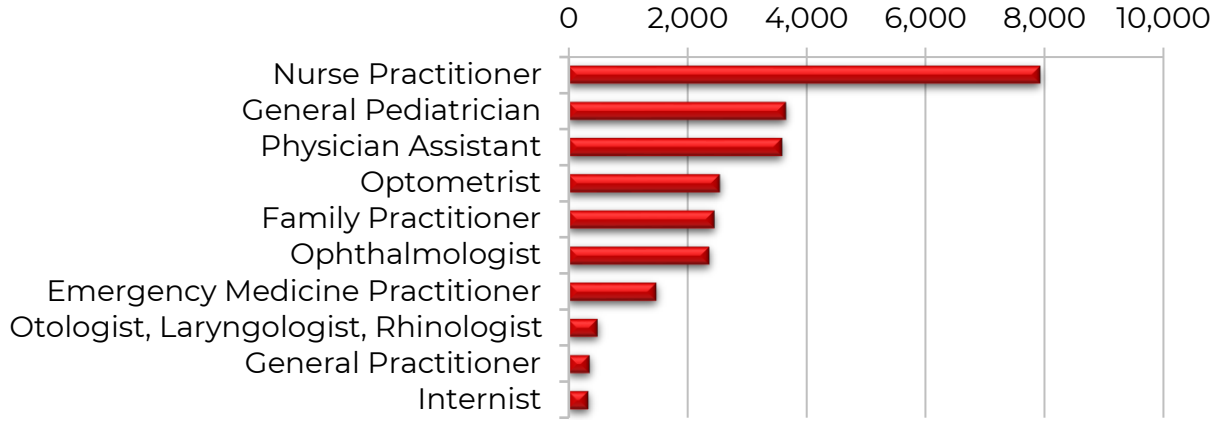
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	34,496	40,095	$891,990.76	$22.25	$1.67	268,575	535,431
2021	21,871	26,102	$606,960.43	$23.25	$1.75	159,348	345,995
% Change	**-36.60%**	**-34.90%**	**-32.00%**	**4.50%**	**4.80%**	**-40.70%**	**-35.40%**
Change	**-12,625**	**-13,993**	**-$285,030.33**	**$1.00**	**$0.08**	**-109,227**	**-189,436**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Ophthalmic Antibiotic Medications



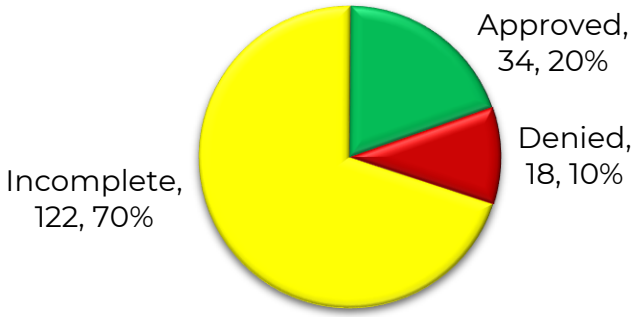
Top Prescriber Specialties of Ophthalmic Antibiotic Medications by Number of Claims



Prior Authorization of Ophthalmic Antibiotic Medications

There were 174 prior authorization requests submitted for ophthalmic antibiotic medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[31]

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

[31] 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 03/2022. Last accessed 03/07/2022.

Recommendations

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

Utilization Details of Ophthalmic Antibiotic Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OPHTHALMIC ANTIBIOTIC LIQUIDS						
TIER-1 PRODUCTS						
OFLOXACIN DRO 0.3% OP	5,920	5,330	$134,988.05	$22.80	1.11	22.24%
POLYMYXIN B/TMP SOL 10,000 UNITS/ML-0.1%	5,315	5,134	$84,736.83	$15.94	1.04	13.96%
TOBRAMYCIN SOL 0.3% OP	1,563	1,463	$23,920.04	$15.30	1.07	3.94%
GENTAMICIN SOL 0.3% OP	1,404	1,319	$20,906.49	$14.89	1.06	3.44%
CIPROFLOXACIN SOL 0.3% OP	1,249	1,156	$22,323.26	$17.87	1.08	3.68%
SULFACET SOD SOL 10% OP	434	420	$16,973.89	$39.11	1.03	2.80%
SOD SULFACET SOL 10% OP	91	87	$4,003.78	$44.00	1.05	0.66%
NEO/POLY/GRAMICIDIN SOL 1.75MG-10,000 UNITS-0.025MG/ML	36	35	$2,001.94	$55.61	1.03	0.33%
TMP/POLY SOL 0.1%-10,000 UNITS/ML	4	4	$66.09	$16.52	1	0.01%
BLEPH-10 SOL 10% OP	4	4	$105.88	$26.47	1	0.02%
SUBTOTAL	**16,020**	**14,952**	**$310,026.25**	**$19.35**	**1.07**	**51.08%**
TIER-3 PRODUCTS						
MOXIFLOXACIN SOL HCL 0.5%	510	327	$13,505.38	$26.48	1.56	2.23%
BESIVANCE SUS 0.6%	91	78	$16,264.58	$178.73	1.17	2.68%
GATIFLOXACIN SOL 0.5%	33	31	$1,522.31	$46.13	1.06	0.25%
AZASITE SOL 1%	15	5	$3,130.59	$208.71	3	0.52%
SUBTOTAL	**649**	**441**	**$34,422.86**	**$53.04**	**1.47**	**5.67%**
LIQUID SUBTOTAL	**16,669**	**14,860***	**$344,449.11**	**$20.66**	**1.12**	**56.75%**
OPHTHALMIC ANTIBIOTIC OINTMENTS						
TIER-1 PRODUCTS						
ERYTHROMYCIN OIN 5MG/GM	6,226	5,567	$131,015.92	$21.04	1.12	21.59%
BAC/POLY OIN 500-10,000 UNITS/GM OP	116	104	$2,581.76	$22.26	1.12	0.43%
GENTAK OIN 0.3% OP	104	103	$2,882.55	$27.72	1.01	0.47%
TOBREX OIN 0.3% OP	54	41	$11,537.74	$213.66	1.32	1.90%
NEO/BAC/POLY OIN OP 3.5MG-400 UNITS-10,000 UNITS/GM	28	25	$1,002.40	$35.80	1.12	0.17%
AK-POLY-BAC OIN 500-10,000 UNITS/GM OP	1	1	$23.31	$23.31	1	0.00%
SUBTOTAL	**6,529**	**5,841**	**$149,043.68**	**$22.83**	**1.12**	**24.56%**
TIER-2 PRODUCTS						
BACITRACIN OIN 500 UNITS/GM OP	53	38	$5,377.88	$101.47	1.39	0.89%
CILOXAN OIN 0.3% OP	2	2	$428.20	$214.10	1	0.07%
SUBTOTAL	**55**	**40**	**$5,806.08**	**$105.57**	**1.38**	**0.96%**

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
OINTMENT SUBTOTAL	**6,584**	**5,854***	**$154,849.76**	**$23.52**	**1.12**	**25.51%**
OPHTHALMIC ANTIBIOTIC/STEROID COMBINATION PRODUCTS						
TIER-1 PRODUCTS						
NEO/POLY/DEX SUS 0.1% OP	1,846	1,682	$37,414.72	$20.27	1.1	6.16%
NEO/POLY/DEX OIN 0.1% OP	686	579	$15,228.22	$22.20	1.18	2.51%
TOBRADEX SUS 0.3-0.1%	155	145	$24,804.10	$160.03	1.07	4.09%
TOBRAMYCIN/DEX SUS 0.3-0.1%	33	31	$2,511.84	$76.12	1.06	0.41%
TOBRADEX ST SUS 0.3-0.05%	22	18	$4,789.97	$217.73	1.22	0.79%
SULFACET/PRED NA SOL 10-0.23% OP	8	8	$169.58	$21.20	1	0.03%
SUBTOTAL	**2,750**	**2,463**	**$84,918.43**	**$30.88**	**1.12**	**13.99%**
TIER-2 PRODUCTS						
TOBRADEX OIN 0.3-0.1%	73	66	$16,709.65	$228.90	1.11	2.75%
ZYLET SUS 0.5-0.3%	21	21	$5,376.07	$256.00	1	0.89%
NEO/POLY/BAC/HC OIN 1% OP	2	2	$74.86	$37.43	1	0.01%
NEO/POLY/HC SUS 3.5MG/ML-10,000 UNITS/ML-1% OP	2	2	$275.50	$137.75	1	0.05%
BLEPHAMIDE SUS 10-0.2% OP	1	1	$307.05	$307.05	1	0.05%
SUBTOTAL	**99**	**92**	**$22,743.13**	**$229.73**	**1.08**	**3.75%**
COMBINATION SUBTOTAL	**2,849**	**2,438***	**$107,661.56**	**$37.79**	**1.17**	**17.74%**
TOTAL	**26,102**	**21,871***	**$606,960.43**	**$23.25**	**1.19**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
BAC = bacitracin; DEX = dexamethasone; DRO = drops; HC = hydrocortisone; HCL = hydrochloride; NA = sodium; NEO = neomycin; OIN = ointment; OP = ophthalmic; POLY = polymyxin; PRED = prednisolone; SOD = sodium; SOL = solution; ST = suspension technology; SULFACET = sulfacetamide; SUS = suspension; TMP = trimethoprim
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Osteoporosis Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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

*Tier structure based on supplemental rebate participation and/or National Average Drug Acquisition Costs (NADAC) or Wholesale Acquisition Costs (WAC) if NADAC unavailable.
†OTC calcium and 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 and vitamin D are only covered for members with osteoporosis who are being treated with a bisphosphonate.
¥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 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 ≤-2.5 at the total hip or femoral neck, smoking, corticosteroid use, rheumatoid arthritis); or
    c. Failed or intolerant to other available osteoporosis therapy; 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.

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.

Forteo® (Teriparatide) and Teriparatide Approval Criteria:

1. A 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.

Tymlos® (Abaloparatide) Approval Criteria:

1. A 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 ≥20% or the 10-year probability of hip fracture ≥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 modulatory (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 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 patient'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 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	525	2,102	$347,611.47	$165.37	$3.30	22,739	105,246
2021	562	1,916	$353,738.39	$184.62	$3.34	18,657	105,773
%	**7.00%**	**-8.80%**	**1.80%**	**11.60%**	**1.20%**	**-18.00%**	**0.50**
Change	**37**	**-186**	**$6,126.92**	**$19.25**	**$0.04**	**-4,082**	**527**

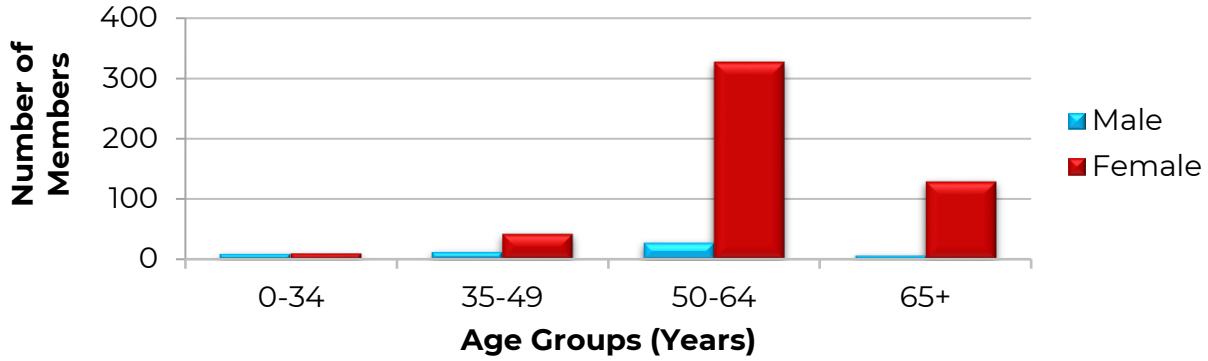
Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Comparison of Fiscal Years: Medical Claims

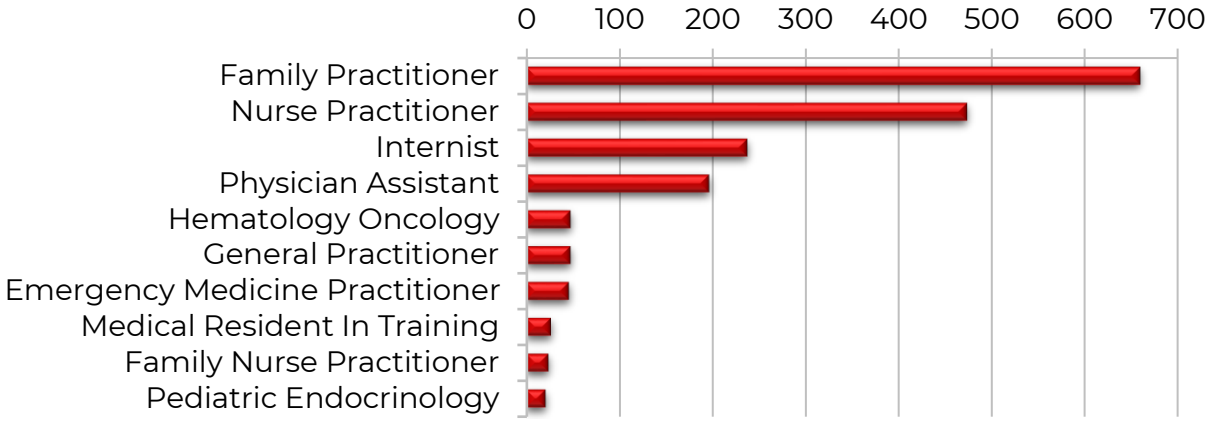
Fiscal Year	*Total Members	†Total Claims	Total Cost	Cost/ Claim	Claims/ Member
2020	193	524	$686,015.41	$1,309.19	2.72
2021	114	206	$54,989.29	$390.32	2.12
% Change	**-40.9%**	**-60.7%**	**-92.0%**	**-70.2%**	**-22.1%**
Change	**-79**	**-318**	**$-631,026.12**	**$-918.87**	**-0.6**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
†Total number of unduplicated claims.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Osteoporosis Medications: Pharmacy Claims



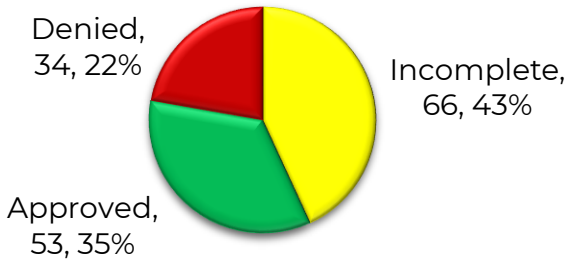
Top Prescriber Specialties of Osteoporosis Medications by Number of Claims: Pharmacy Claims



Prior Authorization of Osteoporosis Medications

There were 153 prior authorization requests submitted for osteoporosis medications during fiscal year 2021. Computer edits are in place to detect lower tiered medications in a member's recent claims history and generate automated prior authorizations where possible. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[32]

- Forteo® (teriparatide injection): March 2025
- Atelvia® (risedronate sodium DR tablet): January 2028
- Binosto® (alendronate effervescent tablet): December 2031
- Tymlos® (abaloparatide injection): April 2038

Pipeline:

- **CT-P41:** CT-P41 is a denosumab biosimilar being developed by Celltrion for the treatment of patients with postmenopausal osteoporosis. It is currently in Phase 3 of clinical trials, with an estimated study completion date of March 2023.[33]
- **GP2411:** GP2411 is a denosumab biosimilar being developed by Sandoz and Hexal AG for the treatment of patients with postmenopausal osteoporosis. It is currently in Phase 3 of clinical trials, with an estimated study completion date of July 2022.[34]
- **SB16:** SB16 is a denosumab biosimilar being developed by Samsung Bioepis for the treatment of patients with postmenopausal osteoporosis. It is currently in Phase 3 of clinical trials, with an estimated study completion date of December 2022.[35]
- **TVB-009:** TVB-009 is a denosumab biosimilar being developed by Teva Pharmaceuticals for the treatment of patients with postmenopausal osteoporosis. TVB-009 is currently in Phase 3 of clinical trials.[36]

Recommendations

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

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[32] 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 03/2022. Last accessed 03/14/2022.
[33] Celltrion. Celltrion Pipeline. Available online at: https://www.celltrion.com/en-us/science/pipelinebiolist. Last accessed 03/14/2022.
[34] Sandoz. Sandoz Biosimilar Portfolio and Pipeline: Available online at: https://www.sandoz.com/our-work/biopharmaceuticals/sandoz-biosimilar-portfolio-and-pipeline#ui-id-1=1. Last accessed 03/14/2022.
[35] Samsung Bioepis. Our Pipeline: SB16.Available online at: https://www.samsungbioepis.com/en/product/product02.do. Last accessed 03/14/2022.
[36] Teva Pharmaceutical Industries, Ltd. Teva Specialty & Biosimilar Product Pipeline. Available online at: https://www.tevapharm.com/product-focus/research/pipeline/. Last accessed 03/14/2022.

Utilization Details of Osteoporosis Medications: Fiscal Year 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
TIER-1 PRODUCTS						
ALENDRONATE PRODUCTS						
ALENDRONATE TAB 70MG	1,471	429	$16,155.15	$10.98	3.43	4.57%
ALENDRONATE TAB 35MG	80	28	$975.78	$12.20	2.86	0.28%
ALENDRONATE TAB 10MG	57	20	$816.72	$14.33	2.85	0.23%
SUBTOTAL	**1,608**	**477**	**$17,947.65**	**$11.16**	**3.37**	**5.07%**
IBANDRONATE PRODUCTS						
IBANDRONATE TAB 150MG	134	48	$2,871.65	$21.43	2.79	0.81%
SUBTOTAL	**134**	**48**	**$2,871.65**	**$21.43**	**2.79**	**0.81%**
ZOLEDRONIC ACID PRODUCTS						
ZOLEDRONIC INJ 5MG/100ML	1	1	$56.46	$56.46	1	0.02%
SUBTOTAL	**1**	**1**	**$56.46**	**$56.46**	**1**	**0.02%**
TIER-1 SUBTOTAL	**1,743**	**526**	**$20,875.76**	**$11.98**	**3.31**	**5.90%**
TIER-2 PRODUCTS						
RISEDRONATE PRODUCTS						
RISEDRONATE TAB 35MG	13	1	$209.58	$16.12	13	0.06%
RISEDRONATE TAB 150MG	12	1	$493.09	$41.09	12	0.14%
RISEDRONATE TAB 5MG	10	1	$922.90	$92.29	10	0.26%
TIER-2 SUBTOTAL	**35**	**3**	**$1,625.57**	**$46.44**	**11.67**	**0.46%**
SPECIAL PA PRODUCTS						
TERIPARATIDE PRODUCTS						
FORTEO INJ 620MG/2.48ML	75	14	$262,549.64	$3,500.66	5.36	74.22%
SUBTOTAL	**75**	**14**	**$262,549.64**	**$3,500.66**	**5.36**	**74.22%**
DENOSUMAB PRODUCTS						
PROLIA SOL 60MG/ML	45	30	$54,541.03	$1,212.02	1.5	15.42%
SUBTOTAL	**45**	**30**	**$54,541.03**	**$1,212.02**	**1.5**	**15.42%**
ALENDRONATE PRODUCTS						
ALENDRONATE SOL 70MG/75ML	12	4	$2,275.38	$189.62	3	0.64%
SUBTOTAL	**12**	**4**	**$2,275.38**	**$189.62**	**3**	**0.64%**
ABALOPARATIDE PRODUCTS						
TYMLOS INJ 3,120MCG/1.56ML	6	1	$11,871.01	$1,978.50	6	3.36%
SUBTOTAL	**6**	**1**	**$11,871.01**	**$1,978.50**	**6**	**3.36%**
SPECIAL PA SUBTOTAL	**138**	**49**	**$331,237.06**	**$2,400.27**	**2.82**	**93.64%**
TOTAL	**1,916**	**562***	**$353,738.39**	**$184.62**	**3.41**	**100%**

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 2021 = 07/01/2020 to 06/30/2021

Medical Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
ZOLEDRONIC ACID J3489	155	78	$6,781.91	$43.75	1.99
PROLIA J0897	48	35	$47,814.11	$996.13	1.37
IBANDRONATE SODIUM J1740	3	1	$393.27	$131.09	3.00
TOTAL	**206***	**114***	**$54,989.29**	**$390.32**	**2.12**

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

Fiscal Year 2021 Annual Review of Parkinson's Disease (PD) Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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^2]; 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 $5HT_3$ 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.

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 indication 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 members 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 diagnosis 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^2]; 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).

Requip XL® [Ropinirole Extended-Release (ER)] and Mirapex ER® (Pramipexole 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.

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 lower cost 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 2021

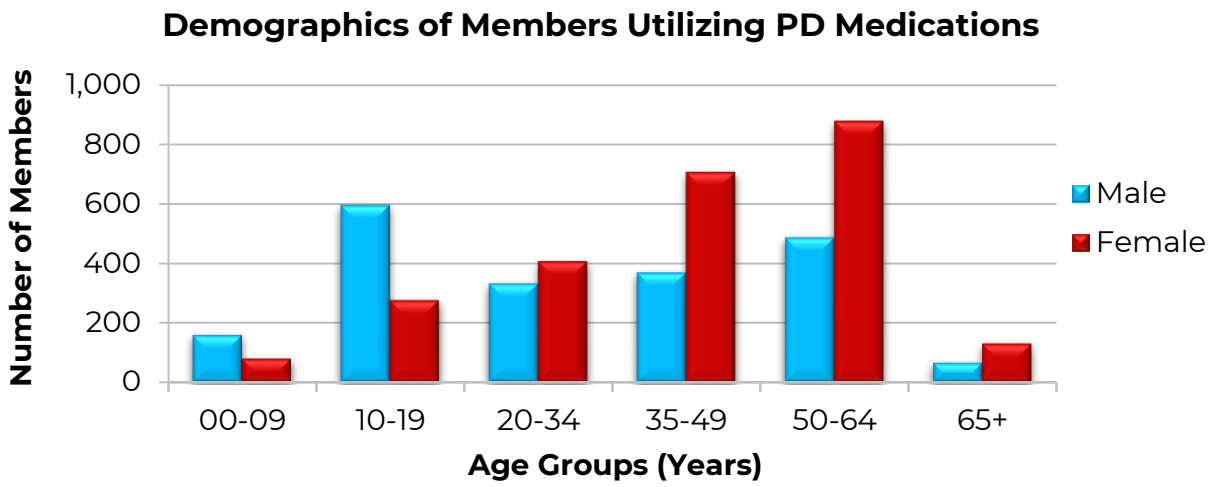
The following utilization data includes PD medications used for all diagnoses and does not differentiate between PD diagnoses and other diagnoses, for which use may be appropriate.

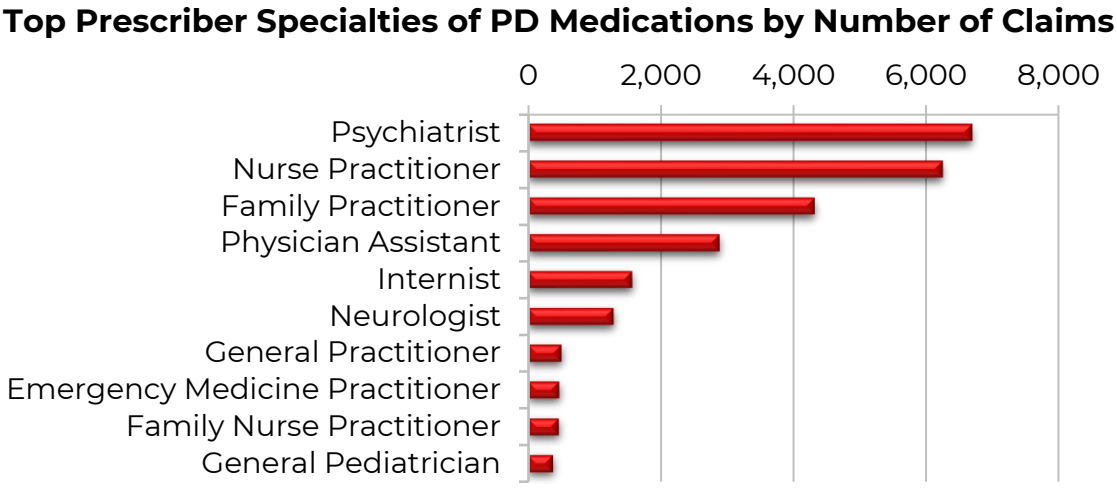
Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	4,385	25,868	$893,952.84	$34.56	$1.07	1,667,752	835,506
2021	4,482	25,910	$828,031.98	$31.96	$0.96	1,736,398	862,894
% Change	**2.20%**	**0.20%**	**-7.40%**	**-7.50%**	**-10.30%**	**4.10%**	**3.30%**
Change	**97**	**42**	**-$65,920.86**	**-$2.60**	**-$0.11**	**68,646**	**27,388**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

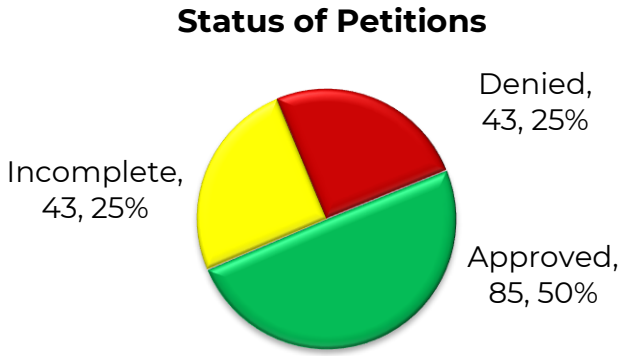
- There were no SoonerCare paid medical claims for Duopa® (carbidopa/levodopa enteral suspension) during fiscal year 2021.





Prior Authorization of PD Medications

There were 171 prior authorization requests submitted for PD medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Market News and Updates

Anticipated Patent Expiration(s):[37]

- Azilect® (rasagiline tablet): August 2027
- Nourianz® (istradefylline tablet): September 2027
- 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

Recommendations

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 2021

Pharmacy Claims

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
AMANTADINE PRODUCTS						
AMANTADINE CAP 100MG	2,853	453	$80,097.12	$0.94	$28.07	9.67%
AMANTADINE TAB 100MG	2,051	354	$114,316.64	$1.82	$55.74	13.81%
AMANTADINE SYP 50MG/5ML	256	50	$4,879.55	$0.63	$19.06	0.59%
GOCOVRI CAP 137MG	13	1	$26,508.33	$67.97	$2,039.10	3.20%
SUBTOTAL	**5,173**	**858**	**$225,801.64**	**$1.44**	**$43.65**	**27.27%**
BENZTROPINE PRODUCTS						
BENZTROPINE TAB 1MG	5,819	1,122	$76,114.80	$0.43	$13.08	9.19%
BENZTROPINE TAB 2MG	2,322	370	$36,875.50	$0.51	$15.88	4.45%
BENZTROPINE TAB 0.5MG	2,104	412	$29,952.28	$0.46	$14.24	3.62%
BENZTROPINE INJ 1MG/ML	1	1	$58.41	$58.41	$58.41	0.01%
SUBTOTAL	**10,246**	**1,905**	**$143,000.99**	**$0.45**	**$13.96**	**17.27%**
ROPINIROLE PRODUCTS						
ROPINIROLE TAB 1MG	1,375	381	$17,435.73	$0.32	$12.68	2.11%
ROPINIROLE TAB 0.5MG	1,180	353	$14,757.47	$0.31	$12.51	1.78%
ROPINIROLE TAB 0.25MG	824	302	$10,274.01	$0.35	$12.47	1.24%
ROPINIROLE TAB 2MG	680	172	$8,572.81	$0.32	$12.61	1.04%

[37] 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 02/2022. Last accessed 03/01/2022.

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
ROPINIROLE TAB 3MG	295	77	$3,933.40	$0.32	$13.33	0.48%
ROPINIROLE TAB 4MG	290	71	$4,282.41	$0.31	$14.77	0.52%
ROPINIROLE TAB 5MG	127	29	$2,181.29	$0.43	$17.18	0.26%
ROPINIROLE TAB 12MG ER	9	1	$1,806.05	$6.69	$200.67	0.22%
SUBTOTAL	**4,780**	**1386**	**$63,243.17**	**$0.33**	**$13.23**	**7.65%**
TRIHEXYPHENIDYL PRODUCTS						
TRIHEXYPHENIDYL TAB 5MG	1,052	150	$14,859.97	$0.46	$14.13	1.79%
TRIHEXYPHENIDYL TAB 2MG	954	196	$11,595.87	$0.39	$12.16	1.40%
TRIHEXYPHENIDYL ELX 0.4MG/ML	191	28	$5,909.23	$1.06	$30.94	0.71%
SUBTOTAL	**2,197**	**374**	**$32,365.07**	**$0.48**	**$14.73**	**3.90%**
CARBIDOPA/LEVODOPA PRODUCTS						
CARB/LEVO TAB 25-100MG	723	155	$15,095.80	$0.59	$20.88	1.82%
CARB/LEVO TAB 25-250MG	191	30	$5,086.65	$0.70	$26.63	0.61%
CARB/LEVO ER TAB 50-200MG	109	19	$4,430.04	$1.16	$40.64	0.54%
CARB/LEVO TAB 10-100MG	108	32	$2,061.56	$0.53	$19.09	0.25%
CARB/LEVO ER TAB 25-100MG	50	13	$1,471.17	$0.84	$29.42	0.18%
CARB/LEVO ODT 25-250MG	15	2	$1,526.07	$3.84	$101.74	0.18%
CARB/LEVO ODT 25-100MG	12	1	$633.00	$1.76	$52.75	0.08%
CARB/LEVO ODT 10-100MG	1	1	$81.39	$0.90	$81.39	0.01%
SUBTOTAL	**1,209**	**253**	**$30,385.68**	**$0.71**	**$25.13**	**3.67%**
CARBIDOPA/LEVODOPA/ENTACAPONE PRODUCTS						
CARB/LEVO/EN 25-100-200MG	33	5	$2,873.20	$3.03	$87.07	0.35%
CARB/LEVO/EN 50-200-200MG	24	3	$1,937.49	$2.85	$80.73	0.23%
CARB/LEVO/EN 37.5-150-200MG	10	1	$1,191.63	$4.20	$119.16	0.14%
CARB/LEVO/EN 12.5-50-200MG	6	1	$825.15	$4.58	$137.53	0.10%
CARB/LEVO/EN 31.25-125-200MG	4	1	$386.69	$3.91	$96.67	0.05%
SUBTOTAL	**77**	**11**	**$7,214.16**	**$3.29**	**$93.69**	**0.87%**
PRAMIPEXOLE PRODUCTS						
PRAMIPEXOLE TAB 0.5MG	360	116	$4,547.02	$0.26	$12.63	0.55%
PRAMIPEXOLE TAB 1MG	355	80	$4,633.80	$0.30	$13.05	0.56%
PRAMIPEXOLE TAB 0.125MG	338	116	$4,154.67	$0.32	$12.29	0.50%
PRAMIPEXOLE TAB 0.25MG	309	88	$3,806.01	$0.29	$12.32	0.46%
PRAMIPEXOLE TAB 1.5MG	74	21	$1,014.16	$0.34	$13.70	0.12%
PRAMIPEXOLE TAB 0.75MG	40	8	$530.33	$0.37	$13.26	0.06%
SUBTOTAL	**1,476**	**429**	**$18,685.99**	**$0.29**	**$12.66**	**2.25%**
BROMOCRIPTINE PRODUCTS						
BROMOCRIPTINE TAB 2.5MG	423	102	$47,228.56	$3.49	$111.65	5.70%
BROMOCRIPTINE CAP 5MG	192	35	$43,736.69	$7.60	$227.80	5.28%
SUBTOTAL	**615**	**137**	**$90,965.25**	**$4.71**	**$147.91**	**10.98%**
ENTACAPONE PRODUCTS						
ENTACAPONE TAB 200MG	16	6	$643.80	$1.38	$40.24	0.08%
SUBTOTAL	**16**	**6**	**$643.80**	**$1.38**	**$40.24**	**0.08%**
RASAGILINE PRODUCTS						

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
RASAGILINE TAB 1MG	17	2	$1,793.86	$3.52	$105.52	0.22%
RASAGILINE TAB 0.5MG	15	2	$1,888.32	$4.20	$125.89	0.23%
SUBTOTAL	**32**	**4**	**$3,682.18**	**$3.84**	**$115.07**	**0.45%**
ROTIGOTINE PRODUCTS						
NEUPRO 4MG/24 HOUR PATCH	19	2	$13,073.67	$22.94	$688.09	1.58%
NEUPRO 2MG/24 HOUR PATCH	2	1	$1,380.70	$23.01	$690.35	0.17%
SUBTOTAL	**21**	**3**	**$14,454.37**	**$22.94**	**$688.30**	**1.75%**
SELEGILINE PRODUCTS						
SELEGILINE CAP 5MG	7	1	$551.47	$2.63	$78.78	0.07%
SELEGILINE TAB 5MG	6	2	$377.66	$2.10	$62.94	0.05%
SUBTOTAL	**13**	**3**	**$929.13**	**$2.38**	**$71.47**	**0.12%**
PIMAVANSERIN PRODUCTS						
NUPLAZID TAB 34MG	54	7	$193,015.14	$121.39	$3,574.35	23.31%
NUPLAZID TAB 10MG	1	1	$3,645.41	$121.51	$3,645.41	0.44%
SUBTOTAL	**55**	**8**	**$196,660.55**	**$121.40**	**$3,575.65**	**23.75%**
TOTAL	**25,910**	**4,482***	**$828,031.98**	**$0.96**	**$31.96**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
CAP = capsule; CARB = carbidopa; ELX = elixir; EN = entacapone; ER = extended release; INJ = injection; LEVO = levodopa; ODT = orally disintegrating tablet; SYP = syrup; TAB = tablet
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Phenylketonuria Medications

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Kuvan® (Sapropterin) Approval Criteria:

1. An FDA approved diagnosis of phenylketonuria; and
2. Documentation of active management with a phenylalanine restricted diet; and
3. Member must not have 2 null mutations in *trans*; and
4. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
5. Concomitant use with Palynziq® (pegvaliase-pqpz) will not be approved; and
6. Initial approvals will be for the duration of 30 days. After which time, the prescriber must verify that the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline.
    a. If the member was initiated at 10mg/kg/day dose, then a subsequent trial of 20mg/kg/day for a duration of 30 days can be approved, after which time the prescriber must verify the member responded to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; or
    b. If the member was initiated at 20mg/kg/day dose, then no additional approvals will be granted after a trial period of 30 days if the member did not respond to treatment as defined by laboratory documentation of ≥30% decrease in blood phenylalanine levels from baseline; and
7. Subsequent approvals will be for the duration of 1 year; and
8. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy.

Palynziq® (Pegvaliase-pqpz) Approval Criteria:

1. An FDA approved diagnosis to reduce blood phenylalanine concentrations in patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations >600µmol/L on existing management; and

2. Documentation of active management with a phenylalanine restricted diet; and
3. Baseline phenylalanine concentration must be documented on the prior authorization request and must be drawn within the last 30 days; and
4. Documentation the member's average blood phenylalanine concentration over the last 6 months is >600µmol/L on existing management; and
5. Concomitant use with Kuvan® (sapropterin) will not be approved; and
6. Prescriber, pharmacy, and member must be enrolled in the Palynziq® Risk Evaluation and Mitigation Strategy (REMS) program and maintain enrollment throughout therapy; and
7. Initial dose must be administered under the supervision of a health care provider equipped to manage anaphylaxis and observe the member for at least 60 minutes following injection; and
8. Member must be prescribed auto-injectable epinephrine and be counseled on its appropriate use; and
9. Initial approvals will be for the duration of 33 weeks to allow for initial titration and for 24 weeks of maintenance treatment with 20mg once daily dosing. Patients should then be assessed for a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600µmol/L.
    a. If member has not achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600µmol/L, approvals may be granted for the 40mg once daily dosing for a duration of 16 weeks; or
    b. If member has achieved a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600µmol/L, subsequent approvals will be for the duration of 1 year; and
10. Members who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration ≤600µmol/L after 16 weeks of continuous treatment with the maximum dosage of 40mg once daily will not be approved for subsequent approvals; and
11. Subsequent approvals will be for the duration of 1 year; and
12. Reauthorization will require the following:
    a. Documentation of active management with a phenylalanine restricted diet; and
    b. Verification from the prescriber of continued response to therapy.

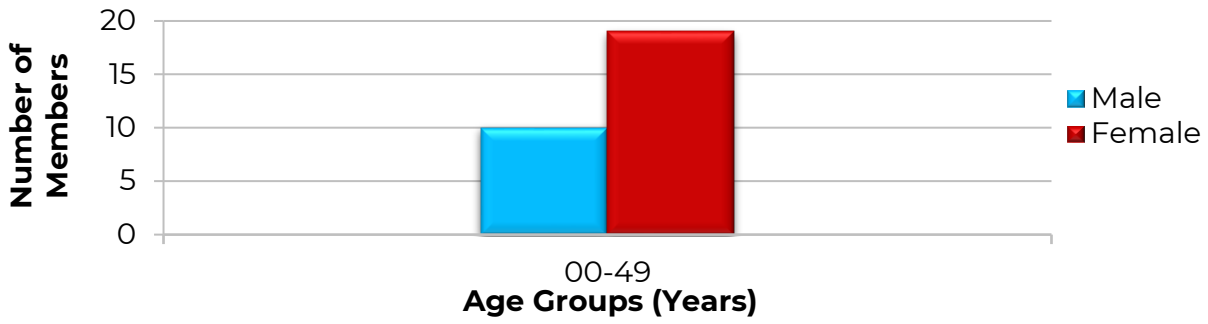
Utilization of Phenylketonuria Medications: Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

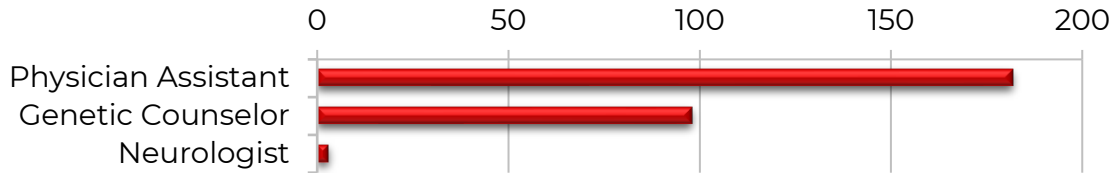
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	26	261	$2,393,331.53	$9,169.85	$307.63	51,347	7,780
2021	29	283	$2,815,183.08	$9,947.64	$333.12	56,535	8,451
% Change	**11.50%**	**8.40%**	**17.60%**	**8.50%**	**8.30%**	**10.10%**	**8.60%**
Change	**3**	**22**	**$421,851.55**	**$777.79**	**$25.49**	**5,188**	**671**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Phenylketonuria Medications



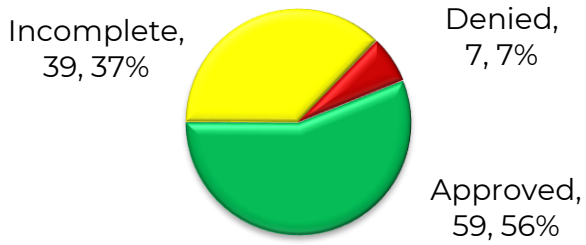
Top Prescriber Specialties of Phenylketonuria Medications by Number of Claims



Prior Authorization of Phenylketonuria Medications

There were 105 prior authorization requests submitted for phenylketonuria medications during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[38]

- Kuvan® tablets (sapropterin): May 2026
- Kuvan® powder (sapropterin): November 2032

News:

- **October 2020:** Endo International announced that its subsidiary, Par Pharmaceuticals, has begun shipping sapropterin dihydrochloride 100mg tablets and 100mg and 500mg powder for oral solution following final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application.[39]
- **October 2020:** Dr. Reddy's Laboratories announced the launch of generic sapropterin dihydrochloride 100mg tablets.[40]
- **April 2021:** Dr. Reddy's Laboratories announced the launch of sapropterin dihydrochloride 100mg powder for oral solution, a therapeutically equivalent, generic version of Kuvan® powder for oral solution.[41]

Recommendations

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

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[38] 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 02/2022. Last accessed 03/01/2022.

[39] Endo International plc. Endo Begins Shipment of Generic Kuvan® Tablets and Powder for Oral Solution (Sapropterin Dihydrochloride). *PR Newswire*. Available online at: https://www.prnewswire.com/news-releases/endo-begins-shipment-of-generic-kuvan-tablets-and-powder-for-oral-solution-sapropterin-dihydrochloride-301144510.html. Issued 10/01/2020. Last accessed 03/02/2022.

[40] Dr. Reddy's Laboratories, Ltd. Dr. Reddy's Laboratories Announces the Launch of a Generic Version of Sapropterin Dihyrochloride Tablets for Oral Use in the U.S. Market. Available online at: https://www.drreddys.com/media/904791/press-release_sapropterin.pdf. Issued 10/03/2020. Last accessed 03/02/2022.

[41] Dr. Reddy's Laboratories, Ltd. Dr. Reddy's Laboratories Announces the Launch of a Generic Version of Sapropterin Dihydrochloride Powder for Oral Solution, 100mg in the U.S. Market. *Business Wire*. Available online at: https://www.businesswire.com/news/home/20210407005452/en/Dr.-Reddys-Laboratories-Announces-the-Launch-of-a-Generic-Version-of-Sapropterin-Dihydrochloride-Powder-for-Oral-Solution-100-mg-in-the-U.S.-Market. Issued 04/07/2021. Last accessed 03/02/2022.

Utilization Details of Phenylketonuria Medications: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ DAY	COST/ CLAIM	% COST
SAPROPTERIN PRODUCTS						
KUVAN TAB 100MG	131	15	$1,814,178.71	$461.62	$13,848.69	64.44%
KUVAN POW 100MG	65	13	$211,332.00	$108.38	$3,251.26	7.51%
KUVAN POW 500MG	46	7	$417,688.86	$302.67	$9,080.19	14.84%
SAPROPTERIN TAB 100MG	15	5	$140,415.15	$312.03	$9,361.01	4.99%
SAPROPTERIN POW 100MG	5	2	$15,520.25	$103.47	$3,104.05	0.55%
SAPROPTERIN POW 500MG	3	1	$29,038.23	$322.65	$9,679.41	1.03%
SUBTOTAL	**265**	**43**	**$2,628,173.20**	**$330.59**	**$9,917.63**	**93.36%**
PEGVALIASE-PQPZ PRODUCTS						
PALYNZIQ INJ 10MG/0.5ML	11	2	$131,786.51	$411.83	$11,980.59	4.68%
PALYNZIQ INJ 2.5MG/0.5ML	4	2	$9,299.64	$102.19	$2,324.91	0.33%
PALYNZIQ INJ 20MG/ML	3	1	$45,923.73	$510.26	$15,307.91	1.63%
SUBTOTAL	**18**	**5**	**$187,009.88**	**$373.27**	**$10,389.44**	**6.64%**
TOTAL	**283**	**29***	**$2,815,183.08**	**$333.12**	**$9,947.64**	**100%**

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

Fiscal Year 2021 Annual Review of Procysbi® (Cysteamine Bitartrate)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Procysbi® (Cysteamine Bitartrate) Delayed-Release Capsule and Granule Approval Criteria:

1. An FDA approved diagnosis of nephropathic cystinosis; and
2. A patient-specific, clinically significant reason why the member cannot use the short-acting formulation Cystagon® (cysteamine bitartrate) must be provided; and
3. Use of Procysbi® granules will require a patient-specific, clinically significant reason why the member cannot use the capsule formulation of Procysbi®.

Utilization of Procysbi® (Cysteamine Bitartrate): Fiscal Year 2021

Comparison of Fiscal Years

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	1	2	$1,740.00	$870.00	$29.00	360	60
2021	0	0	$0.00	$0.00	$0.00	0	0
% Change	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**	**-100%**
Change	**-1**	**-2**	**-$1,740.00**	**-$870.00**	**-$29.00**	**-360**	**-60**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

- There was no SoonerCare utilization of Procysbi® (cysteamine bitartrate) during fiscal year 2021 (07/01/2020 to 06/30/2021).

Market News and Updates

Anticipated Patent Expiration(s):[42]

- Procysbi® (cysteamine bitartrate): August 2036

Recommendations

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

[42] 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 02/2022. Last accessed 02/22/2022.

Fiscal Year 2021 Annual Review of Short-Acting Beta$_2$ Agonists

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Short-Acting Beta$_2$ Agonists	
Tier-1	**Tier-2**
albuterol HFA (ProAir® HFA) – **Brand Preferred**	albuterol HFA (generic)
albuterol inhalation powder (ProAir® RespiClick®)	albuterol inhalation powder (ProAir® Digihaler®)*
albuterol HFA (Proventil® HFA) – **Brand Preferred**	levalbuterol HFA (generic)
albuterol HFA (Ventolin® HFA) – **Brand Preferred**	
levalbuterol HFA (Xopenex® HFA) – **Brand Preferred**	

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$_2$ 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® Digihaler® (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® Digihaler® formulation over all available Tier-1 medications must be provided; and
3. The prescriber agrees to closely monitor member adherence; and
4. Patients should be capable and willing to use the Companion Mobile App and follow the *Instructions for Use* and ensure the ProAir® Digihaler® 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® Digihaler® inhaler; and

6. 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:

1. A free-floating 90 days of therapy per 365 days will be in place.
2. 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
3. A patient-specific, clinically significant reason why the member cannot use a metered-dose inhaler (MDI) must be provided; and
4. Clinical exceptions will be made for members with chronic obstructive pulmonary disease (COPD); and
5. A quantity limit of 288mL per 30 days will apply.

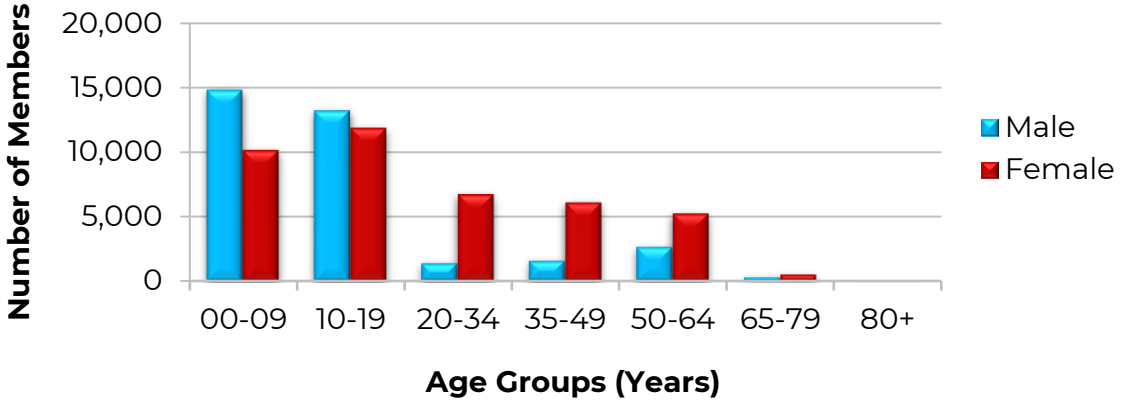
Utilization of Inhaled Short-Acting Beta$_2$ Agonists: Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	87,161	211,229	$13,806,575.70	$65.36	$3.03	10,024,942	4,556,419
2021	74,629	187,701	$9,620,691.51	$51.26	$2.23	8,037,172	4,323,020
% Change	**-14.40%**	**-11.10%**	**-30.30%**	**-21.60%**	**-26.40%**	**-19.80%**	**-5.10%**
Change	**-12,532**	**-23,528**	**-$4,185,884.19**	**-$14.10**	**-$0.80**	**-1,987,770**	**-233,399**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Short-Acting Beta$_2$ Agonists

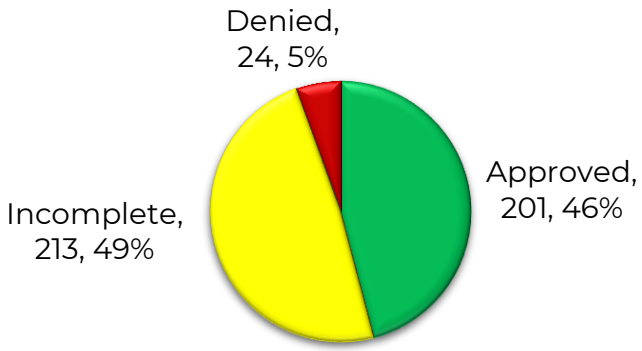


Top Prescriber Specialties of Short-Acting Beta$_2$ Agonists by Number of Claims

Prior Authorization of Short-Acting Beta$_2$ Agonists

There were 438 prior authorization requests submitted for inhaled short-acting beta$_2$ agonists during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Market News and Updates

Anticipated Patent Expiration(s):[43]

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

[43] 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 03/2022. Last accessed 03/08/2022.

Recommendations

The College of Pharmacy does not recommend any changes to the current short-acting beta$_2$ agonists Product Based Prior Authorization (PBPA) category at this time.

Utilization Details of Short-Acting Beta$_2$ Agonists: Fiscal Year 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
SABA TIER-1 PRODUCTS						
PROAIR HFA 90MCG/ACT	32,517	13,715	$2,905,025.45	$89.34	2.4	30.20%
VENTOLIN HFA 90MCG/ACT	3,881	1,717	$258,469.14	$66.60	2.3	2.69%
PROVENTIL HFA 90MCG/ACT	2,163	1,064	$231,058.37	$106.82	2.0	2.40%
PROAIR RESPICLICK 90MCG/ACT	747	472	$54,795.72	$73.35	1.6	0.57%
XOPENEX HFA 45MCG/ACT	655	258	$58,168.41	$88.81	2.5	0.60%
SUBTOTAL	**39,963**	**17,226**	**$3,507,517.09**	**$87.77**	**2.3**	**36.46%**
SABA TIER-2 PRODUCTS						
ALBUTEROL HFA 90MCG/ACT	110,046	53,246	$5,194,873.54	$47.21	2.1	54.00%
LEVALBUTEROL HFA 45MCG/ACT	7	3	$416.32	$59.47	2.3	0.00%
SUBTOTAL	**110,053**	**53,249**	**$5,195,289.86**	**$47.21**	**2.1**	**54.00%**
SABA NEBULIZER SOLUTION PRODUCTS						
ALBUTEROL NEB 2.5MG/3ML	25,928	15,457	$419,105.12	$16.16	1.7	4.36%
ALBUTEROL NEB 1.25MG/3ML	6,046	4,451	$237,289.20	$39.25	1.4	2.47%
ALBUTEROL NEB 0.63MG/3ML	3,723	2,809	$144,074.36	$38.70	1.3	1.50%
LEVALBUTEROL NEB 0.63MG/3ML	894	560	$47,012.88	$52.59	1.6	0.49%
LEVALBUTEROL NEB 1.25MG/3ML	569	282	$29,754.25	$52.29	2.0	0.31%
ALBUTEROL NEB 5MG/ML	344	200	$18,547.22	$53.92	1.7	0.19%
LEVALBUTEROL NEB 0.31MG/3ML	162	121	$10,520.92	$64.94	1.3	0.11%
XOPENEX NEB 1.25MG/3ML	12	1	$9,112.20	$759.35	12.0	0.09%
LEVALBUTEROL NEB 1.25MG/0.5ML	7	6	$2,468.41	$352.63	1.2	0.03%
SUBTOTAL	**37,685**	**23,887**	**$917,884.56**	**$24.36**	**1.6**	**9.54%**
TOTAL	**187,701**	**74,629***	**$9,620,691.51**	**$51.26**	**2.5**	**100%**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
ACT = actuation; HFA = hydrofluoroalkane inhaler; NEB = nebulizer; SABA = short-acting beta$_2$ agonist
Please note: The prior authorization requirement was temporarily removed from Tier-2 generic albuterol HFA products starting in April 2020 as a result of manufacturer shortages related to COVID-19.
Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Fiscal Year 2021 Annual Review of Strensiq® (Asfotase Alfa)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

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'-phophate (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; and
4. The 80mg/0.8mL vial should not be used in pediatric members weighing <40kg.

Utilization of Strensiq® (Asfotase Alfa): Fiscal Year 2021

Comparison of Fiscal Years: Pharmacy Claims

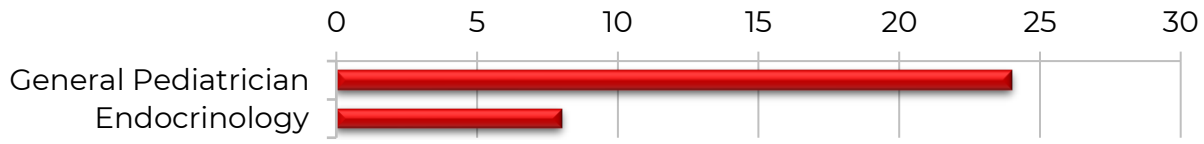
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Cost/ Day	Total Units	Total Days
2020	2	24	$731,286.60	$30,470.28	$1,088.22	256	672
2021	3	32	$1,434,941.12	$44,841.91	$1,601.50	386	896
% Change	**50.00%**	**33.30%**	**96.20%**	**47.20%**	**47.20%**	**50.80%**	**33.30%**
Change	**1**	**8**	**$703,654.52**	**$14,371.63**	**$513.28**	**130**	**224**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Demographics of Members Utilizing Strensiq® (Asfotase Alfa)

- Due to the limited number of members utilizing Strensiq® (asfotase alfa) during fiscal year 2021, detailed demographic information could not be provided.

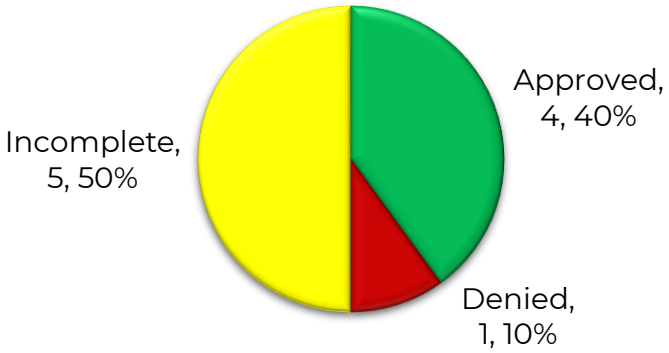
Top Prescriber Specialties of Strensiq® (Asfotase Alfa) by Number of Claims



Prior Authorization of Strensiq® (Asfotase Alfa)

There were 10 prior authorization requests submitted for 3 unique members for Strensiq® (asfotase alfa) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

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 2021

PRODUCT UTILIZED	TOTAL CLAIMS	TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER	% COST
STRENSIQ INJ 40MG/ML	24	2	$823,953.84	$34,331.41	12	57.42%
STRENSIQ INJ 80MG/0.8ML	4	1	$549,165.64	$137,291.41	4	38.27%
STRENSIQ INJ 18MG/0.45ML	4	1	$61,821.64	$15,455.41	4	4.31%
TOTAL	**32**	**3***	**$1,434,941.12**	**$44,841.91**	**10.67**	**100%**

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

Fiscal Year 2021 Annual Review of Xgeva® (Denosumab)

Oklahoma Health Care Authority
Fiscal Year 2021 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 2021

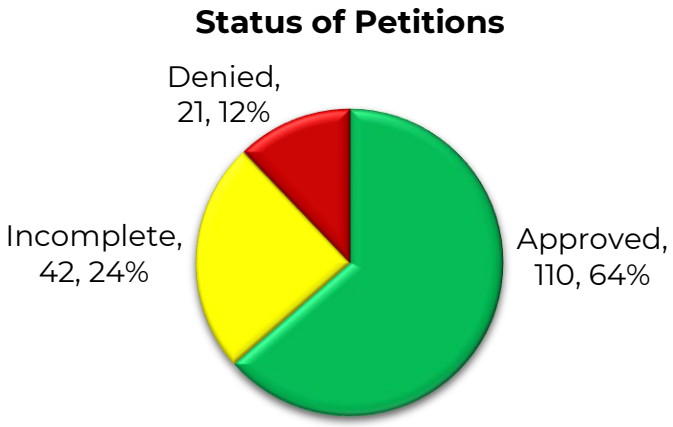
Comparison of Fiscal Years: Medical Claims

Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Claims/ Members
2020	66	282	$640,169.69	$2,270.11	4.27
2021	106	350	$765,527.39	$2,187.22	3.30
% Change	**60.61%**	**24.11%**	**19.58%**	**-3.65%**	**-22.72%**
Change	**40**	**68**	**$125,357.70**	**-$82.89**	**-0.97**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Prior Authorization of Xgeva® (Denosumab)

There were 173 prior authorization requests submitted for Xgeva® (denosumab) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.



Recommendations

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

Fiscal Year 2021 Annual Review of Xiaflex® (Collagenase Clostridium Histolyticum)

Oklahoma Health Care Authority
Fiscal Year 2021 Print Report

Current Prior Authorization Criteria

Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria [Dupuytren's Contracture Diagnosis]:

1. An FDA approved indication of Dupuytren's contracture with palpable cord, functional impairment, and fixed-flexion contractures of the metacarpophalangeal (MP) joint or proximal interphalangeal (PIP) joint of 30 degrees or more; and
2. Member must be 18 years of age or older; and
3. The member must not be a candidate for needle aponeurotomy; and
4. The prescriber must be trained in the treatment of Dupuytren's contracture and injections of the hand; and
5. A quantity limit of 3 doses (1 dose per 4 weeks) per cord will apply.

Xiaflex® (Collagenase Clostridium Histolyticum) Approval Criteria [Peyronie's Disease Diagnosis]:

1. A diagnosis of stable Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy; and
2. Member must be 18 years of age or older; and
3. Member must have pain outside the circumstances of intercourse that is refractory to other available treatments; and
4. Peyronie's plaques must not involve the penile urethra; and
5. Member must have intact erectile function (with or without the use of medications); and
6. Prescriber must be certified to administer Xiaflex® through the Xiaflex® risk evaluation and mitigation strategy (REMS) program; and
7. A maximum of 8 injection procedures will be approved.

Utilization of Xiaflex® (Collagenase Clostridium Histolyticum): Fiscal Year 2021

Comparison of Fiscal Years: Medical Claims

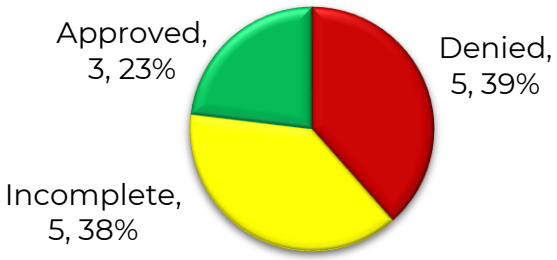
Fiscal Year	*Total Members	Total Claims	Total Cost	Cost/ Claim	Total Units
2020	4	15	$53,961.42	$3,597.43	1,094
2021	2	6	$27,682.20	$4,613.70	540
% Change	**-50.0%**	**-60.0%**	**-48.7%**	**28.2%**	**-50.6%**
Change	**-2**	**-9**	**-$26,279.22**	**$1,016.27**	**-554**

Costs do not reflect rebated prices or net costs.
*Total number of unduplicated utilizing members.
Fiscal Year 2020 = 07/01/2019 to 06/30/2020; Fiscal Year 2021 = 07/01/2020 to 06/30/2021

Prior Authorization of Xiaflex® (Collagenase Clostridium Histolyticum)

There were 13 prior authorization requests submitted for 7 unique members for Xiaflex® (collagenase clostridium histolyticum) during fiscal year 2021. The following chart shows the status of the submitted petitions for fiscal year 2021.

Status of Petitions



Recommendations

The College of Pharmacy does not recommend any changes to the current Xiaflex® (collagenase clostridium histolyticum) prior authorization criteria at this time.

Utilization Details of Xiaflex® (Collagenase Clostridium Histolyticum): Fiscal Year 2021

PRODUCT UTILIZED	†TOTAL CLAIMS	*TOTAL MEMBERS	TOTAL COST	COST/ CLAIM	CLAIMS/ MEMBER
J0775 XIAFLEX INJECTION 0.9MG	6	2	$27,682.20	$4,613.70	3
TOTAL	**6**	**2**	**$27,682.20**	**$4,613.70**	**3**

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